Selkirk College

## Policy Procedures

Effective Date: November 3, 2022
Policy Reference: Policy 8700

# Policy 8700: Ethical Conduct of Research Involving Humans

## Section 1: Ethics Review

### A. Research Requiring Ethical Review

1. (Article 2.1 (a); Article 6.11) All research that involves human participants requires review and approval by the Research Ethics Board (REB) in accordance with this policy and the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans 2nd Edition (TCPS2, 2018), before the research is started, except as stipulated in section A.3 below
2. (Article 2.1 (b); Article 6.11) Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses
3. Exceptions
    a) (Article 2.2) Research publicly available through a mechanism set out by legislation or regulation and that is protected by law; or in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy;
    b) (Article 2.3) Research involving the observation of people in public places where:
        i. it does not involve any intervention staged by the researcher, or direct interaction by the researcher with the individuals or groups;
        ii. individuals or groups targeted for observation have no reasonable expectation of privacy; and
        iii. any dissemination of research results does not allow identification of specific individuals;
    c) (Article 2.4) Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;
    d) (Article 2.5) Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review; and
    e) (Article 2.6) Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

## B. RESEARCH ETHICS BOARD

### 1. Authority of the Research Ethics Board

a) (Article 6.1; Article 6.2; Article 6.3) The College mandates the REB to approve, reject, propose modifications to or terminate any proposed or ongoing research involving a human participant that is conducted within or by members of the College using the considerations set forth in this Policy, as a minimum standard.

b) The REB is an independent standing committee with terms of reference approved by the Vice President (VP) of Education. The REB's decision to approve or deny proposals for research are made independently and may not be set aside without formal appeal.

### 2. Membership of the Research Ethics Board

a) (Article 6,4; Article 6.5) To enhance expertise, multi-disciplinary perspective, and independence, the REB will consist of at least five regular members, including diversity of representation, of whom:

   i. At least two members have expertise in the methods or areas of research that are covered by the REB;

   ii. At least one member is knowledgeable in ethics;

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

   iv. 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 REB who is knowledgeable in the relevant law;

b) In addition to the regular members, the board 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;

c) All members will be appointed by the VP Education. The College will provide staff support and necessary resources for the REB;

d) Appointment to the REB is for a three-year term, with terms of members overlapping. The appointment is renewable to a maximum of two terms;

e) The REB will elect a Chairperson every two years from its membership. The position is renewable; and

f) The Chair may remove members if this action is deemed necessary according to the consensus of the Board. This step should only be contemplated in the face of serious failure to meet the obligations of service to the Board, or a breach of this policy.

3. **Accountability**

The Chair of the REB reports to the VP Education. Chairs of subcommittees struck by the REB report to the Chair of the REB.

## C. REVIEW PROCEDURE

1. **Proportionate Approach to Ethics Assessment**

(Article 2.9; Article 6.12). The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research; the lower the level of the risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full Board review). A proportional approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethics implications of the research. The REB decides on the level of review for each research proposal.

**a) Full Review**

Where a proposal poses more than minimal risk (as defined by the Tri-Council Guidelines in (Article 2.B), the REB will assess the harms and benefits of the proposed research project, may determine if the research design is capable of answering the research questions, and will ensure that the research procedures and materials conform to established ethical standards.

**b) Delegated Review**

Where a proposal poses only minimal risk the Chair and/or designates of the REB will review the proposal and its conformity to established research ethics standards and practices. Researchers may request a delegated review when submitting their proposal.

**c) Local (Course) Review (Research Conducted by Students as Part of Course Requirements)**

Student projects are subject to REB review. In year one and two programs of study, instructors are required to submit a Course Based Research Ethics proposal to the REB on behalf of their students, provided:

i. the research is part of a course requirement; and

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

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

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

If the above conditions are not met, the student must submit the proposal to the REB after review by their instructor.

2. **Proposal Submission to REB. Researchers will submit the following to REB with a request for full or delegated review:**

    a. The research ethics proposal, in sufficient detail to permit the REB to assess its ethical acceptability;

    b. Experimental protocol (where appropriate);

    c. Informed consent statement and forms (as necessary). Normally, participants must be given a copy of the informed consent form which they have signed;

    d. Copies of questionnaires and research instruments (where appropriate);

    e. Statement of formal acknowledgement and/or approval of any agencies or companies whose co-operation is needed to conduct the research or whose support is being or is provided in connection with the research (where applicable);

    f. Copies of any ethical guidelines, other than those approved by the REB, used in preparing the proposal;

    g. Such other material or information as the REB may request.

3. **Decision-making**

    a. (Article 6.13) The REB review shall be based upon fully detailed research ethics proposals or, where applicable, annual progress reports. The REB will function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB will accommodate reasonable requests from researchers to participate in discussions about their proposals, but not to be present when the REB is making its decision. When the 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.

    b. Final decisions in the full review are based on consensus or majority quorum.

    c. The REB will notify the researchers in writing of its decision to:

        i. Approve the proposed research activity as submitted; or

        ii. Require minor modifications of the proposed research activity. The resubmitted proposal will be reviewed by the Chair of the REB and/or delegates; or

        iii. Require significant modifications or additional information or major revisions. The resubmitted proposal will be reviewed by the REB; or

        iv. Disapprove the proposed research activity.

    d. The Chair of the REB will submit an annual report to the VP Education listing the number of proposals reviewed, approved and denied.

4. **Reconsideration**

    a. (Article 6.18) Researchers have the right to request, and the REB has the obligation to provide, reconsideration of decisions affecting a research project.

b. The REB will be guided by principles of natural and procedural justice in their decision-making. Such principles include providing a reasonable opportunity to be heard, an explanation of the reasons for opinions or decisions, and the opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions.

5. **Appeals**

Researcher have the right to appeal a decision taken by the REB by submitting their reasons to the Chair. Such appeals will then be submitted to the Research Ethics Board of Thompson Rivers University with which Selkirk College has an agreement to perform this function. The decision of that Research Ethics Board shall be final.

6. **Post-Approval Monitoring**

a) The REB will be available for additional advice, if necessary.

b) An annual status report on projects lasting more than one year 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 minor change in the research procedures involved in a study, the principal investigator must submit an amendment form.

d) If there is a major change in the research procedures involved in a study, the REB will determine resubmission for a full or delegated review.

e) If the REB becomes aware of non-compliance issues regarding a project, the REB 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, who will deal with the complaint under the appropriate college policy.

f) The REB requires the submission of a final summary report of the project.

7. **Meetings and Attendance**

a) (Article 6.10) The REB shall have regular meetings to discharge their responsibilities, and shall normally meet face to face to review proposed research that is not assigned to delegated review.

b) (Article 6.9) A quorum for committee purposes for a full review must meet the minimum requirements of membership representation outlined in Article B.2.a. Where possible, the REB will reach decisions by consensus; otherwise a simple majority will prevail. The Chair will not vote, except in the event of a tie.

c) The REB Chair will arrange the meetings, distribute relevant documents and organize the recording and distribution of minutes. They will also ensure that all minutes, and relevant records are maintained securely.

8. **Record Keeping**

a) (Article 6.17) Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document members in attendance, 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 are accessible to authorized representatives of the College, researchers and funding agencies.

b) The REB will prepare and maintain adequate documentation of REB activities, including the following:

   i. Copies of all research proposals reviewed, certificates of approval, scientific evaluations, if any, that accompany the proposals, approved sample informed consent documents, progress reports by researchers and reports of injuries to participants;

   ii. Records of continuing review activities;

   iii. Copies of all correspondence between the REB and the researchers;

   iv. A list of REB members; and

   v. Written procedures for the REB.

c) Standards for retention and archiving of data may vary according to discipline, but the College requires that research data must be retained for at least one year after completion of the research. Where legal, scholarly, or other standards mandate a longer period of retention, researchers are expected to comply with these standards.

**9. Multi-Jurisdictional Research**

(Article 8.A) It is the responsibility of the Principal Researcher to ensure that multi-centred research is reviewed by all institutions where the research is undertaken. To facilitate this type of review, the REB may also share documents and findings with REBs at other institutions. The REB may also review the documents and findings of other REBs of other jurisdictions as part of its ethics review process.

## Section 2: Free, Informed and Ongoing Consent

### A. Requirement for Free, Informed and Ongoing Consent

1. (Article 3.3; Article 3.5) Research governed by this Policy may begin only if (1) prospective participants, 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
2. (Article 3.12) 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.
3. (Article 3.7) The REB 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:

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.

**B. INFORMING POTENTIAL PARTICIPANTS**

1. General Conditions

Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research. Throughout the free and informed consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. The information generally required for informed consent includes:

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; and / or

e) the possibility of commercialization of research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of researchers, their institutions or sponsors.

Not all of the listed elements are required for all research, and additional information may be required in some types of research or in some circumstances.

**C. COMPETENCE OF PARTICIPANTS**

1. (Article 3.8; Article 4.6) 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.

## D. RESEARCH IN EMERGENCY HEALTH SITUATIONS

1. (Article 3.8) Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the 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 medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

    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.

## Section 3: Privacy and Confidentiality

### A. Accessing Private Information: Personal Interview

1. (Article 2.2; Chapter 5, Section A) Subject to the exceptions in Section 1 above (Ethics Review), researchers who intend to interview a human participant to secure identifiable personal information shall secure REB approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in Section 2 above. REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

### B. Accessing Private Information: Surveys, Questionnaires and Data Collection

1. (Article 5.3) Researchers shall secure REB approval for obtaining identifiable personal information about participants. Approval for such research shall include such considerations as:
    a) The type of data to be collected;
    b) The purpose for the which the data will be used;
    c) Limits on the use, disclosure and retention of the data;
    d) Appropriate safeguards for security and confidentiality;
    e) Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular participants;
    f) Any anticipated secondary uses of identifiable data from the research;
    g) Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records; and
    h) Provisions for confidentiality of data resulting from the research.

### C. Secondary Use of Data

1. (Article 5.5A) If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:
    a) Identifiable information is essential to the research;
    b) The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

c) The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;

d) The researchers will comply with any known preferences previously expressed by individuals about any use of their information;

e) It is impossible or impracticable to seek consent from individuals to whom the information relates; and

f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

2. (Article 5.5B) Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.
3. (Article 5.6) When secondary use of identifiable information without the requirement to seek consent has been approved under Article 5.5A, researchers who propose to contact individuals for additional information or for reasons related to the welfare of the participant shall, prior to contact, seek REB approval of the plan for making contact.

## Section 4: Conflicts of Interest for Researchers

### A. Disclosure of Conflict of Interest

1. (Article 7.3; Article 7.4) Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. The REB will develop and use mechanisms to address conflict of interest, whether real or apparent.

## Section 5: Fairness and Equity in Research Participation

1. (TPCS2 Article 4.1) Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.
2. Researchers are encouraged to review the Province of BC's Anti-Racism Data Act.

## Section 6: Research Involving the First Nations, Inuit, and Metis Peoples of Canada

1. (Article 9.1-9.18) Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community.
2. Researchers will recognize the First Nations Principles of ownership, control, access, and possession – more commonly known as OCAP® – assert that First Nations have control over data collection processes, and that they own and control how this information can be used.
3. Researchers are also encouraged to review and adopt Social Sciences and Humanities Research Council of Canada Indigenous Research Principles.

Selkirk College

# Policy Procedures

**FORMS**

View Research Ethics Board on MySelkirk.ca for forms.

**OTHER RELEVANT POLICIES**

8710 Integrity in Research
6000 Employee Code of Conduct and Conflict of Interest
6550: Protection of Privacy
8720 Selkirk Management of Surveys