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MEMORANDUM

ATTENTION: Senate

TEL

FROM: Peter Keller, Vice-President, Academic and Provost, and Chair, SCUP

A handwritten signature in black ink, appearing to read "Peter Keller".

RE: Revisions to Policy R20.01 (SCUP 19-11)

DATE: March 13, 2019

TIME

At its March 13, 2019 meeting, SCUP reviewed and approved the revisions to Policy R20.01 (Ethics Review of Research Involving Human Participants).

Motion:

That Senate approve and recommend to the Board of Governors the revised Policy R20.01 (Ethics Review of Research Involving Human Participants).

c: T. Davis



 Memorandum

From: Trevor Davis, Executive Director, Research Operations **Date:** Jan 30, 2019

Re: Updated Policy R20.01

To: Peter Keller, Chair, SCUP.

The Office of Research Ethics recently undertook a review of Policy R20.01 (Ethics Review of Research Involving Human Participants). The Policy last underwent a major revision in 2012 as a result of a 2011 external review of Simon Fraser University's Research Ethics Board and Office of Research Ethics.

Since 2012, Canada's national research ethics policy, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014) has been revised to ensure that the guidance it provides is both current and clear. Also, the research landscape has evolved into one that is increasingly complex in terms of the interactions and partnerships required to be successful. These changes have compelled the Office of the VPR to review Policy R20.01 to ensure that it accurately reflects the prevailing substantive and procedural research ethics policy and practice, thereby ensuring that the protections afforded to research participants are adequate while minimizing any impediments to the ethics approval process.

This review was undertaken by the Director, ORE and the Executive Director, Research Operations, and has resulted in significant revisions to the existing Policy. Key amongst these revisions are the following:

- Separating the Policy from Procedure, creating two related documents, and reorganizing content;
- Referencing the TCPS2 (2014) in the revised Policy document rather than including text directly pulled from the national guidance document;
- Removing the reference to REB subcommittees and continuing with a single REB, as such subcommittees were attempted but deemed impractical;
- Changing recruitment of most members from Faculty nominations/elections to a university-wide call based on requirements for specific expertise, followed by Senate elections, with minimum representation of one per Faculty.
- Simplifying the policy requirements for membership to better reflect federal policy updates and to allow increased flexibility in the face of increased research activity at SFU;
- Modifying policy definitions and board membership to better reflect the needs of Indigenous researchers, research projects, and First Nations community interests; and
- Making research ethics training mandatory for all researchers who plan to conduct research involving human participants, aligning us with Tri-Agency recommendations.

The revised Policy and Procedure documents will strengthen the protections afforded to research participants, reduce administrative burden to researchers seeking research ethics approval, and bring SFU Research Ethics Policy and Procedure in line with those at other Canadian institutions, ensuring

ongoing compliance with changing national research ethics policy and allowing for greater flexibility and responsiveness in adjusting to future changes.

Review History

| | | |
|---------------|---|---|
| Aug 2017 | Draft completed | |
| Sept-Dec 2017 | Research Ethics Board (discussion session, formal feedback) | Modified membership, increased role of senate, removed roles of VPRI |
| Mar 2018 | SCAR (Membership changes reviewed for consistency with Senate processes only) | Approved to proceed |
| May 2018 | VPs | Approved to proceed |
| Oct-Nov 2018 | Individual consultation with Indigenous researchers who have recently interacted with the REB | Added references to UNDRIP and ARC, text in preamble, modified definitions and 5.1.2 on partnering with Indigenous communities... |
| Nov-Dec 2018 | Open consultation | Clarification of course-based review process; additional work on wording re Indigenous communities |
| Dec 2018 | Open sessions (3) | No additional changes |

Rationale – Membership Changes

As a key change in this document is a move from a Faculty-based selection process to one in which REB members are nominated by the REB for Senate ratification, a detailed rationale is provided.

Applications for review sent to the REB are classified into one of two categories: ‘minimal risk’, or ‘greater than minimal risk’. The latter are reviewed by the full board. However, the former – comprising 90% of the applications – are delegated. Delegation speeds review (meetings are not required) and is also less detailed (review depth is normally proportional to risk).

The Tri-Council Policy Statement (TCPS2 - the national requirements for all institutions) allows delegation to one or more board members or to non-members who have experience, expertise and knowledge comparable to what is expected of an REB member. To date, SFU has provided delegated reviews using ORE staff – the Associate Director is responsible for all. To bring us more in-line with federal policy the ORE is now changing the process. For each delegated review a board member will be identified and will be responsible for all aspects of the review.

In recognition of the changing research landscape at SFU and in recognition of the SFU Aboriginal Reconciliation Council Calls to Action, the REB has indicated that the current REB structure and recruitment requires fine-tuning to ensure that the board can easily adapt and review the research studies that are conducted at SFU. In addition, to adequately manage and review the >500 applications that will now be vetted by the members individually, a change in the REB structure and appointment process is needed.

Issues

- The REB struggles with recruitment. The board is already known to have a high workload, which is now increasing. In some areas the ORE staff have to make considerable efforts to directly target individuals with the required background.
- Faculty-based elections do not adequately take REB discipline/background needs into account. To date, this has been a hindrance only. The new delegated review procedures will make it a major impediment.
- A structure where fixed numbers come from specific Faculties makes it difficult to adapt to the rapidly changing discipline makeup of applications the board is now experiencing. Individual members will now be reviewing 90% of these documents. Members are best suited to review applications falling into their discipline. Gaps in expertise will result in less robust reviews, and under- (or over-) representation will result in an unbalanced workload for members.
- The REB also requires more members to manage the increased workload and would like to build the complement gradually as they adapt to the new procedures.

Proposed Changes (Membership)

1. Membership is defined in a more flexible manner (Draft 20.01: Schedule A). Specific needs include the minimum federal requirements, plus an MD, an Indigenous research expert, undergraduate and graduate students, and a provision for alternates.
2. The specific disciplinary expertise required by the remaining members are defined by the REB, based on the current and anticipated applications for review.
3. Open calls and targeted recruiting of faculty, students and outside members are conducted by the ORE at the behest of the board. One member per Faculty is the minimum - otherwise the complement is dependent on discipline and experience.
4. All nominees are voted on by Senate - rather than just voting on students and outside members as is currently the case.



Ethics Review of Research Involving Human Participants

SIMON FRASER UNIVERSITY
Policies and Procedures

Date
October 1, 1992

Number
R20.01

Revision Date:
January 30, 2014

Revision No.

Policy Authority: Vice-President, Research and International.

Associated Procedures: Procedure for 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

Association of Canadian Deans of Education: Accord on Indigenous Education (2010)

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

Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (2014)

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

United Nations Declaration on the Rights of Indigenous Peoples (2013)

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*



Procedure for Ethics Review of Research Involving Human Participants

SIMON FRASER UNIVERSITY
Policies and Procedures

Date
October 1, 1992

Number
R20.01 Procedure

Revision Date:
January 30, 2014

Revision No.

Policy Authority: Vice-President, Research and International

Parent Policy: R20.01 Ethics Review of Research Involving Human Participants

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the appropriate process to ensure that the conduct of Research Involving Human Participants, performed Under the Auspices of the University, follows the highest ethical standards as defined in the Policy.

2.0 DEFINITIONS

- 2.1 “**Course on Research Ethics**” (CORE) is an introduction to the 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2). It consists of eight modules focusing on the guidance in TCPS 2 that is applicable to all research regardless of discipline or methodology.
- 2.2 “**Ethics Approval**” refers to the Research ethics approval granted in accordance with the Policy and its Procedures by the REB for proposed Research Involving Human Participants.
- 2.3 “**Minimal Risk**” refers to 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 the aspects of their everyday life that relate to the research.
- 2.4 “**Policy**” refers to the SFU Policy on the Ethics Review of Research Involving Human Participants.
- 2.5 “**Procedures**” refers to the Procedures in force with respect to this Policy.
- 2.6 “**Protocol Development**” refers to the early stages of a Research Involving Human Participants project, prior to activities that would require REB Research Ethics Approval

- 2.7 **“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.
- 2.8 **“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.
- 2.9 **“Research”** is an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.
- 2.10 **“Research Ethics Appeal Board (REAB)”** refers to the body appointed under the Policy and these associated Procedures to hear appeals of decisions by the REB.
- 2.11 **“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.
- 2.12 **“Research Ethics Board (REB)”** refers to a body of researchers, community members, and others with specific expertise (e.g., in ethics, in 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.
- 2.13 **“Research Involving Human Participants”** means Research involving;
- 2.13.1 Human Participants; or
- 2.13.2 Human Biological Materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, whether derived from living or deceased individuals.
- 2.14 **“Unanticipated Problem”** refers to any incident, experience, or outcome that meets all of the following criteria:
- 2.14.1 Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the REB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- 2.14.2 Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- 2.14.3 Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- 2.15 **“Under the Auspices”** means with the protection or support of someone or something, especially an organization such as a University.
- 2.16 **“University”** refers to Simon Fraser University (SFU) for the purpose of this Policy.

3.0 RESPONSIBILITIES

3.1 Adhering to the policies on the ethical conduct of Research Involving Human Participants is a responsibility shared by constituents across the institution.

3.2 Responsibilities of the Administration

3.2.1 The University is responsible for ensuring that adequate controls are in place so that, until REB approval is in place, research activities involving humans do not take place. To this end, unless University Administration has received notification that Ethics Approval has been granted to Conduct Research Involving Human Participants, or a request for the release of partial funding through the Protocol Development process has been approved, the University will not

- a. open any research accounts; or
- b. authorize spending on any research accounts.

3.2.2 The **Senate** is responsible for the academic governance of the University and this includes the development of new initiatives, the formation of priorities, and the consideration and approval of policies. The Senate has delegated specific responsibilities to the Research Ethics Board (REB) and, as a result, receives annual reports of its activities.

3.2.3 The **Vice-President, Research and International** has been designated with administrative responsibility for the implementation of the University's policies on Research Involving Human Participants. The Vice-President, Research and International shall provide the necessary administrative oversight and resources to both SFU Research Ethics (ORE) and the REB to ensure that the practices and procedures designed to protect the dignity and well-being of human research participants are in compliance with institutional Policy, the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (referenced herein as the "Tri-Council Policy Statement" or TCPS). The Vice-President, Research and International, or their delegate, is responsible for ensuring that the provisions of these policies are followed. This includes investigating allegations of non-compliance and instigating post-approval monitoring where required. The Vice-President, Research and International, or their delegate, is also responsible for entering into any agreements with other institutions to conduct the ethics review and approval of Research involving Simon Fraser University researchers.

3.2.4 Academic administrators such as **Deans, Directors, and Department Chairs** have overall responsibility for the conduct of Research carried out within their Faculties, Schools, and Departments. They should be aware of ongoing Research within their area and have a duty to create a climate for ethical practice in Research by promoting widespread general awareness and knowledge of institutional policy and the need for ethics review. These individuals also share in the responsibility of ensuring that the REB is appropriately constituted and has the expertise needed to properly review the applications that come before it.

3.2.5 SFU Research Ethics is responsible for:

- a. overseeing the process of research ethics review for Research Involving Human Participants for the University;
- b. working with the Office of the Vice-President, Research and International to maintain REB membership;
- c. providing administrative support for the activities of the REB, including but not limited to: recruiting, supervising, training, and managing research ethics coordinators and staff; managing the research ethics component of the SFU's research administration system; liaising with internal (e.g., Research Services, faculty, students) and external (e.g., sponsors, academic institutions) stakeholders on ethics administration issues; providing initial pre-review, review, and post approval continuing review support; and
- d. offering ethics education and training activities for the SFU research community.

3.3 Responsibilities of Researchers

3.3.1 The primary responsibility of researchers is to ensure that their Research is carried out in an ethical manner. All researchers who plan to conduct Research Involving Human Participants must:

- a. familiarize themselves and comply with all University policies relating to Research, including Policy R20.01, these affiliated Procedures, and the Tri-Council Policy Statement;
- b. prior to recruiting human participants (with the exceptions noted in the Policy, section 5.3.1. and TCPS Article 6.1. and Chapters 9 and 10), accessing data, or collecting human biological materials, submit an ethics application accompanied by any supplementary materials necessary for ethics review and approval;
- c. respect all decisions of the REB, including following all Provisos that were required for approval, and conduct all REB approved Research in accordance with:
 - i. the Tri-Council Policy Statement;
 - ii. University policies and procedures governing security and privacy, and all other applicable policies and procedures of the University; and
 - iii. other relevant legal obligations (including provincial, national, and international laws and regulations), policies, standards (including professional and institutional standards), and guidelines, where applicable to a particular area of Research or to the funding of such Research.
- d. promptly report to the REB any Unanticipated Problems that may increase the risk for those human participants involved in the conduct of the approved Research project;
- e. promptly submit to the REB any proposed changes to the Research project and obtain the approval of the REB before implementing the changes, except when necessary to eliminate immediate hazards to human participants; and

- f. notify the REB when the Research project has concluded.
- 3.3.2 The University is committed to ensuring that Research conducted Under its Auspices is done with the highest ethical standards. As part of this commitment, the ORE and REB, with the support of the Vice-President, Research and International, have set completion of the TCPS online tutorial “Course on Research Ethics” (CORE) as mandatory for all researchers who plan to conduct Research Involving Human Participants.
- a. The CORE tutorial must be completed before submitting one’s application to the REB for ethics review. All students (graduate and undergraduate) must submit the tutorial Certificate of Completion with their application for ethics review.
 - b. Students involved in course-based research must submit the certificate of completion with the application provided to their instructor.
 - c. All other study personnel (e.g., faculty and staff) do not need to attach the Certificate of Completion to the application; however, copies should be retained and be made available upon request.

3.4 **Responsibilities of Faculty Members as Supervisors of Student Research**

- 3.4.1 In supervised Research, the term “researcher” includes both the supervisor and the individual(s) being supervised. All student Research must be supervised by a faculty member who accepts responsibility for overseeing the ethical conduct of the student’s Research.
- a. When a graduate student is designated as the principal investigator on an application for ethics approval, the faculty supervisor of the student must act as a co-investigator.
 - b. When an undergraduate student’s Research project is submitted for ethics review, the supervisor must submit the application and be designated as the principal investigator and the student as a co-investigator.
- 3.4.2 The University only endorses graduate student principal investigators conducting research with a faculty supervisor within the jurisdiction of an academic program. If the Research is not being conducted for the purpose of completing a thesis or dissertation or in conjunction with an REB-approved course, the graduate student cannot act as principal investigator.
- 3.4.3 Faculty supervisors should act as a resource for the student when preparing the ethics application, providing guidance and reviewing the application prior to submission. Faculty supervisors must:
- a. ensure that their students have the training and competence necessary to execute the proposed Research in an ethical manner;
 - b. assist students with the preparation of their application for REB review;
 - c. ensure that the application is clearly written, scientifically valid, and provides the appropriate protections for human research participants;
 - d. review and approve the student’s application prior to submission to the REB.
- 3.4.4 After Ethics Approval has been granted, the supervisor is responsible for ensuring that the conditions of the review are properly executed.

3.5 Responsibilities of Student Researchers

- 3.5.1 As stipulated in the Policy, graduate and undergraduate students conducting Research Involving Human Participants, where the data are collected prior to writing a research paper, master's thesis or doctoral dissertation, must obtain the appropriate ethics review and approval before the Research may begin. Such projects will be supervised by a faculty member (acting as the principal investigator in the case of undergraduate students) who shares in accepting responsibility for the ethical conduct of the Research.
- 3.5.2 In the case of undergraduate or graduate course-based Minimal Risk research projects, approval may be granted by the course instructor as delegated by the REB (See 4.10 Course Review).
- 3.5.3 When submitting their first ethics application (whether individually or within a course), all students (both graduate and undergraduate) are also required to submit a certificate of completion of the TCPS online tutorial "Course on Research Ethics" (**CORE**). The CORE is designed to familiarize researchers with the ethical principles associated with the conduct of Research Involving Human Participants. Although a student's Research must be supervised by a faculty member, such supervision does not in any way diminish the obligation of the student to comply with the Policy, the Tri-Council Policy Statement, or other regulations that govern the ethical conduct of Research involving humans.
- 3.5.4 It is the joint responsibility of the student and faculty supervisor to ensure that the Research project receives and maintains the appropriate ethics approval and that, as per thesis regulations, documentation of this approval is included when the thesis is submitted to the library.

3.6 Responsibilities of the Research Ethics Board

- 3.6.1 Specific composition requirements of the REB are attached to this procedure as Schedule A.
- 3.6.2 The REB is responsible for the initial and continuing review of all Research Involving Human Participants in a way that is consistent with this Policy and all applicable ethics guidelines. In discharging this responsibility, the REB shall:
 - a. meet regularly (normally monthly);
 - b. provide fair, impartial, and reasoned reviews of the ethical acceptability of proposed and ongoing Research in an efficient and timely manner;
 - c. ensure that the potential benefits of the proposed Research are sufficient to warrant human participant involvement;
 - d. ensure that all proposed Research involving Indigenous peoples adheres to Chapter 9 in the Tri-Council Policy Statement, and facilitate compliance with the United Nations Declaration on the Rights of Indigenous Peoples, the SFU-ARC report recommendations and the 2010 Dean's Accord on Indigenous Education;
 - e. approve, reject, propose Provisos to, terminate, or suspend any proposed or ongoing Research conducted by members of, or Under the Auspices of, SFU;
 - f. in collaboration with the ORE;

- i. ensure that REB decisions are communicated clearly and in a timely manner to researchers;
- ii. prepare and maintain comprehensive records, including all documentation related to the projects under review, attendance at all REB meetings, and accurate minutes reflecting REB decisions;
- iii. recommend, develop, and implement research ethics educational opportunities for researchers and participants;
- iv. ensure SFU researchers are aware of the Policy and Procedures and make public any issues that will lead to changes in the current review practice;
- g. review the Policy and Procedures biennially, and recommend any necessary policy changes for Vice-President, Research and International implementation and Senate approval when required;
- h. collaborate with other REBs on the review of multi-centred Research projects;
- i. establish, when appropriate, its own internal policies and procedures that do not conflict with those approved by the Senate or the Tri-Council Policy Statement; and
- j. meet at least once a year, in open session, to discuss and approve the internal policies of the REB.

3.7 Responsibilities of the Research Ethics Board Chair

3.7.1 In addition to such other responsibilities as may be delegated to the REB Chair, they are responsible for:

- a. being well-versed in the regulations, guidelines, policies and ethical principles applicable to human participant research, specifically those within the most current version of the Tri-Council Policy Statement;
- b. providing pre-review decisions regarding risk and appropriateness of an application for full board review;
- c. providing leadership for the REB and facilitating the research ethics review process through the sound application of the Policy and Procedures;
- d. appointing ad hoc REB members as required;
- e. conducting any aspects of ongoing review delegated by the REB; and
- f. ensuring appropriate quorum requirements are met for each application reviewed at full board.

4.0 PROCEDURE FOR ETHICS REVIEW

4.1 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 to the participants:

- 4.1.1 the lower the level of risk, the lower the level of scrutiny (e.g., delegated review); and
- 4.1.2 the higher the level of risk, the higher the level of scrutiny (e.g., full review).

- 4.2 A proportionate 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 ethical implications of the Research.
- 4.3 Applications to the REB may be placed in one of two risk categories:
- 4.3.1 **Minimal risk**, which 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.
- 4.3.2 **Above minimal risk**, which applies to applications not covered by 4.3.1 above.
- 4.4 Risks in Research are not limited to just the participants. In their conduct of Research, researchers themselves may be exposed to many forms of risk (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of Research. While it is not a formal part of its responsibilities, the REB may raise concerns about the safety of student researchers as part of its communication to both them and their supervisors. Based on the level of risk, the REB may consider referring these concerns to the appropriate compliance review committee.
- 4.5 Full review by the REB should be the default requirement for all Research Involving Human Participants unless the decision is made to authorize delegated review based primarily on the risks associated with study involvement.
- 4.6 To qualify for delegated review (i.e., a review conducted by the REB Chair or designate, an REB member, or non-member with experience and knowledge comparable to that of an REB member), the Research described in the application must involve no more than Minimal Risk for the participants.
- 4.7 The ORE, in consultation with the Chair of the REB, will initially decide whether the application should receive a full or delegated review and will distribute the submitted application accordingly.
- 4.8 The REB has the sole authority to designate an application as above minimal risk.
- 4.9 **Scholarly Review**
- 4.9.1 When deciding whether or not to approve Research applications designated as above minimal risk, the REB must adopt the “proportionate approach to review” and consider the scholarly merit of the proposal. The primary test of scholarly merit is the application of scholarly standards and methodological approaches appropriate to the discipline(s) of the researcher(s).
- 4.9.2 If the Research has already passed acceptable peer review, such as through a recognized granting agency (e.g., SSHRC, NSERC, CIHR) or through a peer review process established within the University (e.g., dissertation committee), the REB will normally accept documentation of those reviews as evidence that appropriate scholarly standards have been met.
- 4.9.3 If the proposed Research has not yet been subject to external peer review, or if the proposed Research is funded by an independent external contract, the REB will either;

- a. determine scholarly merit itself, if the members of the board have the necessary research expertise in the area(s) in question, or
- b. decide to refer the project for review by up to three external reviewers who have the appropriate qualifications and expertise with respect to the project.

4.10 Course Review

- 4.10.1 The University encourages integration of Research and teaching throughout its academic programming. Course-based research projects, where data are collected from human participants, are used at both the undergraduate and graduate level. These projects may be carried out by individual students or small groups or as a single class project.
- 4.10.2 As Research is the intended purpose of these undertakings, the potential for risks to participants requires that these projects be reviewed by the Research Ethics Board. Also, it is important that the ethical standards that respect and protect human participants in Research are learned and practiced as students continue to develop their research skills.
- 4.10.3 Rather than require students to complete and submit individual applications for ethics review and approval, instructors may be able to complete an application for Ethics Review of Course-based Research Projects Involving Human Participants for all of the Research projects planned for the course, provided that those projects pose Minimal Risk to participants.
- 4.10.4 Course-based approvals shall not be used for larger scale projects conducted to fulfill the requirements for a graduate degree or undergraduate honours thesis. In these cases, students must complete a full ethics application. Also excluded from the course-based approval process are those research activities in which students work on a larger-scale project, such as their instructor's or another faculty member's research program. In these cases, students should be added to the existing approval as research assistants or study personnel through the amendment process.
- 4.10.5 Refer to the SFU Guidelines for Ethical Review of Course-Based Research Involving Human Participants.

5.0 MEETINGS, DETERMINATIONS, RECONSIDERATIONS, AND APPEALS

- 5.1 The REB shall meet monthly, at a minimum, for the review of proposed Research projects that are not assigned for delegated review. Other meetings may be called by the Chair or Deputy Chair as required.
- 5.2 Quorum for the REB shall consist of 50% of the REB voting membership plus one (1) including, at minimum, the core membership representation set out in Schedule A.
- 5.3 Only regular members, or their alternates when replacing regular members, will count toward quorum and be allowed to vote.
- 5.4 The REB may both request and accommodate reasonable requests from researchers to participate in discussions of their applications, but the researchers should not be present when the REB makes its decisions.

- 5.5 Decisions are normally arrived at by consensus. When consensus is not possible, decisions will be made on the basis of a simple majority vote of those members present. The REB will provide the researcher with a written summary of its decision.
- 5.6 The REB can make one of the following four determinations as a result of its review:
- 5.6.1 approved as submitted;
 - 5.6.2 approved pending Provisos (i.e., certain conditions or required changes are met);
 - 5.6.3 deferred, pending receipt of additional information or major revisions that must be submitted for re-review; and
 - 5.6.4 not approved or rejected.
- 5.7 **Reconsideration of REB Decisions**
- 5.7.1 Researchers have the right to request, and the REB has an obligation to provide, prompt Reconsideration of an REB decision.
 - 5.7.2 Initial Reconsideration may simply consist of informal discussions between the researcher and the REB Chair. If the matter is resolved through this process, the resolution will be documented in the ORE online application system and will also be reflected in the application materials as appropriate.
 - 5.7.3 If informal discussions do not lead to a resolution, the researcher may request a formal Reconsideration. The researcher must provide a written request for Reconsideration to the Chair of the REB, outlining the concerns they have with the initial REB review. The researcher has the right to be heard in a meeting with the REB to discuss the issues identified.
 - 5.7.4 When requesting a Reconsideration, the onus is on the researcher to justify the grounds on which the Reconsideration is requested and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision not supported by the Tri-Council Policy Statement.
- 5.8 **Appeal of REB Decisions**
- 5.8.1 If, after having fully exhausted the Reconsideration process, the researcher continues to be dissatisfied with the REB decision, the researcher may utilize the Research Ethics Appeal Process and appeal the decision of the REB to the Research Ethics Appeal Board (REAB).
 - 5.8.2 The appeal may be launched for either procedural or substantive reasons. The onus is on the researcher to justify the grounds on which the appeal is requested and to indicate any breaches to the review process or any elements of the REB decision that are not supported by the Tri-Council Policy Statement.
 - 5.8.3 Researchers may appeal decisions of the REB to the Manager of the REB within 30 working days of the reconsideration and the Manager will notify the REAB of the request for appeal.
 - 5.8.4 Both the researcher and a representative from the REB whose decision is being appealed shall be granted the opportunity to address the REAB, but neither shall be present when the REAB makes its final decision.

5.8.5 The decisions of the REAB are final and binding in all respects for any appeal lodged against a decision of the REB and may include approving, rejecting, or requesting modifications to the Research project.

SCHEDULE A. COMPOSITION OF THE RESEARCH ETHICS BOARD

1.0 MEMBERSHIP

1.1 As per Tri-Council Policy Statement requirements (Article 6.4), the REB shall consist of at least five **Core Members**, of mixed gender, of whom:

- 1.1.1 at least two members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
- 1.1.2 at least one member is knowledgeable in ethics;
- 1.1.3 at least one member is knowledgeable in the relevant law (but that member should not be the University's legal counsel or risk manager). This is mandatory for biomedical Research and is advisable, but not mandatory, for other areas of Research; and
- 1.1.4 at least one community member who has no affiliation with the University but is recruited from the community served by the University.

1.2 It is advisable that each member listed in Section 1.1 be appointed to formally fulfil the requirements of only one of the stated categories.

1.3 **Additional Members** may include, but are not limited to:

- 1.3.1 one medical doctor with relevant knowledge and expertise in medical and health Research;
- 1.3.2 one member with expertise in Indigenous research;
- 1.3.3 one or two graduate student members, recruited in consultation with existing REB members and Academic Deans, who will be appointed for a period of two years;
- 1.3.4 one undergraduate student member, recruited in consultation with existing REB members and Academic Deans, who will be appointed for a period of two years; and
- 1.3.5 alternate members who may be appointed to ensure that appropriate expertise is present on the REB to address the full array of Research areas being reviewed when regular members are absent due to illness or other unforeseen circumstances.

1.4 **Non-Voting Members**

- 1.4.1 Two non-voting representatives from the ORE will serve as ex-officio members on the REB.
- 1.4.2 The REB Chair, in consultation with REB members, may appoint ad hoc members or seek outside expert advice when reviewing a study that requires specific expertise not currently residing on the REB. Ad hoc reviewers shall not be counted toward quorum nor shall they be allowed to vote on REB decisions; they are simply to provide an expert opinion for the REB to consider in its deliberations.

1.5 **Eligibility and Appointments**

- 1.5.1 The Chair of the REB – a faculty member with previous REB experience – will serve a one year renewable term and will be elected by the current board members. At least one Deputy Chair will be appointed by election.

- 1.5.2 A minimum of one member from each Faculty will be appointed to the REB through a nomination process, with priority given to those filling gaps in the roles noted in 1.1 and 1.3. Additional appointments may be made based on the disciplinary expertise needed to review the applications that come before the board, as determined by the Chair of the REB, in consultation with current members and the ORE staff.
- 1.5.3 Nominations from and recruitment of faculty, students, and non-SFU members will be managed by the ORE at the behest of the REB. All potential members will be subject to a Senate ratification or decision vote.
- 1.5.4 To ensure the independence of REB decision making and to avoid perceived conflicts of interest, institutional senior research administrators shall not serve on the REB.
- 1.6 The term of appointment for all members will normally be 3 years (unless otherwise specified), renewable and with staggered appointments when possible to help maintain continuity and ensure diversity of opinion.
- 1.7 An REB member will disclose to the full REB any real, potential, or perceived conflicts of interest (COI) with respect to any Research project being reviewed by the REB. Such conflicts may arise out of personal relationships, financial interests, multiple roles, or other factors. The Chair will determine whether the conflict is relevant and may require that the member recuse him/herself from the review of the project in question. Any such recusal shall be documented in the minutes of the meeting.