Ethics Review of Research Involving Human Participants

1.0 PREAMBLE

1.1 The University is fundamentally committed to the advancement of knowledge through scholarly activities, including Research Involving Human Participants. The University is committed to ensuring the highest level of ethical conduct for Research Involving Human Participants, recognizing that such Research should balance the need for scientific inquiry with the need to respect cultural and community context, human dignity, and well-being.

2.0 PURPOSE

2.1 To cultivate an environment in which the conduct of Research Involving Human Participants, performed Under the Auspices of the University, follows the highest ethical standards;

2.2 To promote an awareness and understanding of how the Core Ethical Principles of Respect for Persons, Concern for Welfare, and Justice are applied within the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014, referenced herein as the “Tri-Council Policy Statement” or “TCPS”), as well as all relevant institutional, national, and international standards and best practices; and

2.3 To establish an independent human research ethics review process.

3.0 SCOPE

3.1 This Policy applies to all Research Involving Human Participants, their biological material, or data that is not specifically exempted by the TCPS that is:

3.1.1 conducted by University faculty, staff or students;

3.1.2 conducted Under the Auspices of or in affiliation with the University; or

3.1.3 conducted using University equipment, space, or resources.
4.0 DEFINITIONS

4.1 “Concern for Welfare” requires that the welfare of Human Participants in research be protected and promoted, and the recognition that the welfare of a person is the quality of that person’s total experience of life, which consists of the impact caused, among other things, by factors such as one’s physical, mental, and spiritual health, as well as one’s physical, economic, social and cultural circumstances and concern for the community to which participants belong.

Concern for Welfare acknowledges the important role of communities in promoting collective rights, interests and responsibilities that also serve the welfare of individuals. Research involving distinct communities should enhance their capacity to maintain their cultures, languages and identities and to support their full participation in, and contributions to, Canadian society.

4.2 “Core Ethical Principles” refers to the three Core Principles of the Tri-Council Policy Statement that together express the overarching value of respect for human dignity. These are: Respect for Persons, Concern for Welfare and Justice.

4.3 “Ethics Approval” refers to the research ethics approval granted in accordance with the Policy and its Procedures by the Research Ethics Board (REB) for proposed research involving human participants.

4.4 “Ethics Review Agreement” refers to an agreement between the University and another research institution or organization that authorizes an alternative model or models for the ethics review of Research Involving Human Participants. Such agreements may or may not be reciprocal in nature.

4.5 “Human Biological Materials” means tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials, and stem cells.

4.6 “Human Participants” are those individuals whose data or responses to interventions, stimuli, or questions by the researcher are relevant to answering the research question.

4.7 “Justice” refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. It should ensure that any knowledge collected/generated is not misappropriated, and that community norms are respected, not violated. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. It should ensure that knowledge is shared with participants and that they are not stigmatized or misrepresented through its dissemination.

4.8 “Misconduct in Research” refers to conduct that breaches the scholarly standards and practices generally accepted within the relevant research/scholarly field and may include, but is not limited to, fabrication or falsification of research results, plagiarism, failure to comply with the requirements of funding applications and agreements, and failure to obtain the necessary approvals before commencing work with human participants.
4.9 “Policy” refers to the SFU Policy on the Ethics Review of Research Involving Human Participants.

4.10 “Procedures” refers to the Procedures in force with respect to this Policy.

4.11 “Provisos” refer to a written explanation of the conditions and/or modifications that must be made to a submitted application for ethics review for it to receive approval.

4.12 “Reconsideration” refers to the process by which a researcher and the REB attempt to resolve any disagreements, through deliberation and consultation, about the decision rendered by the REB.

4.13 “Research” is an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

4.14 “Research Ethics Appeals Process” refers to the process that allows a researcher to request a review of an REB decision when, after reconsideration, the REB has refused ethics approval of the research.

4.15 “Research Ethics Board (REB)” refers to a body of researchers, community members, and others with specific expertise (e.g., in ethics and relevant disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within an institution’s jurisdiction or under its auspices.

4.16 “Research Involving Human Participants” means research involving Human Participants; or Human Biological Materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells, whether derived from living or deceased individuals.

4.17 “Respect for Persons” requires the recognition of the intrinsic value of human beings and the respect and consideration that they are due, whether they are involved in research directly as subjects, or whether they are involved solely by virtue of their data or Human Biological Materials being used in research. This principle also incorporates the requirement that all Human Participants give their free, informed, and ongoing consent as a prerequisite for participation in research.

In research involving First Nations, Inuit and Métis peoples, Respect for Persons extends beyond individual ethical protections to include collective protection, which recognizes interconnections between humans and the natural world, and Indigenous obligations to maintain, and pass on to future generations, knowledge received from Ancestors as well as innovations devised in the present generation.

4.18 “Under the Auspices” means with the protection or support of someone or something, especially an organization such as a University.

4.19 “University” refers to Simon Fraser University (SFU) for the purpose of this Policy.
5.0 POLICY

5.1 Core Ethical Principles

5.1.1 The University will regulate all Research Involving Human Participants in accordance with the Core Ethical Principles contained within the Tri-Council Policy Statement:

a. Respect for Persons – a recognition of the intrinsic value of human beings and the respect and consideration they are due;

b. Concern for Welfare – a requirement of researchers and research ethics boards to aim to protect the welfare of research participants; and

c. Justice – an obligation to treat people fairly and equitably.

5.1.2 Building on Chapter 9 of the TCPS, the University recognizes that research involving Indigenous peoples requires additional ethical considerations, including but not limited to the need to co-create research projects in a community-led process. This recognition is consistent with the United Nations Declaration on the Rights of Indigenous Peoples, and informed by the Truth and Reconciliation Commission of Canada: Calls to Action. The University also takes direction from the SFU Aboriginal Reconciliation Council (ARC) Final Report, particularly in encouraging the "use (of) Indigenous methodologies and respect (for) Indigenous protocols and ethics in conducting research." Thus,

a. The University shall ensure that research involving Indigenous peoples aligns with the standards and recommendations referred to herein.

b. The University shall also ensure that research involving Indigenous peoples aligns with the stated goal on Culturally Respectful Indigenous Research, from the Accord on Indigenous Education, that speaks to “partnering with Indigenous communities at all levels in ethically based and respectful research processes.”

5.1.3 The University shall ensure that those who conduct Research Involving Human Participants understand their responsibilities for the ethical conduct of their research and receive appropriate training in the skills necessary for such conduct. This includes not only awareness of but also understanding of the relevant policies, procedures, professional standards, and practices that both support and promote the responsible conduct of research.

5.1.4 This Policy and its affiliated Procedures conform to the requirements stated within the Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions.

5.2 Roles and Responsibilities

5.2.1 The Research Ethics Board (REB) derives its authority from the Senate.

5.2.2 The Vice-President, Research and International is responsible for administrative and operational aspects of the REB.

5.2.3 The Vice-President, Research and International is responsible for determining ongoing financial and administrative resources that are required for the REB to fulfill its duties and for ensuring that these resources are provided.
5.2.4 The University shall authorize such number of REBs organized around volume and type of submission, as determined to be appropriate by the Vice-President, Research and International.

5.2.5 The REB is responsible for reviewing all research covered by this Policy. It has the mandate to review and maintain ongoing oversight of the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing Provisos to, or suspending or terminating any proposed or ongoing research involving Human Participants.

5.2.6 The REB shall operate in an impartial manner and be independent in its decision making. The decisions of the REB are not subject to review or interference by the Vice-President, Research and International, the Senate, or any other person or body except to the extent that such decisions may be reviewed through Reconsideration or the Research Ethics Appeal Process, pursuant to the Procedures to this Policy.

5.2.7 The Vice-President, Research and International or her/his delegate is responsible for ensuring that members of the REB are informed and educated regarding all ethics requirements of the Tri-Council granting agencies and all other provincial, national, and international laws, as well as regulations, policies, standards, and guidelines that are relevant to research ethics review.

5.3 **Ethics Approval**

5.3.1 A researcher must not initiate Research Involving Human Participants, including through contact with or recruitment of potential participants, until Ethics Approval has been granted. However, REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.

5.3.2 If the REB rescinds or terminates an Ethics Approval, the REB may give notice and direction to the University. Upon receipt of such notice and direction from the REB, the University must freeze or close the relevant research account as appropriate.

5.4 **Non-Compliance**

5.4.1 As required by the Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions, the University shall maintain adequate controls to ensure that the REB has approved all Research Involving Human Participants before research involving humans has commenced, and that approval remains in place as long as such activities are carried out.

5.4.2 Failure to comply with this Policy and pertinent federal, provincial, and international guidelines/legislation for the protection of Human Participants and/or failure to conduct research in the manner in which it has been approved by the REB may be considered Misconduct in Research and may, accordingly, be handled under the procedures of Policy R60.01.

5.5 **Ethics Review Agreements**

5.5.1 In order to facilitate collaborative research projects involving researchers, data, or participants from more than one institution, and in order to avoid a duplication of efforts
with respect to research ethics reviews, the SFU REB may cede review to another institutional REB or it may conduct the research ethics review on behalf of other institutional partners.

5.5.2 The SFU REB must satisfy itself that there is a formal agreement between SFU and the other institution involved and/or that the other institution is compliant with the requirements set out in the Tri-Council Policy Statement.

5.5.3 An Ethics Review Agreement may be limited to a specific Research project.

6.0 DOCUMENTS REFERENCED


SFU Aboriginal Reconciliation Council Final Report: Walk This Path With Us (2017)


Truth and Reconciliation Commission of Canada: Calls to Action (2015)


7.0 POLICY REVIEW

7.1 This policy will be reviewed every five years or as needed.

8.0 AUTHORITY

8.1 This policy is administered by the Vice-President Research and International.

9.0 INTERPRETATION

9.1 Questions regarding interpretation of this policy should be directed to the Director, Research Ethics.

10.0 ASSOCIATED PROCEDURES

10.1 Procedure for Ethics Review of Research Involving Human Participants