

CLASSIFICATION: GENERAL	NUMBER: GEN-BOARD-3022
CATEGORY: GOVERNANCE	DATE: 2009.09.02 – O
ISSUED BY: BOARD OF DIRECTORS	2010.01.07 – A
AUTHORIZED BY: CHAIRMAN OF THE BOARD OF DIRECTORS	Amendment 01/04/02/10

SUBJECT: RESEARCH REVIEW AND APPROVAL PROTOCOL

PREAMBLE

Participation in research activities is not a primary function of the Perley and Rideau Veterans' Health Centre (Perley Rideau). There may, however, be opportunities to participate in the research activities of outside groups. It is expected that these research activities, in addition to existing university and/or hospital research ethics board approvals, be reviewed by the Perley Rideau Ethics Advisory Committee to ensure that participation would be in the best interests of the residents and staff of the Perley Rideau.

Staff members of the Perley Rideau regularly conduct quality assurance studies. These studies, in general, do not qualify as research as the intent is to improve the care provided at the Perley Rideau. If, however, there is a clear intent to disseminate the results to a wider audience through presentation or publication, the activity would be considered research and require the approval of the Perley Rideau Ethics Advisory Committee and the Executive Director.

POLICY

Research is a systematic investigation to establish facts, principles or generalized knowledge. All research involving human subjects or resident medical records conducted at the Perley Rideau must be reviewed and approved by both the Ethics Committee and the Executive Director. The responsibilities of the Ethics Committee include reviewing the scientific merit, risk, ethical, consent and privacy concerns. (See Appendix 1 for the Terms of Reference of the Ethics Advisory Committee.) The Executive Director is responsible for evaluating the resource and reputation considerations, and the extent to which the Board should be consulted to fulfill responsibilities outlined in policy GEN-BOARD-3012, The Perley and Rideau Veterans' Health Centre Ethics Policy Framework. All research at the Perley Rideau is subject to the Perley Rideau Code of Ethics.

PROCEDURE

A) Research Proposed by External Groups:

It is expected that the majority of research at the Perley Rideau will be research conducted by groups with institutional bases outside of the Health Centre. This research must have been reviewed and

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<p>approved by the Research Ethics Board of the lead institution (university, hospital, government or Research Institute).</p> <p>A copy of this approval must be included with the participation request to the Perley Rideau. The Ethics Advisory Committee will additionally review the proposal, using the Research Ethics Review Tool (See Appendix 2), focusing on issues of particular importance to the Perley Rideau including risk, consent and privacy especially with respect to persons not capable of making their own decisions.</p> <p>B) <u>Research which Originates at the Perley Rideau:</u></p> <p>Research activities may also originate at the Perley Rideau. These studies may not have the opportunity to be reviewed by an external Research Ethics Board, though those which have are expected to follow the procedure outlined above. Research originating at the Perley Rideau and not externally reviewed is expected to be of no more than minimal risk. Minimal risk is defined as that which can be reasonably regarded by a participant to be no greater than the risks encountered in everyday life. Each research project requires the approval of the Ethics Advisory Committee, which would review the scientific merit, risk, consent, privacy, conflict of interest, inclusive selection and recruitment of participants, ongoing monitoring of participants' welfare and benefit to provision of care at the Perley Rideau.</p> <p>C) Adequate resources must be available prior to any research involvement approval by the Executive Director.</p> <p>D) The Ethics Advisory Committee meets quarterly and would consider a proposal at any regular meeting. A special meeting may be convened if a more timely response is required.</p> <p>E) If approval of the Ethics Advisory Committee is denied, appeal may be made to the Executive Director.</p>	

ETHICS ADVISORY COMMITTEE TERMS OF REFERENCE

Philosophy:

The Ethics Advisory Committee strives to promote the Vision statement of the Perley and Rideau Veterans' Health Centre “**Together** we improve the well-being of the people **we serve.**” by promoting ethical knowledge and education relating to ethics, and acting as a consensus-building forum for consensus building related to resident care ethical issues.

The fundamental principles and values of ethics in a long-term care setting include only doing good (beneficence), doing no harm (non-maleficence), respect for the person and the individual autonomy of the resident and family, justice, autonomy and truthfulness. The Ethics Advisory Committee is a forum for understanding and resolving the conflicts of differing values while making ethical decisions.

There is mutual respect among all the members of the Ethics Advisory Committee based on the inherent worth of each individual person and his/her opinion.

There is explicit recognition that each member of the Ethics Advisory Committee has perspectives and expertise that contribute to the consultative, educational, policy development, and consensus-building process involved in working through ethical issues at the Perley and Rideau Veterans' Health Centre.

Purpose:

1. To formulate policies and/or guidelines and a decision-making framework for the use of “owners” of ethical issues to bring issues forward to the Committee.
2. To serve as a resource and forum to discuss and, wherever possible, resolve resident care ethical issues within the Perley Rideau.
3. To encourage and develop educational programs in the area of ethical issues and provide an opportunity for all residents/families, medical staff, staff, and volunteers to become sensitive to, and knowledgeable about, the ethical issues in long-term care.
4. To review and approve research proposals involving residents.

ETHICS ADVISORY COMMITTEE TERMS OF REFERENCE

Jurisdiction and Accountability:

The committee is inter-disciplinary and consensus building in nature. As a Standing Committee of the Medical Advisory Committee and Management Committee, advice and guidance in consensus-building may be sought from these Committees if required.

Membership:

(2 members)	Co-Chairs – Medical Director and Manager, Nursing Practice.
(5 members)	Representative from the inter-disciplinary team.
(Up to 3 members)	Residents/families – ideally, all three buildings/community/veterans.
(Up to 3 members)	Others on an ad hoc basis, including the “owner” of the ethical issue and other people requested by the “owner” of the ethical dilemma

Consultants may be called upon, as required, to participate in ethical issues requiring additional expertise.

Secretary:

The secretary will be chosen at each meeting.

Quorum:

50% plus 1.

Frequency of Meetings:

Meetings will be held at least quarterly, and at the call of the Chairpersons when an ethical issue identified by an “owner” of an issue needs to be discussed and resolved.

Distribution of Agenda/Minutes:

The original is kept in the Medical Director’s office and copies distributed to the committee members and the “owner” of the ethical issue. The “owner” of an ethical issue may direct the Committee to keep all information discussed at the Committee confidential.

THE PERLEY AND RIDEAU VETERANS' HEALTH CENTRE
REQUEST FOR APPROVAL FOR RESEARCH STUDY
TO THE ETHICS ADVISORY COMMITTEE

NAME OF RESEARCH PROPOSAL: _____
DATED SUBMITTED: _____ SUBMITTED BY: _____

APPROVED: _____ NOT APPROVED: _____ SIGNATURE: _____ DATE: Year: ____/Month ____/Day: ____	SUBMISSION REVIEWED		COMMENTS
	ACCEPT	NOT ACCEPTED	
INVESTIGATOR(S) • Affiliations/Conflicts			
PROPOSED DATES			
PREVIOUS RFB APPROVAL • Name, Date of Decision			
PURPOSE OF RESEARCH			
PARTICIPANT(S) • Interaction • Talk • Observation • Touch • Invasive • Administration of medications			
RISK • Physical • Psycho • Social			
BENEFIT • Individual • Health Care Team • Society			
RESULTS AVAILABLE TO PARTICIPANTS/SDM			
CONSENT • Full disclosure of process, risk, benefits • Incapable persons: correct Substitute Decision Maker (SDM) requested special consideration • Can be withdrawn for any reason at any time Participants to be aware of process to withdraw			
PRIVACY • Specific consent for Personal Health Information (PHI) • Personal Health Information is safeguarded - storage - access - destruction			
FACILITY • Results available • Staff time			

APPROVED: _____ NOT APPROVED: _____ SIGNATURE: _____ DATE: Year: ____/Month ____/Day: ____	SUBMISSION REVIEWED		COMMENTS
	ACCEPT	NOT ACCEPTED	
<ul style="list-style-type: none"> • Cost to facility participant • Benefit to Perley • Accommodation/equipment 			