



COLLEGE OF THE NORTH ATLANTIC

OPERATIONAL PROCEDURE

TOPIC: RESEARCH ETHICS FOR HUMAN SUBJECTS

Procedure No.	AC-113-PR	Division	Academics
Supersedes	N/A	Board Policy Ref.	N/A
Related Policy	AC-113	Effective Date:	December 22, 2008 (R1)

1.0 Definitions

College: College of the North Atlantic

College Resource: Any device, infrastructure, information, human resource, or funding that is normally used by the College in the exercise of its activities. These resources include those wholly owned by the College and those given or loaned to the College by a third party for use in normal College operation. The use of such donated or loaned resources may have restrictions or conditions placed on them (especially if they were given for the express purpose of research). This document does not supersede or override those restrictions or conditions.

TCPS: Tri-Council Policy Statement: Complete version of this document available at:

<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>.

Researchers are expected to read and understand this document.

REB: Research Ethics Board

OAR: Office of Applied Research of the College

2.0 Implementation

The Vice-President, Academic and Learner Services, with guidance and assistance from the OAR, will monitor the implementation of the policy and ensure that the policy is followed.

Most funding agencies require ethics review of research proposals, which involve the use of human subjects. For these reasons, appropriate regulations and safeguards are deemed necessary to deal with ethical implications of the research. This procedure will enable the College to conduct research on human subjects, of a standard acceptable to all concerned including; the human subjects involved, the granting agencies and the regulatory bodies.

3.0 Proposals to REB

Any person proposing to conduct research on human subjects shall submit a proposal to the REB. The proposal will include a concise description of the research being considered, a description of the data being collected, and a description of the methods being used to collect the data. The proposal shall also include a statement to the effect that all data will be collected, used and stored pursuant to the provisions of the *Access to Information and Protection of Privacy Act*, that data which identifies an individual will not be published or otherwise disclosed (except in accordance with that Act) and that all human subjects will be fully informed by the researcher as to the methods and aims of the research and consents to participation in the research. Please see below for details on obtaining free and informed consent from human subjects.

4.0 Research Requiring Ethics Review

- A. All research that involves living human subjects requires review and approval by an REB in accordance with this policy statement, before the research is started, except as stipulated below.
- B. Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by the REB.
- C. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy.
- D. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

5.0 Responsibilities of REB

The REB is responsible for (1) reviewing research proposals and developing protocols requiring the participation of human subjects for ethical approval; (2) organizing continuing educational activities for REB members in matters

relating to ethics and the use of human participants and (3) advising and recommending on policy-making with respect to research matters

6.0 Authority of the REB

The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.

7.0 Constitution and Governance of Research Ethics Board (REB)

In accordance with the TCPS, the College will establish a Research Ethics Board (REB) comprising at least five and a maximum of nine members including both men and women of whom:

- A. At least two members have broad expertise in the methods or the area of research that are covered by the REB.
- B. At least one member is knowledgeable in ethics and/or law. And
- C. At least one member who has no affiliation with the institution, but is recruited from the community served by the College.

The President will appoint all members of the REB and shall designate one member to act as Chair.

8.0 Jurisdiction and Exemptions

The REB has jurisdiction over all research involving human subjects being carried out within the College and under the auspices of the College. This includes research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.

Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

The following research involving human subjects does not require a proposal or ethics review:

- A. Research about a public figure (i.e. an individual involved in the public arena, an artist, etc.) which is exclusively conducted using publicly available information and sources but does not include research being

conducted about a public figure which involves approaching the subject of the research or other individuals connected with that individual directly for the purposes of interviews or access to private documents held by either the subject or other individuals.

- B. Quality assurance studies, performance reviews or testing within normal educational requirements.
- C. Research involving information from public databases where aggregated information cannot be associated with an individual or specific group.
- D. Research already in the public domain, such as published articles, journals and archives.

Notwithstanding the above, research being carried out by learners for a discrete assignment as part of their course work which would otherwise fit the criteria outlined in this policy does not have to be approved by the REB and must instead be approved by the faculty member overseeing the course. The faculty member will advise the student of the principles in this policy, shall meet with the student to discuss the methodology by which the student shall be conducting the research and shall obtain agreement in writing from the student that she or he has been counseled about this policy, its underlying principles and guidelines and he or she shall abide by the policy, principles and guidelines. Please note that this provision of the policy is meant to apply to learners conducting the equivalent of undergraduate research only for their programs and does not apply to learners conducting independent research under the auspices of the College.

9.0 Scholarly Review as Part of Ethics Review

- A. The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.
- B. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.
- C. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.
- D. Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms-benefits analysis or because of the potentially negative nature of

the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

10.0 A Proportionate Approach to Ethics Assessment

The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

11.0 Meetings and Attendance

REBs shall meet regularly to discharge their responsibilities. Meetings of the REB will be held, at a minimum, once per year and will meet other times as required or requested.

12.0 Record Keeping

The Chair will maintain minutes of all meetings, including a record of decisions taken at such meetings, the reasons underlying such decisions and will note any dissents. The REB will report annually on its activities to the Office of the President. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of the institution, researchers and funding agencies.

13.0 Decision Making

REBs shall meet face-to-face to review proposed research that is not delegated to expedited review. REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers may not be present when the REB is making its decision. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

14.0 Reconsideration

Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

15.0 Appeals

- A. In cases when researchers and REBs cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB decision by an appeal board, provided that the board's membership and procedures meet the requirements of this Policy. No *ad hoc* appeal boards are permitted.
- B. Small institutions may wish to explore regional cooperation or alliances, including the sharing of appeal boards. If two institutions decide to use each other's REB as an appeal board, a formal letter of agreement is required.
- C. The Agencies will not entertain any appeals of REB decisions.

16.0 Conflicts of Interest

If an REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. The REB member may disclose and explain the conflict of interest and offer evidence to the REB, provided the conflict is fully explained to the REB, and the proposer of the research has the right to hear the evidence and to offer a rebuttal.

17.0 Review Procedures for Ongoing Research

- A. Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.
- B. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.
- C. Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

18.0 Review of Research in Other Jurisdictions or Countries

Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

19.0 Free and Informed Consent

- A. Research governed by this Policy (see Article 1.1) may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).
- B. Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.
- C. The REB may approve a consent procedure¹ that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:
- i. The research involves no more than minimal risk to the subjects.
 - ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects.
 - iii. The research could not practicably be carried out without the waiver or alteration.
 - iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation. And
 - v. The waived or altered consent does not involve a therapeutic intervention.
- D. In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

20.0 Voluntariness

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

21.0 Naturalistic Observation

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

22.0 General Conditions

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

- A. Information that the individual is being invited to participate in a research project.
- B. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures.
- C. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm.
- D. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate. And
- E. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

23.0 Competent Research Subjects

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- A. The research question can only be addressed using individuals within the identified group(s).

- B. Free and informed consent will be sought from their authorized representative(s). and
- C. The research does not expose them to more than minimal risk without the potential for direct benefits for them.

24.0 Incompetent Research Subjects:

For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- A. The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected.
- B. The authorized third party may not be the researcher or any other member of the research team.
- C. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.
- D. When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

25.0 Subject's Participation

Where free and informed consent has been obtained from an authorized third party and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

26.0 Research in Health Emergencies

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:

- A. A serious threat to the prospective subject requires immediate intervention. and
- B. Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care. and
- C. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject. and
- D. The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research. and
- E. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so. and
- F. No relevant prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

27.0 Interpretation of Policy and Procedure

Questions of interpretation or application of this policy or its associated procedures shall be referred to the Vice President responsible for Applied Research, who may then refer the matter to the President. The interpretation of policy by the President shall be final.

Approval History	
Approved by President	May 13, 2008
Revision 1	December 22, 2008
Next Review	December 2011