

Health PEI

One Island Health System

Health PEI Ethics Framework

January 14, 2014

Table of Contents:

Executive Summary..... 1

Introduction 2

Education 4

Process and Scope..... 5

Policy Identification and Review 8

Research Ethics 9

Membership and Roles: 10

Quality/Ethics Alignment 11

Trending, Evaluation and Record Keeping 11

Appendices:

Appendix 1: Budget 2012/13 Health PEI Clinical and Organizational Ethics Committee

Appendix 2: Health PEI Clinical and Organizational Ethics Committee Terms of Reference

Appendix 3: Budget 2012/13 PEI Research Ethics Board

Appendix 4: PEI Research Ethics Board Terms of Reference

Appendix 5: Process Map for Urgent Ethical Consult Requests

Appendix 6: Process for Non-urgent Ethical Consult requests

Executive Summary

This document outlines the Ethics Framework for Health PEI, which includes a Health PEI Clinical and Organizational Ethics Committee and the PEI Research Ethics Board. The Ethics Framework links the values of Health PEI to the decisions made by the management, staff and physicians who work within it.

The Health PEI Clinical and Organizational Ethics Committee supports a culture of ethics, where the values of the organization are embedded and are reflected in decision making at all levels within the organization. This committee provides a forum for addressing ethical dilemmas of a clinical or organizational nature. The Health PEI Clinical and Organizational Ethics Committee facilitate education on ethics to Health PEI employees, physicians and management.

The Prince Edward Island Research Ethics Board (REB) is mandated to review the ethical acceptability of all research involving humans conducted within Health PEI's jurisdiction. This includes research involving human participants; research involving biological materials, as well as human embryos, fetuses, foetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Our strong emphasis on the ethical components of the organization encourages staff to recognize the values of the system and ensure they are reflected in the quality of care to the residents of PEI.

The Health PEI Clinical and Organizational Ethics Committee are accountable to the Health PEI Board through the Health PEI Quality and Patient Safety Council. The Research Ethics Board reports to the Board of Health PEI.

Introduction

The Health PEI Clinical and Organizational Ethics Committee started in 2006. While various PEI Research Ethics Boards (REB) have been in place over the years, the current REB is a result of multiple health care restructurings and in its current form reports to the Board of Health PEI.

The Health PEI Clinical and Organizational Ethics Committee (C&O Ethics Committee) is committed to the highest degree of ethical and professional conduct in its provision of services. This committee does not act in isolation, but supports a culture of ethics, where the values of the organization are embedded and are reflected in decision making at all levels within the organization. The committee provides a forum for addressing ethical dilemmas of a clinical or organizational nature. Consult requests may be brought to this multi-disciplinary committee from management, staff, physicians, patients/residents/clients, or family members. The committee acts in an advisory capacity making recommendations in response to an ethics consultation. The C&O Ethics Committee provides and facilitates education on ethics to Health PEI staff and is part of the Quality Framework of Health PEI.

The Prince Edward Island Research Ethics Board's (REB) mandate includes the review of the ethical acceptability of all research involving humans conducted within Health PEI's jurisdiction. This includes research involving human participants; research involving biological materials, as well as human embryos, fetuses, foetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals. The REB evaluates the protocols in relation to research with reference to scientific validity, informed consent, harm/benefit ratios, participant selection procedures, privacy issues, researchers' qualifications and adherence to accepted guidelines and legislation. The procedures regarding protocols and consent forms are included in this evaluation. In order to achieve REB approval, a researcher's protocol must be found to be ethically acceptable and scientifically valid.

The REB is independent in its decision making and has the authority to approve, reject, propose modifications, suspend or terminate any proposed or ongoing research involving human participants.

The REB has the authority to audit and monitor research including examining documents and observing informed consent processes.

The PEI REB is accountable to the Health PEI Board.

Accreditation Canada Leadership Standards recommend the development, implementation and evaluation of an ethics framework, policy and education for both Clinical Ethics and Research Ethics. Since accreditation is one of the roles of the Quality Improvement Teams, an ethics committee that is active and visible to these teams not only assists in achieving optimal patient/client/resident care it is also a national standard for quality patient/client/resident care.

Table 1: Summary of Health PEI Ethics Committees

Committee Function	Health PEI Clinical and Organizational Ethics Committee	Research Ethics Board
Education	<ul style="list-style-type: none"> • Provided to management and staff on ethical issues • Provided to members in preparation for case consultations • Retrospective case reviews • Monitoring/follow up recommendations for implementation and results 	<ul style="list-style-type: none"> • Provided to members and staff on ethical issues related to research conducted within the health system • Provided to members in preparation for REB reviews
Research	<ul style="list-style-type: none"> • Referred to REB 	<ul style="list-style-type: none"> • Review the ethical acceptability of all research involving humans conducted within the health system. • Authority to approve, reject, propose modifications, suspend or terminate any proposed or ongoing research • Authority to audit and monitor research including auditing documents and observing informed consent process.
Policy and Procedure Development and Review	<ul style="list-style-type: none"> • Committee acts as a resource in the evaluation of policies, procedures, rules and regulations that have ethical implications 	
Clinical Ethics	<ul style="list-style-type: none"> • Urgent consultation • Non urgent consultations 	<ul style="list-style-type: none"> • Referred to clinical ethics
Organizational Ethics	<ul style="list-style-type: none"> • Committee acts as a resource • Consultations 	<ul style="list-style-type: none"> • Research Ethics board acts as a resource.

The ethics framework and decision making process for Health PEI is based on the premise that ethics plays a major role in shaping the overall culture of the system. The Health PEI Clinical and Organizational Ethics Committee and the PEI Research Ethics Board are identified as parts of the quality and patient

safety framework and as such will be visible entities to management, staff and the quality improvement teams.

An organization that builds an ethical perspective into its culture is an organization where values are incorporated and integrated into the thinking and actions of staff. The values of the organization become part of everyday life and are reflected in decisions made by all levels of management and staff. It also ensures a process is in place for responding to the ethical concerns of clients/ patients/residents and families; and assists staff in working through ethical dilemmas according to our values, and codes of ethics.

One way to facilitate an ethics framework is to provide staff with an ethical decision making process that is based on the values of the health system. In order for the framework to be successful, it needs to be endorsed by the Chief Executive Officer (CEO), the Board of Health PEI, and Executive Leadership and be well communicated and understood throughout the organization. The ethics framework and the ethical decision making process support staff and quality teams in their decision making and help Health PEI to further develop and maintain an “ethical culture”.

Education

The education function of an ethics committee is perhaps its most important function. An effective ethics committee provides ongoing education to all levels of the organization as well as educating its members to be skilled and knowledgeable within the committee.

Health PEI Clinical and Organizational Ethics Committee

The Health PEI Clinical and Organizational Ethics Committee membership consists of a multidisciplinary group of healthcare professionals as well as a member from the community. Committee members learn the basic principles of conducting an ethical analysis, a history of bioethics, the definition of brain death, the neocortical death and related issues, forgoing treatment, public policy and other principled issues, and lastly the functions and obligations of ethics committees.

There are two avenues that the education function takes. First – the committee members need education themselves in order to fully function as an ethics committee. Second, the committee

provides/facilitates education within the organization. (See: Appendix 1: Health PEI Clinical and Organizational Ethics Committee Proposed Budget and Appendix 2: Provincial Ethics Committee Terms of Reference.)

The Clinical and Organizational Ethical Decision Making (EDM) Guidelines are available in hard copy in the facilities. In addition the EDM Guidelines are available electronically on the Staff Resource Centre which is available to all Health PEI employees. The committee and its members both formally and informally educate staff on the Guidelines and the function of the C&O Ethics Committee.

Provincial Research Ethics Board

The PEI REB membership engages in Advances on a regular basis. During the 2013-2014 fiscal year, efforts will be made to ensure that the REB membership has two Advances per year in order to ensure that members and staff have the knowledge required to conduct their duties. (See: Appendix 3: PEI Research Ethics Board Terms of Reference and Appendix 4: PEI Research Ethics Board Budget)

The PEI REB provides information on its role and responsibilities via its web page on the Health PEI website (<http://www.healthpei.ca/reb>). Further to that, submission deadlines, checklist, guidelines and required forms are also available on the website. The Chair of the REB and the REB coordinator engages with program areas to ensure that they are aware of the requirement to submit research for approval, and provides guidance on the process. Recent examples include; primary health care and incoming medical students conducting independent studies as part of the requirement to finalize their internship.

Process and Scope

Health PEI Clinical and Organizational Ethics Committee

The Health PEI Clinical and Organizational Ethics Committee provide support to staff and the system faced with ethical dilemmas related to patient/client/resident care. Health PEI has invested in education to be able to provide clinical ethical consultation.

It is important that the ethical decision making process used by the staff and committee reflect the values of Health PEI. The ethical decision making process assists staff in the clinical setting to ethically analyze the situation while at the same time ensuring that the decisions made by the team are aligned

with the values of Health PEI. The goal for every clinical area is to use the process to help resolve ethical dilemmas. If the staff cannot resolve the dilemma using the EDM Guidelines the committee will provide an ethical consultation. The time frame for responding to ethical consultations is determined by the Terms of Reference.

Ethical dilemmas can be very difficult for staff. To support their efforts to resolve the ethical dilemmas, use of the EDM Guidelines to apply the principles of ethics and to conduct an ethical analysis and having the Ethics Committee available for consultations is useful and supportive. (See Diagram 1: Ethical Decision Making Process.) (See: Appendix 5: Process for Urgent Consults and Appendix 6: Process for Non-Urgent Consults)

Ethical Decision Making

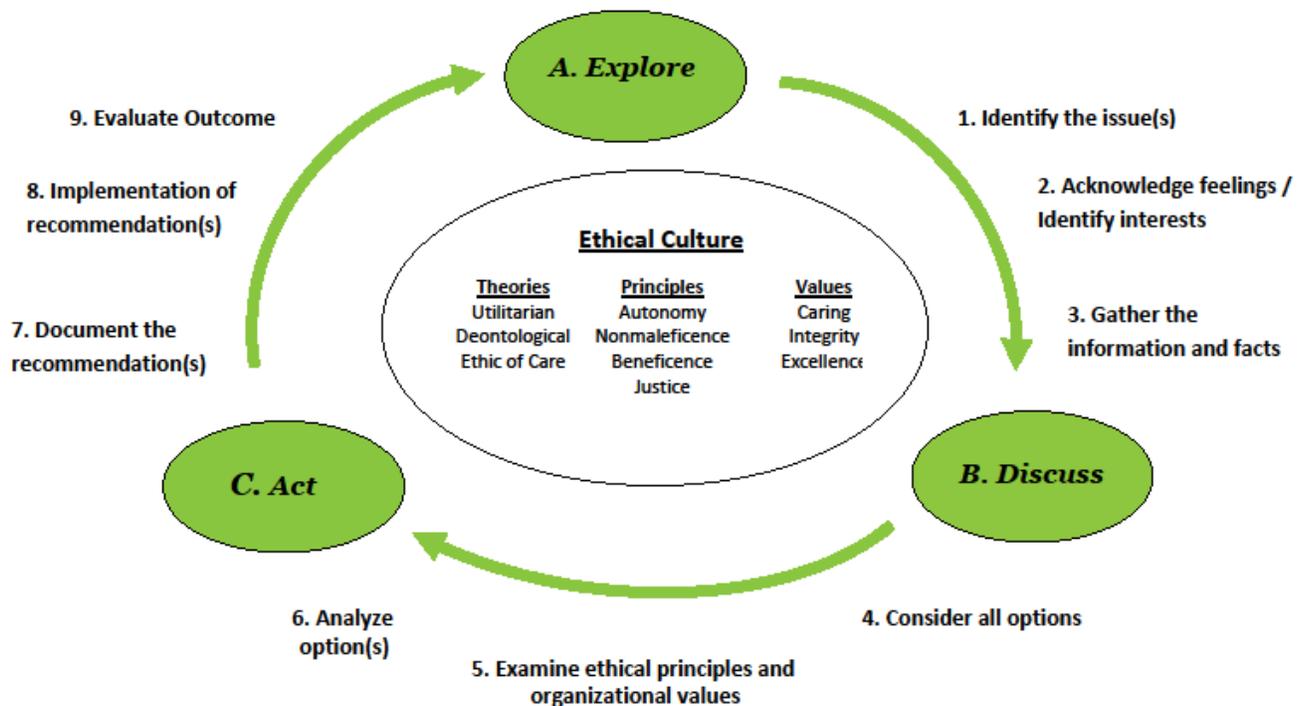


Diagram 1

This framework is adapted from “A Framework for Ethical Discernment,” Appendix 1 of the Health Ethics Guide published by the Catholic Health Association of Canada (CHAC), 2000. Permission was granted by the CHAC for this adaptation

Provincial Research Ethics Board

The process for the Research Ethics Board is more prescribed and is in accordance with the Tri-Council Policy Statement which is endorsed by the Interagency Advisory Panel on Research Ethics, a division of the federal government (TCPS 2). The PEI REB follows “established principles to guide the design, ethical conduct and ethics review process of research involving humans.” The following requires ethics review and approval by an REB before the research commences (TCPS 2, Article 2.1):

- Research involving living human participants;
- Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Research exempt from REB review as per TCPS 2, Article 2.2: Research that relies exclusively on publicly available information does not require review when:

- The information is legally accessible to public and appropriately protected by law;
- The information is publicly accessible and there is no reasonable expectation of privacy.

REB review is not required for research involving observation of people in public places where:

- It does not involve any intervention staged by a researcher, or direct interaction with individuals or groups;
- Individuals or groups targeted for observation have no reasonable expectation of privacy;
- Any dissemination of research results does not allow identification of specific individuals.

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials so long as data linkage, recording or dissemination of results does not generate identifiable information.

Quality assurance (QA) and quality improvement (QI) studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes do not require PEI REB review unless they contain an element of research (TCPS 2, Articles 2.5 & 2.6).

Please note that the PEI REB does not grant *post hoc* approval. If the investigator intends to publish study results in a journal that requires proof of PEI REB approval, this approval must be obtained prior to conducting the study. No research intervention or interaction with human participants, including recruitment, may begin until the PEI REB has reviewed and approved the study.

Clinical use of drugs through Health Canada’s Emergency Drug Release Program does not require PEI REB review. Innovative (experimental) practices should be developed into a research protocol as soon as is feasible so that meaningful information can be collected.

The opinion of the PEI REB should be sought whenever there is any doubt about the applicability of ethics review to any project.

Policy Identification and Review

Health PEI Clinical and Organizational Ethics Committee

Organizational ethics is a relatively new topic for healthcare organizations and for ethics committees. Capital Health in Nova Scotia defines organizational ethics as the “new area of ethics that focuses on decisions and actions at all levels throughout the organization or region, and aims to help ensure that the organization’s mission, vision and values are part of its decision making processes.”¹

The Health PEI Clinical and Organizational Ethics Committee is consulted with, in conjunction with appropriate representatives from administration, to review and identify the need for organizational wide policies related to ethical issues; for example policies related to initiating, continuing, withholding, or withdrawing care or treatment. The Canadian Healthcare Association, the Canadian Medical Association, the Canadian Nurses Association and the Catholic Health Association of Canada developed a joint statement¹ on preventing and resolving ethical conflicts involving health care providers and

¹Capital Health, “A Vision and Strategy for Promoting an Ethics Framework in Capital Health” May 2003, page 9. www.cdha.nshealth.ca

¹Canadian Healthcare Association, Canadian Medical Association, Canadian Nurses Association and Catholic Health Association of Canada. “Joint Statement on Preventing and Resolving Ethical Conflicts Involving Health Care Providers and Persons Receiving Care.” Available on line: www.cha.ca (1999)

persons receiving care. These groups support policy development related to ethical decision making and have recommended that health care facilities develop two policies around conflict resolution; one that outlines a process for dealing with conflict resolution between care providers and the other to deal with conflict resolution processes that arise between care providers and care recipients.

The activities of an Ethics Committee should be aligned with the ethical issues that are presented in the accreditations standards. Accreditation Canada has expectations for health care organizations to identify and address ethical issues. These ethical issues can either be organizational in nature or can have direct patient care consequences. Examples of organizational ethics are: ethical considerations related to allocation of resources, having a code of ethics for business and professional behavior, and policy and procedure review and development. The Health PEI Clinical and Organizational Ethics Committee consult on organizational ethical dilemmas and provide recommendations to Health PEI.

Research Ethics

The Prince Edward Island Research Ethics Board (REB) is mandated to review the ethical acceptability of all research involving humans conducted within Health PEI's jurisdiction. This includes research involving human participants; research involving biological materials, as well as human embryos, fetuses, foetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

The Research Ethics Board is independent in its decision making and has the authority to approve, reject, propose modifications, suspend or terminate any proposed or ongoing research involving human participants. The Research Ethics Board has the authority to audit and monitor research including auditing documents and observing informed consent process.

The Research Ethics Board shall evaluate the protocols with reference to scientific validity, informed consent, harm/benefit ratios, participant selection procedures, privacy issues, researchers' qualifications and adherence to accepted guidelines and legislation and the Research Ethics Board procedures regarding protocols and consent forms. For approval, a protocol must be found by the Research Ethics Board to be ethically acceptable.

The PEI Research Ethics Board complies with the *Food and Drug Regulations, the ICH Harmonized Tripartite Guidelines: Good Clinical Practice, and the Tri-Council Policy Statement. (See Appendix 5.)*

The PEI Research Ethics Board has a defined set of Standard Operating Procedures (SOP). These comply with the TCPS 2 Guidelines and other relevant standards. The PEI Research Ethics Board has also developed organizational policies and procedures regarding research that are awaiting approval.

Membership and Roles

Health PEI Clinical and Organizational Ethics Committee

The Health PEI Clinical and Organizational Ethics Committee have a Chair and Vice Chair and membership includes administration, multidisciplinary clinicians, physicians and community representatives. The membership is representative of geography and divisions. Ad hoc members may be invited to join for their specific expertise as is necessary. This may include legal, clinical, patient representative, community representative or researcher.

The committee provides a multi disciplinary discussion of ethical dilemmas (clinical and organizational). Using a standard case consultation process, the Committee will discuss and provide recommendation(s) to management, staff, physicians, clients, families and/or advocates.

The Chair upon receipt of a request for consultation refers the consultation to a three (3) (minimum) member ad hoc subcommittee or will refer the consultation to the full Ethics Committee for review. The Chair updates the committee at each meeting of current consultations.

Any member of the committee who is a participant, interested party or has a personal conflict in a consult being considered by the Health PEI Clinical and Organizational Ethics Committee will withdraw and not participate in deliberations on said consultation.

For further clarity, the committee may make recommendations on ethical issues in the evaluation and formulation of policies for Health PEI. The Committee may also be a resource in the process of evaluating policies, procedures, rules and regulations that have ethical considerations.

PEI Research Ethics Board

The PEI Research Ethics Board consists of at least five members. To ensure a competent independent research ethics review, the REB will consist of both men and women of whom:

- at least 2 members are knowledgeable in research disciplines, fields and methodologies specific to the studies being reviewed by the REB;
- at least 1 member is knowledgeable in ethics;
- at least 1 member is knowledgeable in the law; and
- at least 1 community member who has no affiliation with Health PEI.

The REB may consult ad hoc with advisors when it is acknowledged that they require the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. This may include specialists affiliated with academic institutions or specific medical disciplines.

Alignment with Quality Improvement

The alignment of ethics with the Quality and Patient Safety Framework, and support for a close association between the two, ensures that the Health PEI Ethics Framework is visible to the client/patient/resident care teams and the system support teams which are also part of the quality structure. Each of these teams is multi-disciplinary, and their primary purpose is to monitor and improve the quality and safety of patient/client/resident care within their respective areas. These teams are often faced with ethical issues in their clinical settings; therefore having access to an ethical process to support them in decision making, and an ethics committee for support on difficult cases is considered a valuable resource.

Trending, Evaluation and Record Keeping

Health PEI Clinical and Organizational Ethics Committee

The chair, or designate, of the Health PEI Clinical and Organizational Ethics Committee maintains a record of consult requests, recommendations and evaluation/monitoring of recommendations which is reported at each meeting. The Health PEI Clinical and Organizational Ethics Committee present an

annual summary of activities undertaken, results achieved, identification of trends related to ethical issues as well as work plans for the upcoming year to the Leadership Quality Improvement Team (QIT). The Leadership QIT brings the update forward to the Quality and Patient Safety Council annually.

PEI Research Ethics Board

The Coordinator of the PEI REB maintains a record of requests and queries from potential investigators, as well as ongoing correspondence with individuals who have submitted a proposal for review. These are kept on file for the duration of the study and retained as per the organization's retention schedule. The REB's Standard Operating Procedures (SOP) contain in-depth information on record keeping. Trending is a component of the annual evaluation of the REB, which is reported to the Board of Health PEI. Trending includes a review of the types of submissions. This may inform potential changes to the REB membership. The REB underwent an internal evaluation in 2012 with the appointment of the new REB Chair. This evaluation resulted in a number of improvements to the REB, including the establishment of Standard Operating Procedures, organizational research policies and procedures, and a renewal of forms, templates and guidelines. Further to this, the membership of the REB was evaluated to ensure that members have the qualifications and knowledge required to carry out the responsibilities mandated by the REB.

Conclusion

There are a number of next steps to further develop a culture of ethics. The main building block to this is the education of the people who make up Health PEI. Those who need to live and breathe the ethical dilemmas in their everyday work and practice as well as the people making the decisions on policies and the direction of Health PEI. This framework provides the roadmap for Health PEI's ethics lens, but as trends emerge it may be necessary to review and refine the current direction to meet the needs of the organization and the public. This is in alignment with National and Accreditation Canada Standards.

Appendix 1

Budget for Health PEI Clinical and Organizational Ethics Committee

Health PEI

Health PEI Clinical and Organizational Ethics Committee

Budget 2013-2014

Education Sessions

Educational Sessions for Department of Health Employees

Fall 2013

Speaker Charge-\$ 2000.00 \$ 4000.00

Speaker Travel cost-\$ 1500.00

Education location- \$500.00

Mini-series \$ 1000.00

Continuing Education for Committee Members \$2000.00

To attend National Conference

Learning Tools

Books/Journals/E Journals etc. \$ 500.00

Misc

Supplies/Monthly Meeting expense \$ 400.00

Total \$7900.00

Appendix 2

Health PEI Clinical and Organizational Ethics Committee - Terms of Reference

Clinical Ethics Committee Terms of Reference

1. Purpose:

Health PEI is committed to the highest degree of ethical and professional conduct in its provision of services. The Clinical Ethics Committee does not act in isolation, but supports a culture of ethics, where the values of the organization are embedded and are reflected in decision making at all levels within the organization. The Health PEI Clinical Ethics Committee provides a forum for addressing ethical dilemmas of a clinical or organizational nature. Consult requests may be brought to this multi-disciplinary committee from management, staff, physicians, clients, or family members. The committee acts in an advisory capacity making recommendations in response to a consult request. The Clinical Ethics Committee will facilitate education on ethics to Health PEI. The Clinical Ethics Committee is part of the Quality Framework of Health PEI.

2. Committee Responsibilities:

- A. The committee will provide a multi disciplinary discussion of ethical dilemmas (clinical and organizational). Using a standard case consultation process, the Committee will discuss and provide recommendation(s) to management, staff, physicians, clients, families and/or advocates.
 - I. The Chair will refer the consultation to a minimum of three (3) member subcommittee or will refer the consultation to the full committee for review. The Chair will update the committee at each meeting of current reports.
 - II. Any member of the committee who is a participant, interested party or has a personal conflict in a consult being considered by the Health PEI Ethics Committee will withdraw and not participate in deliberations on said consultation.
- B. For further clarity, the committee may make recommendations on ethical issues in the evaluation and formulation of policies for Health PEI. The Committee may also be a resource in the process of evaluating policies, procedures, rules and regulations that have ethical considerations.

3. Confidentiality:

- A. All information made available to the Ethics Committee will be held in strictest confidence.
- B. A record of consult requests, recommendations and evaluation will be maintained by the chair or designate.

4. Membership:

A. Purpose:

- I. To promote a culture of ethics in the workplace;
- II. To participate in consultations and provide recommendations;
- III. To promote an understanding of ethics in the workplace;

B. Membership:

- I. The committee will have a Chair and Vice Chair as members;
- II. Membership will be including administration, multidisciplinary clinicians, physicians and community representatives.
- III. Membership will be representative of geography and divisions.
- IV. Ad hoc members may be invited to join for their specific expertise as is necessary. This may include legal, clinical, patient representative, community representative or researcher.

C. Terms and Appointment:

- I. The Chair will be appointed by the Director of Quality and Access Management in consultation with at least two representatives of the Clinical Ethics Committee;
- II. Chair serves a 2 year term with the possibility of an extension at the discretion of the Director of Quality and Access Management;
- III. The Vice Chair will be nominated by the Ethics Committee and will be approved by the Director of Quality and Access Management;
- IV. In the absence of the Chair, the Vice Chair shall assume all of the chair's duties;
- V. If the chair cannot complete the term, then the vice chair shall assume all duties of the chair for the remainder of the term;
- VI. Upon the completion of the term of Chair the Vice Chair will be appointed by the Director of Quality and Access Management to be the incoming Chair.
- VII. Members serve a minimum two (2) year term. Members may serve up to a maximum of three (3) consecutive terms;
- VIII. Notwithstanding, the committee will follow a succession plan to ensure continuity is maintained;
- IX. A resource person will be appointed by the Director of Quality and Access Management;

D. Roles and Responsibilities:

I. Chair:

- To chair all meetings;
- To set an agenda;
- To set a meeting schedule;
- To maintain records on consults, recommendations and evaluation/monitoring of recommendations. This is reported at each meeting;
- To liaise with the broader Health Care system.

II. Vice Chair

- To assume duties of the chair in the absence of the chair;
- To guide the planning for educational needs.

III. Administrative Support Person

- To record minutes and submit to chair for review;
- To circulate minutes, agenda and notify members of meetings;
- To schedule meeting in advance and communicate to membership;
- To fulfill other duties as required.

IV. Resource Support Person

- To provide support to the Chair, committee and working groups;
- To liaise with Health PEI, committees, and individuals as needed;
- To facilitate meetings.

5. Frequency and Length of Meetings:

- A.** The committee will meet at least five times per year, with additional meetings as needed;
- B.** Maximum meeting length of two hours, unless otherwise agreed.

6. Decision Making

- A.** Quorum: 50% of membership is required for decision making;
- B.** Decisions will be made through consensus where possible;
- C.** If administrative decisions cannot be reached, the issue will be escalated to the Director of Quality and Access Management.

7. Reporting:

- A.** Clinical Ethics Committee will present an annual summary of activities undertaken and results achieved by the committee to Leadership Quality Improvement Team (QIT). The Leadership QIT brings the update forward to the Quality and Patient Safety Council once per year.

8. Review:

- A.** The terms of reference will be reviewed every second year at the September meeting.

Creation Date: March 29, 2007

Approved by:

Review Date: September, 2014

Revision Date: April 5, 2013

Appendix 3

Budget for PEI Research Ethics Board

<u>Research Ethics Board</u>		
<u>Budget Vs Actuals</u>		
Staff Resources		Budget
Administrative Staff		\$28,334.00
Overtime		
Total Compensation		\$28,334.00
Expenses:		
Meals	\$	500.00
Travel / Mileage	\$	100.00
Conference / Training	\$	3,000.00
Telecommunications	\$	400.00
Communication	\$	100.00
Total Non-comp	\$	4,100.00
Total Budget	\$	32,434.00

Appendix 4

PEI Research Ethics Board - Terms of Reference

PEI Research Ethics Board

Terms of Reference

ACCOUNTABILITY

The PEI REB is accountable to the Health PEI Board of Directors through its Quality and Safety Subcommittee.

MANDATE

The Prince Edward Island Research Ethics Board (REB) is mandated to review the ethical acceptability of all research involving humans conducted within Health PEI's jurisdiction. This includes:

- research involving human participants;
- research involving biological materials, as well as human embryos, fetuses, foetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

The REB is independent in its decision making and has the authority to approve, reject, propose modifications, suspend or terminate any proposed or ongoing research involving human participants. The REB has the authority to audit and monitor research including auditing documents and observing informed consent process.

SCOPE OF REB REVIEW

The REB shall evaluate the protocols with reference to scientific validity, informed consent, harm/benefit ratios, participant selection procedures, privacy issues, researchers' qualifications and adherence to accepted guidelines and legislation and the REB procedures regarding protocols and consent forms. For approval, a protocol must be found by the REB to be ethically acceptable.

REB COMPOSITION

REB Membership Requirements

To ensure competent independent research ethics review, the REB will consist of at least five members, including both men and women of whom:

- at least 2 members are knowledgeable in research disciplines, fields and methodologies specific to the studies being reviewed by the REB;
- at least 1 member is knowledgeable in ethics;
- at least 1 member is knowledgeable in the law;
- at least 1 community member who has no affiliation with Health PEI.

Substitute REB members may be considered so that the REB can continue to function when regular members are unable to attend. The appointment of substitute members should not, however, alter the REB membership composition. Substitute REB members may be nominated by any member of the REB and must be approved in advance by the Chair.

Ad Hoc Advisors

The REB may consult ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. This may include specialists affiliated with academic institutions or specific medical disciplines.

Terms of Appointments of REB members

Members will be appointed to serve a 3-year term. By mutual consent between the REB member and the REB Chair, the board member may be appointed for additional terms. Terms will be staggered to ensure continuity.

Appointment Process

The Chair and Vice Chair will be chosen from the membership of the REB (a recommendation will be put forward by the members), and formally appointed by the Health PEI Board of Directors.

In cooperation with the REB Chair, REB members will search for replacement members as required.

Members will be invited as REB members by the REB Chair and formally appointed through the Health PEI Board of Directors.

REB Chair

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the Tri-Council Policy Statement (TCPS2).

Quorum

Quorum shall consist of at least 5 members meeting the composition requirements. Only REB members may be involved in deliberations or voting.

Signing Authority

Signing authority resides with the Chair and Vice-Chair.

REB MEETINGS & ATTENDANCE

The REB shall have regular meetings to discharge its responsibilities, and shall normally meet face to face to review proposed research that is not assigned to delegated review. When necessary, videoconferencing, teleconferencing, or the use of other technologies may be used when there is no other way of holding a meeting.

Special meetings may be called by the Chair and may be requested by any member.

Members are expected to attend at least 80% of the meetings. Frequent unexplained absences may be construed as a notice of resignation.

DECISION PROCESS

Decisions will be made by consensus; only in exceptional circumstances will decisions be made by majority vote.

CONFLICT OF INTEREST

The REB does not allow participation in the initial or continuing review of any project in which the member has a personal or financial involvement in the study. Members involved in a research study under review or in conflict of interest because of personal or financial relationships will verbally indicate this conflict to the Chair and step outside the meeting room during the discussion and decision-making on the particular study. The minutes of the meeting must state that such a member was absent from the room during the deliberations of any relevant project.

Appendix 5
Process for Urgent Consults

Process for Urgent Ethics Consult Request			
	Ethics Committee Member who received request	Chair/Vice Chair	Committee Members
	<p>Confirm that the work site has used the Ethical Decision making guidelines to try to resolve the dilemma</p> <p>Ethics Consult requested</p> <p>Gather initial Information</p> <p>Contact Chair/Vice Chair</p> <p>Complete Request for consult form</p> <p>Gather additional information</p> <p>Invite person(s) making the request to consult meeting</p> <p>Monitor/follow up on implementation of recommendations</p>	<p>Contact committee via e-mail that an urgent consult is requested</p> <p>Communicate time, place and teleconference details</p> <p>Communicate recommendations to the person(s) requesting consult</p> <p>Document recommendations and maintain document</p> <p>Monitor/follow up on implementation of recommendations</p>	<p>Respond with availability to participate and how</p> <p>Participate in Consultation</p> <p>Develop Recommendations</p> <p>Monitor/follow up on implementation of recommendations</p>

Appendix 6
Process for Non Urgent Consults

Process for Non-Urgent Ethics Consult Request

	Ethics Committee Member who receives request	Chair/Vice Chair	Committee Members
	<p style="border: 1px solid black; padding: 5px; margin-bottom: 10px;">Confirm that the work site has used the Ethical Decision making guidelines to try to resolve the dilemma</p> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; width: fit-content; margin: 10px auto;">Ethics Consult requested</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Gather initial Information</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Complete Request for consult form</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Advise Chair that a request has been received</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Monitor/follow up on implementation of recommendations</div>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Communicate to committee that a consult will be part of next meeting</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Share relevant documentation</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Document and communicate recommendations and maintain document</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Monitor/follow up on implementation of recommendations</div>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Participate in Consultation</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Develop Recommendations</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto; margin-top: 20px;">Monitor/follow up on implementation of recommendations</div>