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**MEMORANDUM**

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**ATTENTION** Senate **DATE** December 12, 2012  
**FROM** Jon Driver, Vice-President, Academic and **PAGES** 1/1  
Provost, and Chair, SCUP  
**RE:** Revised Policy R20.01 – Ethics Review of Research Involving Human Subjects (SCUP 12-50)

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At its December 5, 2012 meeting SCUP reviewed and approved the revised Policy R20.01 – Ethics Review of Research Involving Human Subjects.

**Motion:**

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

encl.

c: M. Pinto



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**MEMORANDUM**

<b>ATTENTION</b>	Jon Driver Vice-President, Academic and Provost Chair, SCUP	<b>DATE</b>	November 26, 2012
<b>FROM</b>	B. Mario Pinto Vice-President, Research	<b>PAGES</b>	1/21
<b>RE:</b>	Revised Policy R20.01 for SCUP's Approval		

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In Fall 2011, an external review of SFU's Research Ethics Board (REB) and Office of Research Ethics (ORE) was undertaken. The External Reviewers submitted a final report in January 2012 with the ORE Director (DORE) and REB Chair submitting responses in February and March 2012 respectively.

After reviewing the report and its recommendations, the REB Chair, DORE, and Vice-President, Research undertook a Senate-mandated review of Policy R20.01 (Ethics Review of Research Involving Human Subjects), starting in Spring 2012. The draft policy was scrutinized by the Vice-Presidents and Deans in Fall 2012 and presented to the SFU community for feedback through in-person community consultations and email comments. Following the community consultations, Policy R20.01 was revised to incorporate the community comments with the final policy submitted to SCUP for approval.

To this end, the revised Policy R20.01 is attached and the following motion is submitted to SCUP:

**Motion:**

That SCUP approve the revised Policy R20.01 and forward the Policy to Senate for final approval.

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Dr. B. Mario Pinto  
Vice-President, Research

Attachment (1)



## **Ethics Review of Research Involving Human Participants (Proposed Revision, November 2012)**

### **Preamble:**

Simon Fraser University is committed to ensuring the highest level of ethical conduct for research involving human participants and to following the guidelines outlined in the Tri-Council Policy Statement, **Ethical Conduct for Research Involving Humans**, (the TCPS-2).

University researchers enjoy special freedoms and privileges, which include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thoughts, freedom from institutional censorship, and the privilege of conducting research on human participants with the trust and support of the general public, often with public funding. With these freedoms come responsibilities to ensure that research involving human subjects meets high scholarly and ethical standards, is honest and thoughtful inquiry, involves rigorous analysis and complies with professional and disciplinary standards for the protection of privacy and for methodological approaches. Review of research proposals by a Research Ethics Board takes into account these freedoms and responsibilities and provides accountability and quality assurance both to colleagues and to society.

Click here for instructions on accessing the electronic [Ethics Applications](#).

### **Policy:**

This Policy provides a mechanism for ethics review of research involving human participants to protect those participants, researchers, support staff, students, and third parties, and to educate those involved in this type of research. Its procedures are consistent with the educational and research mandates of Simon Fraser University and respect the academic freedom and responsibilities of faculty members and the principle of informed consent with respect to potential participants. No more than three years after the implementation of this Policy, and no more than every five years thereafter, Senate will undertake a review of the Policy and Procedures for Ethics Review of Research Involving Human Participants, and make amendments should they be deemed necessary.

### **1. Definitions:**

“embryo” means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being;

“fetal tissue” includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus;

“fetus” means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth;

“human biological materials” means tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva, and other body fluids. Materials related to human reproduction include embryos, fetuses, fetal tissues, and human reproductive materials;

“human reproductive materials” mean a sperm, ovum or other human cell, or a human gene, as well as a part of any of them;

“human biological materials” includes materials related to human reproduction;

“human participants” means those individuals whose data, or responses to interventions, stimuli, or questions by the researcher, are relevant to answering the research question;

“publicly available information” means existing stored documentary material, records or publications, which may or may not include identifiable information and includes ‘all information that is available under FOI (Freedom of Information) legislation in British Columbia and Canada, whether or not the information has been exposed to the public;

“research” means an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation;

## **PART I - PRINCIPLES**

### **2. Proportionate Approach to Ethics Review**

A proportionate approach to research ethics review shall be adopted 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 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 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.

### **3. Risk Analysis**

**3.1** As research is a step into the unknown, its undertaking can involve harms to participants and to others. Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical, or economic.

Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties.

A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.

**3.2** Researchers should assess all reasonably foreseeable risks involved in, and benefits expected to arise from, research projects. Researchers involved in greater-than-minimal risk projects should be prepared to fully document the reasonably foreseeable risks and benefits of their proposed research.

**3.3** Researchers should employ methods that avoid or reduce possible risks, and maximize benefits in keeping with disciplinary and epistemological norms and standards.

**3.4** To facilitate risk-assessment and mitigation, researchers must complete the analysis-of-risk checklist in their online application.

**3.5** Researchers should consider not only the likelihood of a given risk, but also variables such as its duration and the likely reversibility of its impact should it materialize.

**3.6** Benefits include specific advantages to participants, to third parties, or to society or a segment thereof, and any general increase in human knowledge. Benefits may arise from advantages or increases in knowledge that are actively sought by the researcher or as by-products of the research (e.g. serendipitous events).

**3.7** In projects involving greater-than-minimal risk, it is the responsibility of both researchers and the Research Ethics Board (REB) to balance risks and benefits. Projected benefits should outweigh reasonably foreseeable risks. With regard to greater-than-minimal risk, the more incalculable the risks or the less tangible the benefits, researchers and the REB must be more cautious.

**3.8** In a project involving greater-than-minimal risk the REB should be satisfied that the research design and proposed implementation procedures are consistent with sound research standards and with accepted standards of disciplinary conduct and practice.

**3.9** In the conduct of their approved research, should unanticipated issues arise that may increase the level of risk or have other ethical implications, researchers shall report them to the Office of Research Ethics in a timely manner. Researchers shall also submit to the Office of Research Ethics in a timely manner requests for changes to their approved research.

**3.10** The REB must always be conscious of the importance of academic freedom for researchers, particularly where risks are the subject of informed consent, or will devolve upon the researchers personally. Nothing in Policy R20.01 is intended to inhibit the rights of researchers to engage in critical inquiry and disseminate that information.

#### **4. Risks to Researchers**

Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (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 the student researchers, and to their supervisors. Based on the level of risk, the REB may consider referring these concerns for review by the Office of Risk Management.

#### **5. Obtaining Informed Consent**

**5.1** Individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible.

**5.2** Under no circumstances may researchers proceed to conduct research with anyone who has refused to participate.

**5.3** Those who lack the capacity to decide for themselves should nevertheless have the opportunity to participate in research that may be of benefit to themselves or others. Authorized third parties acting on behalf of these individuals may decide whether participation would be appropriate. For the purposes of this Policy, the term "authorized third party" (also known as "authorized third party decision makers") refers to any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project.

**5.4** Where it is appropriate to do so, the REB may permit certain elements of the consent process to be adapted to the requirements of a particular research project. However, such adaptation must conform to the requirements specified in [Chapter 3 of TCPS-2](#).

**5.5** The principal investigator in a research team is responsible for ensuring that the consent process is followed. This person is also responsible for the actions of any member of the research team involved in the consent process.

**5.6** In addition to this Policy and TCPS-2, researchers are responsible for ensuring that all applicable legal and regulatory requirements with respect to consent are met.

**5.7** With respect to consent:

- a. Consent shall be given voluntarily.
- b. Consent can be withdrawn at any time.
- c. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials. Withdrawal of data does not apply to Health Canada-regulated or U.S. Food and Drug Administration-regulated research. Withdrawal of data or human biological materials does not apply when the data or human biological materials were collected anonymously and there is no way of re-linking the data or human biological materials to a participant's identity.

**5.8** Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

**5.9** Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

**5.10** Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

"Incidental findings" is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having important welfare implications for the participant, whether health-related, psychological, or social.

**5.11** Research shall begin only after the participants, or their authorized third parties, have provided their consent.

**5.12** Permission is not required from an organization to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's

permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation

**5.13** The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with paragraphs 5.7 to 5.11 where the REB is satisfied, and documents, that all of the following apply:

- a. the research involves no more than minimal risk to the participants;
- b. the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
- c. it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
- d. whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with paragraphs 5.7 to 5.10, at which point they will have the opportunity to refuse consent in accordance with paragraph 5.7; and
- e. the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

**5.14** For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

- a. the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
- b. the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
- c. the authorized third party is not the researcher or any other member of the research team;
- d. the researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and
- e. when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

**5.15** Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the importance of the research, the

researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation.

**5.16** Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, these directives should guide researchers and authorized third parties during the consent process.

**5.17** Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. In certain types of research and for particular participants or groups of participants, written consent may be inappropriate: in these cases, there are other means of obtaining consent that are ethically acceptable (e.g. oral consent, a verbal agreement, or a handshake). In the case of gathering oral evidence, informed consent is distinct from providing the researcher with consent to publish and archive the data.

Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes, and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant (e.g. through the return of a completed questionnaire). Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented.

**5.18** The age of majority in British Columbia is 19 years and parental consent is required for subjects younger than 19. Written consent from parents or legal guardians (as well as authorization from appropriate school authorities) is normally required for research in the public schools. An opportunity must be given to the individual to refuse to participate or withdraw at any time. A copy of what is written or said to the individual must be included for review by the REB. The REB considers minors attending University, who are 17 to 18 years of age, to be emancipated adults for the purposes of minimal-risk research. Parent or legal guardian consent will generally only be required if the research study is deemed greater-than-minimal risk or represents an invasion of the family's right to privacy. In either case, justification must be provided in the application for ethics review. The REB may make an exception to these requirements on a case-by-case basis, but the investigator must provide adequate justification in the application for ethics review (e.g. the child no longer lives with parent or guardian, there is no invasion of privacy or sensitive issue involved, etc.).

## **6. Privacy and Confidentiality**

**6.1** Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use, and/or disclosure of information.

The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss, or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project.

**6.2** Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it.

6.3 Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements:

- a. in application materials they submit to the REB; and
- b. during the consent process with prospective participants.

6.4 Researchers shall familiarize themselves with [Chapter 5 of TCPS-2](#) and indicate in their applications how they are meeting the privacy and confidentiality requirements of that chapter that pertain to their projects.

## PART II - SCOPE

### 7. Scope of Requirement for Ethics Review

7.1 The following types of research require ethics approval:

- a. research involving living human participants;
- b. research involving human biological materials (from both living and deceased individuals), as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. An individual whose data and/or biological materials are used in research becomes a participant.

This requirement applies to research conducted by any employee or student of Simon Fraser University, or Adjunct faculty member of any Department, School, or non-Departmentalized Faculty of Simon Fraser University. Where external agencies or non-SFU researchers are involved, the applicant should seek advice from the Director of the Office of Research Ethics (DORE) regarding the potential need for ethics review.

Research that utilizes human biological materials as well as research involving human embryos, fetuses, fetal tissue, reproductive materials, and stem cells requires review and approval by the REB before research is started, except as stipulated in 7.5 below. In addition, such research must first be reviewed by the Bio-Safety Committee who will provide the REB with a statement as to the nature of any risk(s) that may be posed to those who may come into contact with the human biological materials, etc. The Chair or Deputy Chair of the REB will decide whether the approval of an application involving such research should be delegated or should be subject to a full Board review.

Distinctions with respect to human biological materials that are relevant to REB review include:

- a. **Primary Tissue Cultures**, which are the mixture of cells that grow out of or from tissue samples taken from participants placed into culture;
- b. **Secondary Tissue Cultures** which are derived from cells in Primary Tissue Culture by serial passages and dilution, often leading to clonally derived lines of cells having relatively uniform properties that have adapted to growth in tissue culture. Once characterized and described in the public domain, these cultures may be considered Established Cell Lines that can be maintained or stored indefinitely. Established Cell Lines can normally be obtained commercially or as a gift, but identifying information about the donor is not provided with the cells. REB approval is not required for the use of human secondary tissue cultures (providing appropriate ethical approval was obtained for creation of the primary culture), nor for the use of established cell lines.

**7.2** Research involving living human participants occurs when data are derived from:

- a. information that is collected through intervention or interaction with a living individual (e.g. interviews, questionnaires, observations taken that are noticeable by the individual);
- b. secondary sources/non-public sources (e.g. interviews about a living individual, company personnel records, student records collected by an educational institution); or
- c. identifiable private information about a living individual.

**7.3** Research that relies exclusively on publicly available information does not require ethics review when:

- a. the information is legally accessible to the public and appropriately protected by law; or
- b. the information is publicly accessible and there is no reasonable expectation of privacy.

**7.4** Ethics review is not required for research involving the observation of people in public places where:

- a. it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- b. individuals or groups targeted for observation have no reasonable expectation of privacy; and
- c. any dissemination of research results does not allow identification of specific individuals.

**7.5** 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. These studies involve assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training.

**7.6** All course-based research assignments involving living human participants, including Directed Studies require ethics review.

**7.7** Certain classes of research involving human participants are excluded from the requirement of ethics review:

- a. research conducted by a member of the academic staff as an ***Outside Professional Activity*** ([see Policy A30.04](#)), or by other employees or students, as long as the research data are not collected by asserting connection or affiliation with Simon Fraser University, and the results are not disseminated in the public domain

indicating association with Simon Fraser University, and the research is not conducted at Simon Fraser University or using Simon Fraser University resources;

- b. research undertaken by students outside the auspices of Simon Fraser University and/or its academic programs (e.g. students on co-op or work terms outside the University) that does not require Simon Fraser University resources and is not directly supervised by Simon Fraser University faculty;
- c. research undertaken by Adjunct Faculty outside the auspices of Simon Fraser University and/or its academic programs that does not require Simon Fraser University resources;
- d. REB review is not required for 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.

Secondary use refers to the use in research of information or human biological materials originally collected for a purpose other than the current research purpose. Anonymous information and human biological materials are distinct from those that have been coded, and also from those that have been anonymized.

**7.8** Research on public policy issues, public institutions, and other matters that in a free and democratic society can properly be considered as part of the public domain is not required to undergo ethics review, even when interviews with individuals occupying positions connected to such matters are involved, provided there is no reasonable expectation of privacy. Public policy is defined as follows:

- a. Research protocols that require contact with human participants as part of the study and whose regular occupational duties involve communicating with the public on behalf of their organizations (such as public relations officers, official spokespersons, diplomatic officials, freedom of information officers, archivists, etc., or the Chief Executive of an organization) do not require ethics review, to the degree that answering questions posed by the public is within the ordinary duties of the participant and are within the acceptable limits of disclosure defined by the participants' employers;
- b. Research protocols in which inquiries are referred to other members of an organization by a public-relations officer, official spokesperson, etc., of the organization, do not require ethics review, to the degree that their inquiries are in keeping with the initial protocol and the substance of the interviews are attributable.

**7.9** The opinion of the DORE or Associate DORE should be sought whenever there is doubt whether or not a particular research project requires ethics review.

### **PART III – RESPONSIBILITIES**

#### **8. Researchers' Responsibilities in Relation to Ethics Review**

**8.1** In supervised research, the term "researcher" includes both the supervisor and the individual(s) being supervised. When a graduate student is shown as the principal investigator on an application, the supervisor of the student must be the co-investigator. 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 the co-investigator. Before submitting their first ethics application, graduate students are required to submit a certificate of completion of the graduate student tutorial, which is designed to familiarize them with the process of online submission (the tutorial is available at: [ore.code.sfu.ca](http://ore.code.sfu.ca)).

**8.2** It is the responsibility of researchers to obtain ethical approval as described in this policy for any project, funded or not, involving human participants before commencing the research.

**8.3** It is the responsibility of researchers to ensure that there is adequate lead time available for ethical review in relation to other deadlines.

**8.4** Project funds will not be released by the University to the project principals until ethics approval for the project has been obtained and a copy of the approval is on file in the Office of Research Ethics.

## **9. Research Involving the First Nations, Inuit and Métis Peoples of Canada**

Researchers who propose to conduct research involving the First Nations, Inuit, and Métis Peoples of Canada should familiarize themselves with community customs and codes of practice, including the traditional and contemporary cultural and political protocols of the Aboriginal groups involved in the research. Researchers will also familiarize themselves with [Chapter 9 of TCPS-2](#) and indicate in their applications how they are meeting the requirements of that chapter that pertain to their projects.

### **9.1 Community Engagement and Consent**

Researchers collecting primary data will obtain informed consent from individuals, communities, and/or governing bodies, as appropriate to the research project. The researchers and participants should be apprised of the project's research design and the potential research risks. Researchers are ethically bound to respect the First Nations, Inuit, and Métis Peoples' cultures, customs, languages, governance structures, and codes when engaging communities prior to, during, and following the conclusion of research involving these groups.

Secondary use of data and human biological materials that are publicly available or legally accessible does not require informed consent. If an Aboriginal group, community, or segment can be identified by the secondary use of data or human biological materials, researchers will engage with the group, community, or segment in question to identify the research risks and potential benefits.

### **9.2 Intellectual Property and Products of Research**

The First Nations, Inuit, or Métis individual or community owns their intellectual property, including intellectual and cultural property rights and traditional knowledge (IP). A distinction will be made between the ownership of IP and the ownership of the products of research in the form of research analysis data. The latter is subject to Policy [R30.03](#) (Intellectual Property Policy).

Researchers should respect and endeavour to accommodate all participants regarding ownership of the research results generally and the various attributes of ownership specifically, including title, attribution, access and usage rights (e.g. scholarly & academic consideration and publication, internal research, and individual, community, public and commercial purposes); control, possession, economic rights (e.g. commercialization including protection, development, and marketing); and risk. These accommodations will be made in accordance with applicable federal, provincial, and territorial privacy legislation, with due regard to complying with Policy [R30.03](#), and in keeping with the cultural protocols of the Aboriginal individual, community, or organization in question.

Resolution of the issues regarding the research results, generated from primary data collection, will be determined by consensus between the researcher and the First Nations, Inuit, or Métis individuals and/or community, and, where practicable, documented in a research agreement.

### **9.3 Use and Storage of Data**

A research agreement between the researcher and the Aboriginal individual, community, and/or organization should specify details for the use of primary data and research analysis data including: timelines for the retention of data, the arrangement for secure storage and retrieval, potential and actual secondary uses of data, and limits on data disclosure. The research agreement may include provisions for the storage of data on behalf of an Aboriginal individual, community, and/or organization without disclosure of the data to a third-party, as permitted by applicable federal, provincial, and territorial privacy legislation. The research agreement should be in keeping with the cultural protocols of the Aboriginal individual, community, or organization in question and should be established before the commencement of research.

## **10. Qualitative Research**

**10.1** Qualitative research aims to understand how people think about the world and how they act and behave in it. This approach requires researchers to understand phenomena based on discourse, actions and documents, and how and why individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter.

**10.2** Researchers who propose to conduct qualitative research will familiarize themselves with [Chapter 10 of TCPS-2](#) and indicate in their applications how they are meeting those requirements of that chapter that pertain to their projects.

## **11. Clinical Trials**

**11.1** A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.

**11.2** Researchers who propose to conduct a clinical trial will familiarize themselves with [Chapter 11 of TCPS-2](#) and indicate in their applications how they are meeting those requirements of that chapter that pertain to their projects.

## **12. Human Biological Materials, Including Materials Related to Human Reproduction.**

**12.1 Human biological materials** include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues, and human reproductive materials.

**12.2** Researchers who propose to conduct research with human biological materials will familiarize themselves with [Chapter 12 of TCPS-2](#) and indicate in their applications how they are meeting those requirements of that chapter that pertain to their projects.

## **13. Human Genetic Research**

**13.1** Human genetic research involves the study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.

13.2 Researchers who propose to conduct human genetic research will familiarize themselves with [Chapter 13 of TCPS-2](#) and indicate in their applications how they are meeting those requirements of that chapter that pertain to their projects.

## **PART IV – ADMINISTRATION**

### **Research Ethics Administration**

#### **14. Research Ethics Board (REB)**

14.1 The REB is a committee of Senate. It is responsible for the timely review of all research protocols or projects covered by this Policy to ensure that they meet acceptable ethical standards.

14.2 The REB is administratively independent in its decision-making and is accountable to Senate.

14.3 The REB has the authority to approve a protocol or project, approve a protocol or project subject to modifications, or reject a protocol or project. In the latter two cases, detailed written reasons will be provided to assist researchers in the preparation of revised applications for ethics approval.

14.4 The REB has the responsibility to monitor ongoing research and to terminate any project that does not conform to ethical standards.

14.5 The REB is responsible for responding to inquiries from external agencies with responsibility to monitor ethics review procedures at universities.

14.6 The REB is responsible for ensuring that the research community at Simon Fraser University is aware of the principles and practices of ethical conduct of research and for publicizing issues that will lead to changes in its current review process.

14.7 The REB shall provide an annual report of its activities in the previous year to Senate at its September meeting.

14.8 At least once a semester, the entire membership of the REB will meet in open session to discuss and approve the internal policies of the Board.

14.9 The REB has the authority to establish its own procedures and internal policies that do not conflict with those established by Senate or TCPS-2 and to make recommendations to Senate for revisions to the Policy.

#### **15. REB Membership**

15.1 The REB shall consist of 20 voting members, endeavouring to represent each gender, plus the DORE and the Associate DORE, who will be *ex officio* (non-voting) members, and one of whom will serve as Secretary. The membership will be constituted as follows:

- a. One faculty member to be elected by and from each of the following Faculties: Applied Sciences, Business Administration, Communication Arts and Technology, Education, and Environment;

- b. Two faculty members to be elected by and from each of the following Faculties: Health Sciences and Sciences (at least one of whom will be from the Department of Biomedical Physiology and Kinesiology);
- c. Three faculty members to be elected by and from the Faculty of Arts and Social Sciences;
- d. Three graduate students to be elected by Senate; and
- e. Five members to be elected by Senate from the SFU community (at least one of whom will be an undergraduate student).

**15.2** The REB will be divided into subcommittees for a) Biomedical and Health Research, b) Clinical Trials, and c) Social and Behavioural Sciences. When the Principal Investigator is not affiliated with SFU, the REB may choose to have proposals evaluated by external REBs through reciprocal arrangements.

In addition to the Chair or Deputy Chair, each subcommittee will consist of the following members, endeavouring to represent each gender:

- a. at least two members who have expertise in relevant research disciplines, fields, and methodologies covered by the subcommittee of the REB;
- b. at least one member who is knowledgeable in ethics;
- c. at least one member who is knowledgeable in the relevant law;
- d. at least one community member;
- e. one graduate student;
- f. for biomedical and health research and clinical trials: a member with a medical degree and a member with experience in statistics (if not already included in (a) above).

**15.3** Every two years, Senate will approve a list of individuals with medical degrees and/or law degrees qualified to serve on the REB.

**15.4** In the event that there is no member elected who has a law degree and is familiar with the law related to ethics review, the Chair of the REB will select the next available person from the approved list to serve on the relevant subcommittees as required.

**15.5** In the event that there is no member elected who has a medical degree, the Chair of the REB will select the next available person from the Senate list to serve on the relevant subcommittees as required.

**15.6** Even if there is an elected REB member with a law or medical degree, the Chair may select the next available person from the Senate list in the case of absence of the elected member or in order to maintain a reasonable workload for the elected member.

**15.7** Every two years, Senate will approve a list of individuals with expertise in ethics.

**15.8** In the event that there is no member elected with expertise in ethics, the Chair of the REB will select the next available person from the Senate list to serve on the relevant subcommittees as required.

**15.9** Even if there is an elected REB member with expertise in ethics, the Chair may select the next available person from the Senate list in the case of absence of the elected member or in order to maintain a reasonable workload for the elected member.

**15.10** Membership of the subcommittees will be determined in accordance with 15.2 above and on the basis of the research expertise of the elected members from the Faculties. The members not elected from Faculties will be selected by rotation and on the basis of availability.

**15.11** The subcommittees of the REB will operate in closed session.

**15.12** The term of office for voting members of the REB will be three years except for the graduate student and undergraduate student member who shall be elected for a two-year term.

**15.13** In the event that a member of the REB is unable to attend a meeting of a subcommittee and her or his presence is necessary to fulfil the requirements of 15.2 above, the Chair of the REB has the authority to appoint a temporary replacement to act in place of the regular member until that member returns or until an election can be held.

**15.14** Prior to serving, all members of the REB will attend a workshop or orientation session, organized by the DORE or Associate DORE, to ensure that they have an understanding of the principles and practices of ethical review. The workshop requirement may be substituted by the on-line tutorial accessed at <http://www.pre.ethics.gc.ca/english/tutorial> or a similar tutorial approved by the REB.

**15.15** On an annual basis, in open session, the full membership of the REB will elect a Chair and a Deputy Chair who will act in the absence of the Chair. These persons will be faculty members of Simon Fraser University who have served on the REB previously, normally for at least two years.

**15.16** Unless there is no business to transact, the subcommittees of the REB will normally meet at least once per month, with no more than six weeks between meetings. The full membership of the REB will meet at least once a semester in open session to discuss and approve the internal policies of the Board.

**15.17** The *quorum* for the subcommittees for meetings, at which applications involving greater-than-minimal risk will be considered, is the Chair or Deputy Chair plus a minimum of six or seven members, depending on the subcommittee, required to participate in accordance with 15.2 above.

**15.18** The *quorum* for the full REB meetings in open session is the Chair or Deputy Chair plus 10 of the elected members.

## **16. Research Ethics Appeal Board**

**16.1** Researchers have the right to a reconsideration of a negative decision on any of the grounds enumerated in paragraph 16.3. Researchers may appeal decisions of the REB to the Research Ethics Appeal Board (REAB) within 15 working days.

**16.2** The REAB will be the University of Victoria's Human Research Ethics Committee. The decisions of the REAB shall be final and binding in all respects for any appeal lodged against a decision of the REB.

**16.3** Appeals may only be heard on the basis of a procedural error that materially and adversely influenced the decision of the REB, including real or reasonably apprehended bias, including epistemological bias, or undeclared conflict-of-interest on the part of one or more members of the REB. The REAB will first determine whether a procedural error, bias or a conflict of interest (as described above) occurred, and if so, refer the matter back to the REB. The REB will then determine whether to amend the procedures used based on the recommendations of the appeal body and make a final determination on the research proposal.

## **17. Director of the Office of Research Ethics (DORE)**

**17.1** The DORE reports administratively to the Vice-President (Research).

**17.2** The appointment of the DORE will be made by the Vice-President (Research), in accordance with Policy [AD10.03](#), after receiving advice from a search committee that includes the Chair of the REB and four additional REB members, selected by the REB. The DORE will have experience in research involving human participants and will normally hold a doctoral degree.

**17.3** The duties and responsibilities of the DORE are stated in the job description for the position. The DORE will work in consultation with the REB to perform duties that include, but are not limited to:

- a. reviewing all applications submitted to the REB for the completeness of these applications and their compliance with this Policy;
- b. approving applications that are minimal-risk, and providing written summaries of the reasons for such approvals to the REB;
- c. acting in an *ex officio*, non-voting capacity as Secretary to the REB;
- d. managing the Office of Research Ethics;
- e. monitoring, data collection, and communication with other universities and granting councils;
- f. liaising on behalf of REB with external boards and sponsors, and internal University committees concerning ethics matters. Responds to requests for information or reports from such boards and external sponsors;
- g. completing activity reports concerning human subject ethics review and ethical research conduct required by national boards and granting agencies;
- h. conducting workshops and seminars focusing on ethical issues in the conduct of research. Reference is made to research integrity issues as well as human subject research ethics. Develops corresponding educational reference materials;
- i. receiving and investigating any concerns or complaints from research participants about their involvement in SFU research;

- j. regularly attending and participating in educational workshops and conferences concerned with the field of ethical conduct in research.

## **18. Associate Director, Office of Research Ethics (Associate DORE)**

**18.1** The appointment of the Associate DORE will be made by the Vice-President (Research), in accordance with Policy [AD10.03](#), after receiving advice from a search committee that includes the Chair of the REB and four additional REB members, selected by the REB. The Associate DORE will have experience in research involving human participants and will normally hold a doctoral degree.

**18.2** The duties and responsibilities of the Associate DORE are stated in the job description for the position. The Associate DORE will work in consultation with the DORE and REB to perform duties that include, but are not limited to:

- a. reviewing applications submitted to the REB for the completeness of these applications and their compliance with this Policy;
- b. assisting researchers in the preparation of research and course approval applications prior to submission to the REB;
- c. communicating to applicants any requirements of the REB to arising from REB's review of expedited or non-expedited applications, in consultation with the DORE;
- d. implementing and delivering educational workshops and seminars developed in consultation with the DORE;
- e. approving applications that are minimal-risk, and providing written summaries of the reasons for such approvals to the REB; and
- f. assisting in managing the Office of Research Ethics.

## **PART V - PROCESS**

### **19. Research Ethics Review Process**

**19.1** Applications to the REB may be placed in one of three categories. These categories are:

- a. **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.
- b. **Greater-than-minimal-risk**, which applies to applications not covered by a) above;
- c. **Course**, which applies to undergraduate and graduate courses that require or allow students to participate in research projects as part of their training or for the purpose of assessment.

**19.2** When the DORE or Associate DORE considers that an application might appropriately be designated greater-than-minimal risk, the DORE or Associate DORE will consult with the Chair of the REB who will decide whether the application should be forwarded to the REB for review

by the appropriate subcommittee. The relevant subcommittee of the REB has the sole authority to designate an application as “greater-than-minimal risk.”

**19.3** The REB may delegate its authority to approve minimal-risk applications to the DORE and Associate DORE. The DORE or Associate DORE shall approve minimal-risk applications on behalf of the Board, if the DORE or Associate DORE is satisfied that the applications conform to the definition of minimal-risk stated in 19.1(a) above. If the DORE or Associate DORE is not satisfied that the application conforms to this definition of minimal-risk or is incomplete, the application may be returned to the applicant for revisions and/or forwarded to the Chair of the REB, who will decide whether to refer it to the appropriate subcommittee for review. Upon a request by the DORE or Associate DORE, the Chair or Deputy Chair of the REB may approve an application as minimal-risk without a meeting of the appropriate subcommittee of the REB. Written Summaries of the reasons for all approvals by the DORE, Associate DORE, Chair or Deputy Chair will be brought to the next regular meeting of the appropriate subcommittee of the REB. The subcommittee of the REB may review and amend any decisions made independently by the DORE, Associate DORE, Chair or Deputy Chair with respect to minimal-risk applications. Normally, any amendments made by the subcommittee will be only minor in nature.

**19.4** If the relevant subcommittee of the REB designates a project as greater-than-minimal risk, it shall inform the applicant(s) in writing of its reasons and shall also give the applicant the opportunity to ask the REB to reconsider the designation of the project as greater-than-minimal risk and propose a process, in consultation with the REB, that might assist the REB in its reconsideration. If the Chair of the REB considers that it is possible that the relevant subcommittee of the REB may designate an application as greater-than-minimal risk, the Chair may invite the applicant(s) to meet with the members of the subcommittee at its regular monthly meeting to answer questions and to make any presentation(s) that might assist the subcommittee in reaching a decision as to the appropriate designation of the application.

**19.5** When deciding whether or not to approve research proposals designated as greater-than-minimal risk, the relevant subcommittee of the REB must adopt the “proportionate approach to review.” An important element in this approach is the consideration of 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).

Proposed research that has been submitted to a recognized granting agency (e.g. SSHRC, CIHR, NSERC) for funding under peer review will be considered to have scholarly merit if the work is funded by that agency. If the proposed research has not been approved for funding, or if the proposed research is funded by an independent external contract, the appropriate REB subcommittee will either determine scholarly merit itself, if the members of the subcommittee have the necessary research expertise in the area(s) in question, or it may decide to refer the project for external review by experts who have the appropriate qualifications with respect to the project. The DORE will send a description of the project to two external reviewers. These experts will be external to Simon Fraser University (they shall be neither faculty members nor adjunct faculty members and there should be no appearance of a conflict of interest).

One reviewer will be chosen by the applicant(s) and the other by the Chair or Deputy Chair of the REB in consultation with members of the REB who have experience in the discipline of the applicant(s) or the methodologies associated with the project. If the decision of the two reviewers is not unanimous, the Chair of the REB will consider the views of the two reviewers and cast the deciding vote. The reviews by external experts must be completed no later than three weeks from the date of the requests made by the REB. The application will then be brought to the next meeting of the relevant subcommittee of the REB.

**19.6** When a project has been determined to have scholarly merit, it will be reviewed by the REB. Normal outcomes of the review process are:

- a. when a majority of the relevant subcommittee of the REB votes to approve the research protocol, approval will be granted and the research may be initiated;
- b. when the relevant subcommittee of the REB identifies problems such that ethical approval cannot be granted, the problems will be communicated to the applicant(s) in writing;
- c. when a majority of the relevant subcommittee of the REB does not vote to approve the research protocol, and attempts to address ethical problems have been unsuccessful, the Chair or Deputy Chair will disallow the research on ethical grounds;
- d. if the application has not been completed after one year of being sent an access code to on-line ethics application forms, the application will be closed by the DORE.

**19.7** An academic unit wishing to offer an undergraduate or graduate course that requires or allows students, as part of their academic training, to participate in research projects involving human participants will submit to the DORE:

- a. a description of the course;
- b. the course outline;
- c. a general description of the type(s) of research projects that are likely to be part of the course;
- d. an undertaking that the only type of research to be conducted is minimal-risk (see 19.1(a) above);
- e. the means by which the students in the course are made familiar with the appropriate ethical standards articulated by this Policy and TCPS-2, with copies of printed materials;
- f. the means by which students submit their research plans to the instructor(s);
- g. the means by which those plans are assessed and approved by the instructor(s);
- h. the means by which the conduct of the in-course student research projects is monitored; and
- i. other relevant information.

**19.8** The application for course approval shall be submitted by the current instructor of the course with the approval by the Chair, Director or Dean of the academic unit. When the DORE is satisfied that this course poses only minimal-risk to research participants and student participants and otherwise meets the standards established in this policy, she/he will grant approval for the course to be designated as a "Research Ethics Board approved course." If the course is designated minimal-risk a written summary of the reasons for such approvals will be forwarded to the next meeting of the relevant subcommittee of the REB. This designation will remain with the course as long as the course description and the general method of teaching the course do not change (i.e. there is no need for the course to be approved each time it is offered

if it does not change). However, the Chair, Director, or Dean of the academic unit is responsible for ensuring the maintenance of the agreement for the course when the instructor(s) of that course change(s).

**19.9** If a course may involve greater-than-minimal risk projects, each project must be submitted for ethics approval to the DORE and will be considered on a case-by-case basis by the relevant subcommittee of the REB. If approval is not given, the application will be returned to the department with an explanation and appropriate suggestions or contingencies. In order for a course to be offered as a designated "Research Ethics Board approved course," the instructor of the course must sign a statement to the effect that he/she undertakes to include ethical issues related to the research projects in the subject matter of the course. The instructor will also take all reasonable efforts to ensure that his/her students comply with the terms of the approval in carrying out the research. If the instructor or the DORE deems a research project to involve an element of greater-than-minimal risk, it is the responsibility of the instructor to ensure that the project be changed to conform with minimal-risk requirements or to be submitted to the Office of Research Ethics as an individual application for ethics approval.

**19.10** Any discussion of course applications shall take place in closed meetings of the relevant subcommittee of the REB. After approval, the course application and approval shall be in the public domain.

**19.11** If a student in an REB-approved course wishes to publish any element of a research project, she or he must submit an application for ethics approval. The DORE, the Chair or Deputy Chair of the REB, or the relevant subcommittee of the REB may grant retroactive approval in appropriate cases.

**19.12** Once a year, the Chair, Director, or Dean of the academic unit concerned will submit a report to the DORE which affirms that, for each of the REB-approved courses offered in her or his academic unit, every instructor has provided an undertaking to apply the ethical principles articulated in this Policy and in TCPS-2.

## **20. Multi-Jurisdictional Research**

Where research involving humans requires the involvement of multiple institutions and/or multiple REBs, the REB at Simon Fraser University may accept reviews undertaken by an external REB of the ethical acceptability of research. The REB must satisfy itself that there is a formal agreement between Simon Fraser University and the other institution(s) involved and that this agreement includes a commitment to adhere to the requirements of TCPS-2.

## **21. International Projects**

When a protocol requires collaboration with universities, agencies, or individuals in other countries:

- a. The REB, in conjunction with the Office of Research Services, shall normally require confirmation by the collaborating universities, agencies or individuals of compliance with TCPS-2 as part of a contract between Simon Fraser University and the collaborating university, agency, or individual;
- b. The REB may review the protocols and responsibility of those international universities, agencies, or individuals;

- c. The REB may accept the decision of an international university, or agency as a substitute for their own review if the procedures adopted by that university, agency, or individual require compliance of protocols with the TCPS-2 or similar policy, as determined by the REB.