Selkirk College **Policies and Procedures**		Number **8700**	**Title** **Research Involving Human Participants**		
		Replaces	B0001.2 Research Ethics		
		Effective	2015-09-01	Next review :	2020-05-01
Executive Responsibility	Administrative Responsibility	Recommended by Policy Review Committee		2015-06-17	
Vice-President Education and Students	REC-HP Chair	Recommended/Approved by Education Council			
		Approved by President		2016-06-16	

A. PURPOSE

Selkirk College has declared its commitment to applied research in its Strategic Directions Framework document. The college recognizes applied research as valuable activity for faculty professional development and for enhancement and enrichment of learning experiences. As well, it can expand the college's role in meeting its mandate to the communities it serves. The college sees direct benefit to the learners in being able to directly develop applied research opportunities. At the same time, the College is committed to conducting research according to principles of scientific rigour and in an efficient, impartial, and ethical manner. The purpose of this policy is to ensure an ethical approach to research involving human participants in accordance with the three core principles of the Tri-Council Policy Statement. (TCPS2)[1]

B. SCOPE / LIMITS

All members of the college wishing to pursue applied research must consider scientific rigour and impartial and ethical conduct when proposing, developing, or engaging in any applied research activity that is associated with the college, and such activities must be closely monitored to ensure that this is the case. Thus, except where exempt under Part 7.2 of this policy, the researcher must seek and receive approval for research from the Research Ethics Committee - Human Participants (REC-HP) as described herein. The college assigns the REC-HP the right to approve/disallow any research proposal on its behalf.

Unless expressly exempted by the REC-HP, all research that involves any living human participant or which falls under Part 7.1 of this policy, whether undertaken by faculty, staff or students, and regardless of the location where the research is conducted, requires prior review and approval by the REC-HP. Research being conducted without prior approval of the REC-HP will be suspended immediately, pending REC-HP review.

Violation of this policy will be referred to the VP Education and Students. Procedures for dealing with the investigation, determination and sanctions will be the same as those detailed in Policy 8710, "Integrity in Research", articles 7 and 8.

C. PRINCIPLES

1. Applied research activities will be self-funded through research grants, contracts, etc., that comply with current applicable college policies and standards.
2. Any such applied research will adhere to established ethical principles and standards as well as appropriate scientific rigour and be vetted by the REC-HP, unless deemed exempt under Part 7.2.

---

[1] TCPS2 refers to the Tri-Council Policy Statement regarding the "*Ethical Conduct for Research Involving Humans*", developed jointly by the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institution for Health Research (CIHR) and the Social Sciences and Humanities Research Council (SSHRC). A copy of the policy statement is available at http://www.pre.ethics.gc.ca/eng/index/

3. Where such research is approved, the college will provide the support services in the form of suitable facilities, clerical support, and mentors/professional development when required.
4. All research will be approached with scholarly integrity. Such integrity of scholarship will require attention to authorship and publication rights as well as disclosure of any potential conflicts of interest.
5. Students will be involved in applied research activities whenever appropriate to provide them with new and enhanced opportunities for learning.
6. Such research will enhance the knowledge and experience of Selkirk College's faculty and staff, and work to build a positive reputation for the college in the realm of applied research.
7. Applied research will serve to establish collaborative and mutually beneficial arrangements and/or partnerships with businesses or agencies in the public/private sectors in the college region and beyond.

D. DEFINITIONS

1. For the purpose of this policy:
   a) *Research* mean any gathering of information from or about living individuals or groups of living individuals, such as publicly identifiable social, ethnic, religious or economic groups.
   b) *Human Participant* means any living person who is a source of primary data.
   c) *Researcher* means anyone who carries out research.
   d) *Principal Investigator* means the researcher who has primary responsibility for a given research project.
   e) *Therapeutic Research* means research regarding a treatment involving participants who could benefit from the treatment.
   f) *Non-therapeutic Research* means research performed regarding a treatment that involves participants who will not benefit from the treatment.
   g) The standard of *minimal risk* is commonly defined as follows: 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 participant in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk.

2. "Tri-Council Core Ethical Principles" are the following principles:

   a) Respect for Persons: This principle requires the recognition of the intrinsic value of human beings and also requires that all participants give their free, informed, and ongoing consent as participants in a research study.

   b) Concern for Welfare: This principle requires that the welfare of Human Participants in research be protected and promoted.

   c) Justice: This principle requires that all Human Participants in research be treated fairly and equitably so that individuals or groups are not inappropriately included in or excluded from participation in research.

   d) For further information, reference may be made to the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

E. TERMS OF REFERENCE

1. **Establishment of the Research Ethics Committee - Human Participants**

   The VP Education and Students will appoint members for the REC-HP and select the Chair of the REC-HP in consultation with the Selkirk College Education Council. Prior to appointment,

candidates will disclose actual, perceived, or potential conflicts of interest to the REC-HP, the VP Education and Students, and the Education Council.

2. **Composition of the Research Committee**

To enhance expertise, multi-disciplinary perspective, and independence, the REC-HP will consist of six regular members, including the Chair, of whom:

a) At least two members have expertise in the methods or areas of research that are covered by the REC-HP;

b) At least one member is knowledgeable in ethics;

c) At least one member is not an employee or student of Selkirk College, but is recruited from the communities served by the institution.

The committee will attempt to maintain an appropriate gender balance.

Although it is not envisioned that the college will be involved in biomedical research, should such research take place in the future, there must be one member of the REC-HP who is knowledgeable in the relevant law.

In addition to the regular members, the committee may occasionally include appropriate ad hoc members, when the need arises for specific expertise not available from regular members or to provide particular community or research subject representation.

The appointment of regular members is for a three-year term and can be renewed.

A quorum of the committee will consist of at least four regular members who possess the range of expertise reflected in its membership. Ad hoc committee members may not be counted for the purpose of establishing quorum.

3. **Responsibilities**

The REC-HP is responsible for:

a) functioning in an impartial manner, providing a fair hearing to those involved and providing reasoned and appropriately documented options and decisions;

b) reviewing research proposals for scientific rigour and ethical considerations. In regard to ethics assessment, the REC-HP will adopt a proportionate approach based on the principle that the more invasive the research, the greater should be the care in assessing the research (TCPS2: Article 2.9)[1]. If the research poses more than minimal risk, the responsibility of the committee regarding scholarly review is increased;

c) waiving the requirements for review as per Part 7.2;

d) approving proposals which meet Selkirk College's requirements;

e) advising researchers about measures that can be taken to ensure their project is acceptable under the conditions of this policy and other applicable college policies;

f) initiating college-wide education on research ethics and monitoring ongoing research;

g) conducting a yearly review of ongoing research for compliance with the terms of the approved proposal. More frequent reports may be required if the committee deems this necessary;

h) holding regular face-to-face meetings in order to fulfill its responsibilities;

i) preparing and maintaining minutes of all committee meetings. The minutes shall clearly document the committee's decisions and any dissents and the reasons for them. Minutes must be accessible to authorized representatives of the institution, researchers and funding agencies; and

j) terminating any ongoing research that ceases to meet policy standards.

[1] TCPS2 refers to the Tri-Council Policy Statement regarding the "*Ethical Conduct for Research Involving Humans*", developed jointly by the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institution for Health Research (CIHR) and the Social Sciences and Humanities Research Council (SSHRC). A copy of the policy statement is available at http://www.pre.ethics.gc.ca/eng/index/

4. **Conflict of Interest**

Members of the committee will disclose any actual, perceived or potential personal interest in research presented to the REC-HP and shall be absent during discussion or decision-making when these proposals are reviewed. Conflict-of-interest situations include, but are not limited to: when an REC-HP member's own research is being reviewed, or when he/she has been in direct academic conflict or collaboration with the researcher whose program is being reviewed.

The REC-HP member may disclose and explain the conflict of interest and offer evidence to the REC-HP, and the proposer of the research has the right to hear the evidence and to offer a rebuttal.

5. **Communication**

The administrative contact for the REC-HP will be the first point of contact for applicants who wish to submit a proposal for ethics review. The administrative contact will also track projects and request submission of annual status reports.

Once a proposal has been submitted to the REC-HP for review, the committee Chair will be responsible for communicating with the principal investigator(s) to advise them of the results. The Chair will also communicate with the administrative assistant on policy issues.

Although the committee normally meets face-to-face, factors (rural area, multiple campuses, summer holidays, or an emergency situation) may sometimes make it difficult to reach quorum. In order for the committee to respond to submissions in a timely manner, the committee may choose to discuss submissions and other issues via email or other electronic means of communication. The committee chair or administrative contact will distribute information electronically to committee members. Committee members have seven calendar days to respond to the information. A minimum of four (quorum) must respond in writing for any decision to be made by the committee.

Publicly declared emergencies pose unique research challenges and opportunities; the committee will attempt to expedite the review of any related research applications while upholding the Tri-Council Core Ethical Principles.

6. **Accountability**

The Chair of the REC-HP reports to the VP Education and Students. Chairs of subcommittees struck by the REC-HP report to the Chair of the REC-HP.

F. PROCEDURE

1. **Approval Process**

a) The principal investigator is responsible for initiating the review process by submitting fully detailed research proposals to the administrative contact. The principal investigator is also responsible for filing interim reports to the REC-HP as required.

b) A proposal must contain a form for participants to indicate their informed consent; see section 9, form B.

c) The REC-HP will accommodate reasonable requests from investigators to participate in discussions about their proposals, but investigators will not be present when the REC-HP is making its decision.

d) After the preliminary proposal is reviewed, the REC-HP will notify the principal investigator in writing that the proposal is accepted or rejected or that more information is required before the submission can be considered.

e) If an application is not approved, the REC-HP will advise the principal investigator as to the reasons for non-approval with suggestions as to what is required to make the proposal acceptable. The principal investigator may then resubmit a revised proposal for review.

f) If a proposal is rejected, the REC-HP will advise the principal investigator of its decision in writing, and will provide a copy of the decision to the VP Education and Students.

g) The REC-HP will advise the investigator of the decision within four weeks for a full review, and

within two weeks for a review pre-approved by another institution.

h) Researchers have the right to request, and the REC-HP has the obligation to provide, reconsideration of decisions affecting a research project.

2. **Appeal**

a) If a principal investigator disagrees with the decision of the REC-HP, he/she may initiate an appeal to the VP Education and Students within 10 days of the decision of the REC-HP.

b) An appeal must be in writing and must set out the reasons why the principal investigator believes the decision of the REC-HP to be wrong.

c) The appeal will be heard by the Research Ethics for Human Participants Committee of Thompson Rivers University, whose decision will be final.

3. **Post-Approval Monitoring**

a) The REC-HP will maintain a continuing interest in the project after it has undergone ethical approval and will be available for additional advice, if necessary.

b) An annual status report on the research project must be submitted by the principal investigator. This report must describe the progress made since the last report was filed and any modifications to the project.

c) If there is a major change in the research procedures involved in a study, the research proposal will have to be re-submitted for a full review by the REC-HP.

d) If the REC-HP becomes aware of non-compliance issues regarding a project, the REC-HP will request a meeting with the principal investigator; if the meeting does not result in a satisfactory outcome, the Chair will alert the VP Education and Students, who will deal with the complaint under the appropriate college policy.

G. RESEARCH SUBJECT TO REVIEW

1. **Research Subject to Ethics Review by the REC-HP.**

Unless specifically excluded, all research involving living human participants, including naturalistic observation, requires review and approval by the REC-HP.

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses requires review by the REC-HP.

2. **Research Topic Exemptions Procedure**

The following categories of research do not require approval by the REC-HP, but one should consult the Chair of the REC-HP prior to initiating the project if there is uncertainty as to whether a project constitutes research or requires approval from the REC-HP.

a) Research about a living individual involved in the public arena, -, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interview is exempt. Such research only requires ethics review if the participant is approached directly for interviews or for access to private papers. The review will ensure that such approaches are conducted according to professional protocols.

b) Research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REC-HP review since it can be expected that the participants are seeking public visibility.

c) Quality assurance studies, performance reviews or testing within normal education requirements are exempt, as are studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training. For example, students under the supervision of a faculty member or a professional, performing activities governed under the code of ethics of that profession, would not be required to submit an application for ethics review.

d) Students in the School of Health and Human Services who are regulated by a professional

code of ethics, and who are engaged in assignments designed only to develop professional skills, may not be subject to review. Assignments are considered professional skill development when:

(i) the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions, or general advice for a client; or

(ii) the intent is to develop skills which are considered standard practice within a regulated profession (e.g., observation, assessment, intervention, evaluation, auditing); or

(iii) the information-gathering process is part of the normal relationship between the student and the participants (e.g., nurse and client, social worker and client).

When an assignment includes a research component in addition to skill development, then a review and approval by the REC-HP is required.

e) Research conducted by Selkirk College employees or students in other roles that are in compliance with Selkirk College policy 6000: Employee Code of Conduct and Conflict of Interest. Such research must not involve the use of their Selkirk College titles, the Selkirk College name, or any form of communication that one might construe as support or involvement in the research by Selkirk College.

3. **Review of Student Projects**

Student projects are subject to REC-HP review. In lieu of an REC-HP review, a School can use its own procedures, in compliance with this policy, to approve student research projects or experiments involving human participants, provided:

a) the research is part of a course requirement; and

b) the risks brought about by the research are minimal (TCPS2, Chapter 2, Section B); and

c) the research does not involve unsolicited telecommunications contact of research participants not personally known by the student who carries out the research; and

d) the research is not part of a faculty member's own research program.

If the above conditions are not met, the instructor must submit the proposal for review by the REC-HP. In cases where a student plans and coordinates a research project independently and the research is not a course requirement, the student will be considered to be the principal investigator. Such research must be submitted for approval to the REC-HP.

4. **Eligibility for Delegated Reviews**

Research that has already passed through research ethics approval review by an external agency and which has been approved by the agency will only require an delegated review, unless there are changes to the methodology. This includes research approved by the research ethics board of another research institution. Such a board must be duly constituted under the TCPS2. Please note that the Natural Sciences and Engineering Research Council; the Social Science and Humanities Research Council; and the Canadian Institutes for Health Research conduct scholarly reviews, not ethical reviews.

The delegated review will be conducted by a smaller committee of members of the REC-HP that will examine the research project from the perspective of due process being carried out. The membership of the smaller review team will normally be the Chair and two other regular members of the REC-HP, and an abbreviated turnaround time of two weeks is ensured.

H. FREE AND INFORMED CONSENT

1. **Requirement for Free and Informed Consent**

Research may begin only after participants or authorized third parties have given their written free and informed consent about their voluntary participation. The participants' consent should be maintained throughout their participation in the research. This consent should be obtained in writing (see section 9,form B), and should be clear and free of coercion. Any rewards or incentives for participation should be clearly presented in the research proposal. Any such rewards or incentives will be reviewed by the REC-HP to ensure that they do not act as an undue

enticement.

Evidence of free and informed consent by the participant 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.

The REC-HP may approve a consent procedure which alters some or all of the elements mentioned above, or may waive the requirement to informed consent provided that it finds and documents that (TCPS2: Article 3.7):

a) the research involves no more than minimal risk to the participants;

b) the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

c) the research could not practicably be carried out without the waiver or alteration;

d) whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and

e) the waived or altered consent does not involve a therapeutic intervention.

2. **Minimum Disclosure**

At a minimum, researchers should disclose to prospective participants 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 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;

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.

3. **Naturalistic Observation**

Research involving naturalistic observation requires review by the REC-HP. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REC-HP review.

4. **Competence of Participants**

Competence refers to the ability of prospective participants to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent.

Researchers must comply with all applicable legislative requirements. Subject to applicable legal requirements, individuals who are not legally competent will only be asked to become research participants 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 risks without the potential for direct benefits for them.

Researchers wishing to study participants who are incompetent must obtain free and informed consent from an authorized third-party individual representing the participant. The researcher will show how the free and informed consent will be sought from the authorized third party, and how

the participant's best interests will be protected. The authorized third party individual may not be a member of the research team. The consent must be maintained throughout participation in the research. If the participant becomes competent during the research project, his or her informed consent must be sought for continued participation in the project.

In regards to participation in the study, a researcher must seek to obtain the wishes of a legally incompetent individual in circumstances where the legally incompetent individual understands the nature of the study. If the legally incompetent individual does not wish to be involved in the study, then his/her wishes must be respected, regardless of any free and informed consent obtained from an authorized third party.

5. **Research in Emergency Health Situations**

The REC-HP may allow research in emergency health situations to be carried out without free and informed consent if all of the following apply (TCPS2: Article 3.8):

a) a serious threat to the prospective participant requires immediate intervention;

b) either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with standard care;

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 participants;

d) the prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research;

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 participant is known to exist.

When a previously incapacitated participant regains capacity or an authorized third-party individual is found, free and informed consent must be obtained for continuation in the project.

I. FORMS

View Research Ethics Committee on MySelkirk for forms.

J. OTHER RELEVANT POLICIES

8710 Integrity in Research

Acknowledgements

Selkirk College would like to thank the Natural Sciences and Engineering Research Council of Canada for granting permission to use wording from the "*Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*" (December 2010) in the development of this policy.