



*Balancing Research
With
Ethical Considerations*

Last Update 1 October 2009

Office of Research Ethics
www.sfu.ca/vp-research/ethics

SFU Senate Research Ethics Policy
<http://www.sfu.ca/policies/research/r20-01.htm>

Deadlines For Course Applications

Summer Semester	April 1
Fall Semester	Aug 1
Spring Semester	Dec 1

Terms of Approval

Undergraduate Students	2 years
Graduate Students	3 years
Staff	3 years
Faculty	4 years

Annual progress reports are required. Terms of approval may be extended by amendment to dore@sfu.ca

Course progress reports are now also required by the Dean, Director or Chair.

Student Amendment Requests

All amendment requests from students must be accompanied by an email from the student's Supervisor approving the request.

Minimal Risk

Minimal Risk is defined as risk which occurs when potential subjects can reasonably be expected to regard the probability and magnitude of possible harms incurred by participating in the research to be no greater than those encountered by the subjects in those aspects of his or her everyday life.

Personal Health Information Access and Protection of Privacy Act

http://www.leg.bc.ca/38th4th/1st_read/gov24-1.htm

This is important new legislation that controls the access and use of health information in a research context, including:

- ★ Establishment or designation of health information banks.
- ★ Collection and use of personal health information.
- ★ Disclosure of personal health information.
- ★ Requests for information by authorized persons.
- ★ Complaints respecting requests for information.
- ★ Authorization of disclosure directives.
- ★ Making and revoking disclosure directives.
- ★ Effect of disclosure directives.
- ★ Establishment of a Data Stewardship Committee.
- ★ Role of data stewardship committee.
- ★ Appointment of data stewardship committee.
- ★ Disclosure for planning or research purposes.
- ★ Disclosure for health research purposes.
- ★ Reports by data stewardship committee.
- ★ One's own personal health information to be available.
- ★ Purposes for which disclosure always authorized.
- ★ Information-sharing agreements required for disclosure.

Secondary Use of Data

Secondary use of data, which was not anticipated, at the time that the data were originally collected, will ordinarily receive approval by the REB if the proposal meets the following conditions:

That the original participants' identities are adequately protected through the implementation of protocols A, B or C.

A - The data are anonymous and subjects cannot be identified in the data. These circumstances will fulfill the conditions of adequate protection and approval will normally be granted.

B - The data are anonymous but there is a reasonable probability that participants could be identified in the data (e.g., where the data include population Unique or Near-Unique categories or cells). These circumstances will normally require the REB to conduct a proportionate review before approval may be granted.

C – The data are not anonymous. If the following procedures are followed, approval will normally be granted:

Where feasible, the data will be rendered anonymous before they are received by the PI - either at the source or by an approved third party.

Where it is not feasible to anonymize the data before they are received by the P.I., the P.I. will be required to anonymize the data and keep all cross references to the data in a separate and secure location. There should be a signed confirmation from the researcher that the data linkage will not be revealed. In addition, the P.I. must

assume responsibility for maintaining confidentiality and ensuring that the research assistant, or the individual responsible for anonymizing the data, is apprised of the consequences if confidentiality is breached. Where the P.I. is a student, this responsibility must be assumed by the faculty member who is the student's supervisor. It is the responsibility of the P.I. to budget for any costs that are incurred in anonymizing the data.

Secondary Use of Data

It should be shown that :

- 1) The proposed use of the data cannot redound to the detriment of the original participants.
- 3) The proposed use of the data is consistent with the purpose of the original intent for use of the data.
- 4) The proposed use of secondary conforms to SFU policy with respect to Conflict of Interest.

Applications must also fulfill all of the relevant requirements specified in the Freedom of Information and Protection of Privacy Act, RSBC 1996, c. 165 (as amended), and Bill 24-2008, E-Health (Personal Health Information Access and Protection of Privacy) Act (B.C.). In addition, where secondary data may be stored in the United States of America, applications must comply with the recommendations of the Information and Privacy Commissioner of B.C. (October 2004).

The REB should apply the principle of "proportionate review," which requires that decisions take into account the potential importance of novel discoveries to be made in archived data and includes the requirement that such reviews are sensitive to the requirements that participants be protected physically, psychologically, financially and socially.

Retroactive Approvals

Normally retractive approvals are only for data that has been previously collected by students acting as a research assistant for their supervisor and which, at the time was not being collected for the purposes of a thesis.

If a student is a Co-Investigator of a project, and by virtue of that is co-owner of the data, then a separate application for approval of that project for the purposes of a thesis does not require separate ethics approval. If the title of thesis differs from the title of the project that has been approved for the student's supervisor the ORE requires a confirmation that the project with the thesis title was part of the study that was approved and utilized the same protocols, consent and other relevant documents as were approved for the supervisor's study.

Age of Consent

For minimal risk protocols only, persons greater than or equal to 16 years of age may consent to participate in research projects without parental consent. For non-minimal risk projects all participants less than 19 years of age must receive parental consent.

Persons under the age of 16 may not participate in minimal risk or non-minimal risk projects without parental consent. All persons who are registered students at Simon Fraser University are considered adults and may consent to participate in research studies without parental consent.

Secondary Data For A Thesis

A student who is or was not a Co-Investigator may use data collected by their supervisor at some previous time as secondary data with the approval of their supervisor.

Secondary data is usually used for additional or new analysis of data that has already been collected.

However, the a student using secondary data must apply for approval from the Research Ethics Board for secondary use of the data and it must comply with the general requirements for the use of secondary data. This includes the provision that the use of the data is consistent with the informed consent that was originally required of the original protocol.

Verbal Consent

The REB may waive the requirement to obtain informed consent, provided that the REB finds and documents that

- i. the research involves no more than minimal risk to the participants;
- ii. the waiver or alteration will not affect the rights and welfare of the participants;
- iii. the research could not practically be carried out without the waiver or alteration;
- iv. whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
- v. the waived or altered consent does not involve a therapeutic intervention.

Master's Projects in Health Sciences

1. Any Master's Project that would access data in the public domain, acquire information from persons who have the authority to disseminate information to the public, or acquire data in a manner approved by privacy legislation in Canada or in other countries would not require ethics approval.

2. A Master's project that acquires data from human participants that is not excluded by (1) above, or uses secondary data that is not excluded by (1) above would require ethics approval. This requirement of prior ethics approval would apply if the project is carried out under the auspices of Simon Fraser University. If the research is contained in a Master's Thesis or project paper that is published in libraries or other agencies in the public domain, it will require ethics approval.

MITACS Applications

In accordance with SFU procedures, for MITACS projects, the supervisor of students must certify there is no non-disclosure agreements that infringe on the rights of student to publish data or information, resulting from their role in MITACS. If there is a nondisclosure agreement that agreement must be approved by the Dean of Graduate Studies.

If there is a non-disclosure agreement please include a copy of that agreement and send the agreement to the Director of Office of Research Ethics. The procedures and forms are in the help files when application is made.

Internet Surveys

The DORE will evaluate all research that proposes to use the internet in accordance with the following:

- a) The method of giving informed consent;
- b) The method of communicating data between respondent and researcher;
- c) The method of storing data;
- d) Who will be able to legitimately access the data and why?
- e) How were the names and email addresses of the potential respondents collected?

