

## ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN PARTICIPANTS PROCEDURE

This procedure is governed by its parent policy. Questions regarding this procedure are to be directed to the identified Procedure Administrator.

<b>Functional Category:</b>	Academic
<b>Parent Policy:</b>	Ethical Conduct for Research Involving Human Participants Policy
<b>Approval Date:</b>	March 21, 2013
<b>Effective Date:</b>	April 2, 2013
<b>Procedure Owner:</b>	Vice President, Teaching and Learning
<b>Procedure Administrator:</b>	Senior Manager, Academic Research and Development

### Overview:

The ethical conduct of research is a vital concept of the Applied Research mandate of NorQuest College (College). The ethical conduct of research involving human participants is guided by three overarching principles: respect for persons, concern for welfare, and justice.

Authority to establish this procedure is derived from the [NorQuest College Board of Governor's Policy No. 5](#), which delegates authority to the President and CEO to establish policies and procedures for the College's management and operation.

### Procedures:

In order to ensure that researchers at the College adhere to the ethical conduct standards reflected in the Tri-Council Policy Statement the following information is necessary to reference and include, but it is not sequential.

#### **Ethical Standards**

##### Free and Informed Consent

At the commencement of the informed consent process, researchers or their qualified representatives shall provide prospective participants with the following:

- Information that the individual is being invited to participate in a research project.
- A comprehensive statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures.
- 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 potential for physical or psychological harm.
- An assurance that prospective participants 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.
- Evidence of informed consent by the participant or authorized third party should ordinarily be obtained in writing and a copy of which is retained by the participant.
- Where written consent is culturally unacceptable or where a substantial rationale is provided for not documenting consent in writing, the procedures used to seek informed consent from the

participant(s) shall be fully documented.

- Information on the possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest of the researchers, their institutions or sponsors.
- The Research Ethics Board (REB) may approve a consent procedure which does not include, or which 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:
  - the research involves no more than minimal risk to the participants (defined as research involving a probability and magnitude of possible harms implied by participation to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to research),
  - the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,
  - the research could not practicably be carried out without the waiver or alteration,
  - whenever possible and appropriate, the participants shall be provided with additional pertinent information after participation,
  - the waived or altered consent does not involve a therapeutic intervention.

#### Privacy and Confidentiality

- Researchers who intend to collect personal information from participants shall secure College REB approval for the procedures used and shall ensure the informed consent of the participants. Approval for such research shall include, but is not limited to, such considerations as:
  - type of data collected,
  - purpose for which data is used,
  - limits on the use, disclosure, and retention of the data,
  - appropriate safeguards for security and confidentiality,
  - modes of observation or access to information in the research that allow identification of particular participants,
  - anticipated secondary uses of identifiable data from the research,
  - anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records, and
  - provisions for confidentiality of data resulting from the research.
- For research proposing to use secondary data (i.e. data contained in records collected for a purpose other than the research itself), College REB approval shall be sought if identifying information is involved. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:
  - identifying information is essential to the research,
  - the researcher will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harm to participants, and
  - individuals to whom the data refer have not objected to secondary use.
- For research proposing to use secondary data that involves identifying information and more than minimal risk for participants

(as defined in TCPS Articles 2.9, and 3.1 to 3.5)<sup>1</sup> the REB shall also require that the use of such data be dependent upon:

- the informed consent of those who contributed data or of authorized third parties,
- an appropriate strategy for informing participants,
- consultation with representatives of those who contributed data, and
- researchers who wish to contact individuals to who data refer shall seek the authorization of the REB prior to contact.

#### Incompetent individuals

Subject to applicable legal requirements for research involving incompetent individuals, the REB shall ensure that:

- The research question(s) can only be addressed using individuals within the identified group(s),
- The research does not expose the participants to more than minimal risk (as defined in TCPS Articles 2.9, and 3.1 to 3.5)<sup>2</sup> without the potential for direct benefits to them, or for the benefit of other persons in the same category,
- Free and informed consent of an appropriately authorized third-party is obtained and continues as long as the participant remains incompetent,
- When a participant who has entered into a research project through third-party authorization becomes competent during the project, his/her informed consent must promptly be sought as a condition of continuing participation,
- When a participant who has voluntarily entered into a research project but becomes incompetent during the course of the research, the free and informed consent of an authorized third-party must be obtained and continue as long as the participant remains incompetent,
- The authorized third-party is not the researcher or a member of the research team,
- The researcher demonstrates how free and informed consent is obtained from the authorized third-party, and how the participants best interests are protected, or
- Where free and informed consent is 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 seeks to ascertain the wishes of the individual concerning participation. The potential participant's dissent will preclude his/her participation.

#### Emergency Health Situations

- The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the individual(s) concerned or of his or her authorized third-party if ALL of the following apply:
  - a serious threat to the prospective participant requires immediate intervention,
  - either no standard efficacious care exists or the research

<sup>1</sup>See Tri-Council Policy Statement <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epct2/Default/>

<sup>2</sup> See Tri-Council Policy Statement <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epct2/Default/>

offers a real possibility of direct benefit to the participant in comparison with standard care,

- 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,
- the prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research,
- third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so no relevant prior directive of the participant is known to exist, and
- when a previously incapacitated participant 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 examination or tests related to the study.

### **Research Ethics Board**

#### Responsibilities of the REB

- Prior approval for research activity or study involving human participants within the context of this policy must be obtained by the researcher from the designated College REB in accordance with its procedures before any research or study is undertaken, before any College facilities or services are used, and before any funds are accepted or accounts opened.
- Failure by a researcher to observe this policy and related procedures may render the researcher personally liable should harm be caused by human participants because of the research.
- The procedures to be followed by the College REB will be those of the Red Deer College that is consistent with the Tri-Council policy and may be modified, as required, by the Red Deer College Chairperson, Research Ethics Board.
- The REB shall meet face-to-face to review proposed research and the review shall be based on 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.
- An annual activity report from the Red Deer College REB will be forwarded to the College Applied Research Office.

#### Membership of the REB

- The Red Deer College REB will act as the College REB for research conducted by faculty or staff. The Red Deer College REB membership structure adheres to the guidelines set out in the most current version of the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans.

#### Scholarly Review

- The College 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.
- 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.

- Research in the humanities and social sciences that poses, at most, minimal risk shall not normally be required by the College REB to be peer reviewed.
- The College REB must be satisfied that a project posing more than minimal risk to participants has undergone appropriate scholarly review.
- Certain types of research, particularly in the social sciences and 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.

Principle for review of new and ongoing research

- The College REB adheres to the principle of proportionate review: the degree of scrutiny of an application for ethics approval is apportioned according to the risk to the study participants. This proportionate approach is based on the general principle that the more invasive the research, the greater should be the requirements for assessing, explaining, defending and cataloguing the potential consequences for all involved in the research. Regardless of the degree of scrutiny, the ethical requirements for approval are identical.
  - Research deemed to be of minimal risk to participants may be given an expedited review. The College REB will provide the guidelines for expedited review as defined in TCPS Article 6.12<sup>3</sup>. All decisions regarding expedited reviews will be reported to the full REB at the first meeting after the decision has been made.
  - College REB review is normally required for research involving naturalistic observation. However, research involving observation of participants at political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.
  - All research conducted under the auspices of the College involving human participants, including research involving human remains, cadavers, tissue, biological fluids, embryos and fetuses' require approval of the REB before the research begins, except in those excluded categories that are stipulated below.
  - Proposed modifications to research approved by the REB, such as changes in design, procedures, instruments, sampling and so forth that substantively alter the research shall be approved by the REB prior to the implementation of such modifications.
  - The opinion of the College Applied Research Office shall be sought whenever there is doubt about the applicability of this policy to a specific research project.
  - Researchers have the right to request, and the College REB has the obligation to provide, reconsideration of a decision. In

<sup>3</sup> See Tri-Council Policy Statement <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

cases where the REB and the researcher cannot reach an agreement through discussion, the researcher has the right to appeal the decision of the REB as outlined under TCPS Article 6.19<sup>4</sup>.

#### Criteria for expedited review

- Research proposals that are of minimal risk to participants, including research conducted as part of course work, may not require a full review by the REB.
- The College REB will observe the Tri-Council policy statement on minimal risk, “For the purposes of this Policy, ‘minimal risk’ research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research”<sup>5</sup>.

#### Reconsideration and appeal

- Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting the research project.
- The researcher may request reconsideration by the REB.
- The researcher will have an opportunity to clarify any portion of their research proposal or provide additional information to the REB.
- In cases where the REB and the researcher cannot reach agreement through discussion, the researcher has the right to file an appeal.
- The REB will reach a decision and communicate to the researcher in writing.
- The researcher and the REB must have fully exhausted the reconsideration process and the REB must have issued a final decision before the researcher initiates an appeal.
- Appeals may only be heard on the basis of a procedural error that materially and adversely influenced the decision of the College REB. Procedural error includes real or reasonably apprehended bias, including bias based on validity, method, theory of the method, theoretical grounds or scope, or undeclared conflict of interest on the part of one or more members of the REB.

#### Review of New and Ongoing Research

- Reviews of studies posing more than minimal risk must be conducted in a face to face meeting of the College REB.
- When the College 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 respond before making a final decision.
- Normally, College REB decisions are made by consensus. If decisions are made by a majority vote, the views of the minority will be communicated to the researcher.
- If the College REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g. as

<sup>4</sup> See Tri-Council Policy Statement <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epct2/Default/>

<sup>5</sup> See Tri-Council Policy Statement <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epct2/Default/>

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 offer a rebuttal.

- Research proposals that require multi-centered research, when several REBs consider the same proposal from the perspectives of their respective institutions, the College REB is responsible for determining the ethical acceptability of research undertaken within its institution. Multi-centered research will also be reviewed by the Applied Research Office for institutional, administrative and operational purposes to help ensure that local issues and values are taken into account.
- When submitting a proposal for multi-centered research the researcher may wish to indicate on the application what other institutions will be conducting an ethical review of the proposal and, upon the request of the researcher, the College REB will facilitate a coordinated review of multi-centered projects and communicate any concerns they have with other REBs reviewing the same project.
- Research to be performed by College researchers outside the College jurisdiction or country shall undergo prospective ethics review at both the College REB and by the REB, where such exists, with the legal responsibility and equivalent procedural safeguards in the country or jurisdiction where the research is to be done.
- Ongoing research is subject to continuing ethics review that is based on a proportionate approach to risk assessment.
- 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.
- Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB will decide on the specific process for ongoing review after consultation with the researcher and the funding agency. This may include more detailed and/or frequent reporting or other additional requirements.
- Projects that are classified as minimal risk will require annual status reports and a formal request for continuing approval. A project can only be approved through this mechanism for a maximum period of three years, after which a new ethics application must be submitted.
- The REB requires applicants to consult the Tri-Council Policy for special requirements that may pertain to particular kinds of research (e.g. secondary use of data, human genome investigations, clinical trials) or particular groups of participants (e.g. competency issues, ethnicity, age, etc.) and to ensure that the safety, welfare and rights of participants are protected.
- In all cases, the researcher will promptly notify the College Applied Research Office and the College REB of any modifications, safety/ethical problems, or the termination of a project. Researchers are obliged to immediately notify, in writing, any known serious adverse event to the Applied Research Office and the REB.
- In addition to REB approval, some research projects may also require approval from the Vice President of Teaching and Learning

Definitions:
Related Information:
Related Documentation:
Next Review Date:
Revision History:

or the Vice President of Transformation and CAO.

**Member:** means a member of the College community and includes all faculty, staff members and students.

- [Academic Freedom Policy](#)
- [Applied Research and the Promotion of Innovation Policy](#)
- [Code of Conduct Policy](#)
- [Integrity in Research and Scholarship Policy](#)

N/A

March 2016

April 2013: New  
 August 2013: update for document links and branding  
 November 2014: update for change in procedure administrator