

SUBJECT: RESEARCH INVOLVING HUMAN PARTICIPANTS

1. Purpose

It is the intent of the University of Northern British Columbia, where research involving human participants is conducted under the auspices of the University, to ensure that:

- 1.1 the safety, welfare and rights of participants are protected;
- 1.2 before beginning research, the amount and the kind of information communicated to participants is appropriate to ensure that informed consent will be obtained from participants;
- 1.3 participants are made aware that their participation is voluntary and that they have the right to withdraw from the research at any time; and
- 1.4 multi-centred research projects and research under other jurisdictions also receives appropriate ethical approval from those centres and jurisdictions.

To meet these objectives, this policy governs the conduct of research involving humans in accordance with the most current version of the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans (the Tri-Council Policy) which can be found at: <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> among other guiding documents.

2. Scope

This policy applies to all research and research-related activity involving human participants conducted under the auspices of the University of Northern British Columbia.

3. Authority

This policy is administered by the Vice President Research.

4. Definitions

In this policy, "human participant(s)" means living individuals, groups of living individuals (for example, social, ethnic, religious or economic groups), human remains, cadavers, tissues, biological fluids, embryos or foetuses. "Participants" means those who are to participate in or be the subjects of research.

5. General

The mandate of the UNBC Research Ethics Board (REB) is to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants which is conducted under the aegis of the University, using the Tri-Council Policy as the minimum standard.

Prior approval for research activity or study involving human participants within the context of this policy must be obtained by the researcher from the REB in accordance with its procedures before any research or study is undertaken, before any University facilities or services are used, and before any funds are accepted or accounts opened by the Accounting

Section. Failure by a researcher to observe this policy and related procedures may render the researcher personally liable should harm be caused to human participants as a result of the research.

6. Research Requiring Ethics Review

All research conducted under the aegis of the University involving human participants, except in those excluded categories stipulated below, requires approval of the REB before the research begins.

Failure to adhere to this policy will result in an investigation conducted by the Office of the Vice President Research according to the relevant article of the Faculty Agreement governing fraud and misconduct in academic research, and may result in disciplinary action or sanctions.

In those situations where researchers believe they are conducting research in an excluded category, they must consult with the Chair of the REB to confirm that this is the case. Examples of excluded categories (per Tri-Council Policy) are:

- Research concerning a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances or archival materials.
- 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.
- Research in the manner of quality assurance studies, performance reviews or testing within normal educational requirements.
- Research involving secondary data which does not contain identifying information.

7. Research Ethics Board (REB)

The Research Ethics Board, a Sub-Committee of the Senate Committee on Research and Graduate Studies, governs research involving human participants. The REB will submit an annual report to the Senate Committee on Research and Graduate Studies in December.

7.1 Membership

The REB shall consist of at least five members, including both men and women, of whom:

- at least one member is knowledgeable in ethics;
- at least two have broad expertise in the methods or in the areas of research that are covered by the Research Ethics Board;
- at least one is a community member with no affiliation with the institution;
- four members are faculty, all of whom are active in research with human participants.

Other members who may serve on the REB include:

- ad hoc members appointed by the Vice President Research in consultation with the REB and the Chair for special purpose reviews;
- alternate members appointed by the Vice President Research in consultation with the REB and the Chair to serve as replacements for regular members when they are unable to attend;
- for biomedical research or other research involving special legal risks, at least one member knowledgeable in the relevant law; Members of the REB will serve a term of three years, renewable for a total of two terms. Membership terms will be staggered to ensure continuity.

- A quorum consists of two thirds of the total membership of the REB that shall include at least one member knowledgeable in ethics and at least two members active in research with human participants.
- The REB shall schedule its own meetings to ensure a timely flow of reviews such that research is not unduly impeded.

8. Principles for Review of New and Ongoing Research

- 8.1 The 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. Regardless of the degree of scrutiny, the ethical requirements for approval are identical.
- 8.2 Research that is deemed to be of minimal risk to participants (see Tri-Council Policy definition) may be given an expedited review. Expedited review consists of a review by two REB members and the Chair (refer to REB Guidelines for Expedited Review for further information).
- 8.3 Research conducted by undergraduate students as part of course work, or carried out within formal course requirements, shall be reviewed using the criteria developed by the REB in accordance with Tri-Council Policy and published in its Terms of Reference available at: www.pre.ethics.gc.ca.
- 8.4 The REB must be satisfied that a project posing more than minimal risk has undergone appropriate scholarly review. The REB does not normally conduct scholarly review.
- 8.5 Reviews of studies that pose more than minimal risk must be conducted in a face to face meeting of the REB.
- 8.6 Normally REB decisions are made by consensus. If decisions are made by majority vote, the views of the minority will be communicated to the researcher.
- 8.7 Minutes of all REB meetings, including all decisions, dissents, and the reasons for them shall be prepared and maintained by the secretary to the REB. Minutes of all REB meetings are accessible to authorized representatives of the institution, researchers and funding agencies.
- 8.8 Researchers have the right to request, and the REB has the obligation to provide, reconsideration of a decision. In 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 under Appeal Process, Section 10.
- 8.9 Ongoing research is subject to continuing ethics review that is based on a proportionate approach to risk assessment (see Section 9 below).
- 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.
 - For projects above the minimal risk threshold, the REB will decide on a process for ongoing review after consultation with the researcher and the funding agency.
 - In all cases, the researcher will immediately notify the REB of any modifications, safety/ethical problems, or the termination of a project.

In addition to the above procedures, the REB requires applicants to consult the Tri-Council Policy for special requirements that may pertain to particular types of research (e.g. secondary use of data, human genome investigations, clinical trials) or particular groups of participants (competency issues, ethnicity, age, etc.) and to ensure that the safety, welfare and rights of participants are protected.

9. Criteria for Expedited Review

Research proposals that are of minimal risk or are conducted as part of course work may not require a full review by the REB. The Review Ethics Board observes the Tri-Council Policy statement on minimal risk, "if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his/her everyday life that relate to the research, then the research can be regarded as minimal risk." Applicants have the right to make a formal appeal regarding the results of the expedited review, using the stipulated procedure.

10. Appeal Process

In the event that a researcher is dissatisfied with the decision of the REB, and satisfactory agreement cannot be reached, the researcher may appeal the decision under the following mechanism agreed with the University of Victoria (UVic) that is consistent with the Tri-Council Policy.

Appeals may only be heard on the basis of a procedural error that materially and adversely influenced the decision of the UNBC REB. Procedural error includes real or reasonably apprehended bias, including bias based on validity, method, theory of the method, theoretical grounds of the work or scope, or undeclared conflict-of-interest on the part of one or more members of that REB.

The appellant will provide the Administrative Assistant in the UNBC Office of Research (the "UNBC Representative") with a written description of the alleged procedural error that is the basis of the appeal (the "Submission"). The appellant must also sign a waiver in favour of each of UNBC and UVic, in the prescribed form, to protect the institutions from any liability or legal claim related to the review.

As soon as is practicable, the UNBC Representative will send the appellant's submission to the Chair of UNBC's REB.

Within thirty (30) working days of receipt of the appellant's submission, the Chair of UNBC's REB will file with the UNBC Representative a written response to the allegation. As soon as is practicable, the UNBC Representative will send a copy of the Chair's response to the appellant. The appellant will have the opportunity to provide a written reply to that response within thirty (30) working days of receipt of the response.

Once the file, comprising the original application for ethics approval and the documents referenced above, is complete, the UNBC Representative will forward the file to the Associate Vice President Research, University of Victoria with a cover letter requesting an Appeal Board review.

The procedures to be followed by UVic's Appeal Board will be those of the University of Victoria and may be modified, as required, by UVic's Human Research Ethics Coordinator, (the "UVic Representative"). The appellant and the Chair of the UNBC REB have the right to meet with the UVic REB regarding the appeal. In reviewing the appeal, the UVic REB will determine if there has been a procedural error that materially and adversely influenced the decision of the UNBC REB, normally within thirty (30) working days of receipt of the file, and will transmit its decision and reasons to the parties.

If the UVic REB determines that there has been such a procedural error, it will direct the UNBC REB to reconsider the application, employing any changes in procedure outlined by the UVic REB within its decision and reasons.

Normally, within ten (10) working days of the decision of the UVic REB, the written results of the appeal and reasons will be forwarded to the appellant and the Chair of the UNBC REB. The results will be binding on the appellant and UNBC and any reconsideration of the application will be binding and not subject to further appeal.

Should any costs be associated with the appeal (e.g. travel of the appellant, lawyers' fees, etc.), the appellant and UNBC will each bear their own costs.