



Simon Fraser University *Office of Research Ethics Newsletter*



Balancing Research With Ethical Considerations

PDF Versions of Electronic Applications

<http://www.sfu.ca/vpresearch/ethics/applications/index.html>

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

Student Amendment Requests

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

Harmonization of Research Ethics in B.C.

Research stakeholders across BC have identified the need for an effective, coordinated, value-add provincial approach to ethical approval – one that improves quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects. Over the past year, a number of organizations have launched separate and, to date, uncoordinated initiatives in an attempt to address concerns at least with respect to their own institutional context.

While many agree that there is a clear need for such a provincial approach to ethics, it is not clear what potential approaches or solutions might be acceptable to stakeholders. Options vary widely from adoption of harmonized core guidelines and institutional review reciprocity to a coordinated, shared, provincial ethics review mechanism.

At the request of provincial health research stakeholders, and with the endorsement and support of the Ministry of Health and the Ministry of Advanced Education, the Michael Smith Foundation for Health Research has agreed to facilitate a process to explore options in greater depth. The scope of the initiative is:

A three stage process:

1. BC REB Scan: description of mechanisms and structures for ethical review of research involving human participants in the academic institutions, health authorities and communities of British Columbia, including identification of the issues and barriers related to ethical review that exist in the provincial health research environment. This will include the description of processes and structures adopted in other jurisdictions, particularly across Canada but also including selected other countries such as England and Australia.

2. BC Investigator Survey: survey of BC researchers to identify and prioritize the key barriers/areas of concern with respect to quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects.

3. Workshop:— A gathering of stakeholder representatives from key BC research institutions and organizations to receive the results of the survey, to hear from expert speakers, and discuss options for a co-ordinated response in meeting the need for a provincial approach to ethical approval. Following the workshop, MSFHR would produce and circulate a report that identifies issues, barriers and options for coordinating a provincial approach to improving the quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects in British Columbia.

Certification of Equipment

The researcher must confirm that the equipment used in the protocol of the application for Ethics Approval for human research has been certified by CSA or other acceptable national or international agencies, and meets Medical Devices Regulations. If the equipment has not been certified as safe or the PI does not know if the equipment has certification the researcher must contact the Environmental Health and Safety (EHS) Office for guidance on the certification and approval process.

Use of Internet Surveys

If confidentiality is promised survey companies that are subject to the US Patriot Act or to other international legislation that allows access to survey information may not be used for research.

Simon Fraser University has available a survey system that may be accessed by contact with George Lee (glee@sfu.ca).

All survey results of confidential information must be stored on a secure server.

Interviews With Public Officials **Current internal policy of the Research Ethics Board.**

Research protocols that require contact with human participants in the study, whose regular occupational duties involve communicating with the public on behalf of their organizations (such as public relations officers, official spokespeople, 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 are within the ordinary occupational duties of the subject. Researchers whose inquiries are referred to other members of an organization by a public relations officer, official spokesperson, etc. for the organization are not required to submit their projects for ethics review, to the degree that their inquiries are in keeping with the initial protocol and the substance of the interviews are attributable.

Interviews with elected officials are exempt from ethics review to the degree that such interviews are part of their ordinary obligations to communicate with the public. The same exemptions apply to declared candidates for public office. The interpretation of 'public domain' includes all information that is subject to FOI (Freedom of Information) provincial, federal and SFU policy, whether or not the information has been exposed to the public.

Educational Sessions

The Office of Research Ethics will make presentations to classes in the Burnaby, Surrey or Vancouver sites upon request. The scheduling of these presentations should be made at least 1 month in advance if possible. If there is a special emphasis on an aspect of research ethics that is required for the presentation that should be indicated. Scheduling of presentations should be made by email contact with dore@sfu.ca or by telephone: 778 782 3447. Special requests may be made for presentations to classes or agencies that are not part of Simon Fraser University.

Use of Secondary Data for Research

This policy applies to anticipated secondary uses of identifiable data collected during the research, and anticipated linkages of data with other data about research participants.

If a database is used by an investigator as secondary data, and the use of that data is not consistent with the use to which the participant consented, explicitly or implicitly, or if the information to the participant at the time of consent did not inform the participant that the data may be used for other purposes in the future than the use for which they consented, then the data must be anonymous and published in an aggregate form and no attempt must be made to contact the original providers of the data. Projects using secondary data must include acceptable consent procedures used in the protocol of the original project that included the possibility of use of the data in the way in which the current application for secondary use proposes, unless the data is in the public domain.

Secondary use of data not anticipated at the time that participants gave informed consent, will ordinarily receive approval by the REB if the proposal meets the following conditions:

1. That such secondary use is not performed for any profit by the investigators,
2. That the proposed use of the data is not inconsistent with the purpose of the original proposed use of the data to which the participants gave informed consent.
3. That the proposed use of the data cannot rebound to the detriment of the original participants.
4. That original identities are adequately protected.

Applications failing any one of these considerations, may still receive approval, if the REB decides that the proposal still falls within the bounds of the Tri-Council Policy and complies with policies of the Information and Privacy Acts of B.C. and Canada.

Definition of Adult

For minimal risk protocols only, persons greater than or equal to 14 years of age and less than 19 years of age, may consent to participate as a research participant in the absence of parental consent, subject to specific approval by the REB. Persons under the age of 14 may not participate as research participants in either minimal or non-minimal risk protocols, without parental consent. Persons greater than or equal to 19 years of age are considered adults and may consent to participate as research participants in both non-minimal and minimal risk protocols.

Any person registered as a student at Simon Fraser University is considered an adult.

Approval of Assistants to Amend Projects

Faculty who are the PI for many approved projects have assigned assistants to administer the project, and to insure compliance with provisions of the approval. These faculty frequently have obligations that make it difficult for them to respond to requests by the ORE for approval of minor changes to the protocol of minimal-risk studies. Therefore the REB has approved the following:

The PI may authorize 'Assistants' to the PI for the purpose of requesting minimal-risk amendments to minimal-risk studies.

Minimal-risk amendments to minimal-risk studies, requested by the Assistants, and approved by the DORE, be sent to the PI by email as notification. Implementation of the amendments can begin without prior approval of the PI.

Letters by Faculty PI authorizing an Assistant to request amendments will be included in the file of the project and reported to the REB as information at their monthly meetings.

Class Exercises

The ORE requests instructors of classes to not require student to ask for electronic access to application forms for the purpose of class exercises unless each student is carrying out a research project that requires ethics approval by the ORE.

Application forms may be downloaded from the ORE website as pdf documents for the purpose of class exercises: (www.sfu.ca/vp-research/ethics).

Consent Forms: A and B Options

Option A assures confidentiality within the limits of existing provincial and / or federal law. Option B: Under some unusual circumstances the PI may wish to promise the participant that confidentiality will not be breached under any circumstances and is reviewed by the REB on a case-by-case basis.

If either of these options are not suitable the PI may construct a consent form that is specific to the protocol of the study and submit the form as an electronic document to dore@sfu.ca for inclusion in the file for review.

Notification Of Completion of Application

It is important that the Office of Research Ethics is notified when electronic applications have been completed and ready for review. The ORE has no way of knowing if the application has been completed and therefore if notification is not received by email to dore@sfu.ca the application cannot be reviewed.

Completion of Data Collection

The PI must notify the Office of Research Ethics when data collection has been completed. When data collection has been completed the file is closed and sent to the university archives for retention of a period that depends on classification of the project.

Research Ethics Board

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Dr. Felix Breden	Biological Sciences
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