S.01-55
Amended by Senate 9 July 01

SIMON FRASER UNIVERSITY
University Secretariat
MEMORANDUM

To: Senate
From: Alison Watt, Director, University Secretariat
Subject: Research Ethics Policy
Date: 20 June, 2001

The University has had a Research Ethics Policy R 20.01 in place for many years. In 1998, NSERC, SSHRC and MRC (now CIHR) developed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The Tri-Councils indicated that universities needed to develop policies consistent with this policy statement in order to be eligible for continued federal research grants. SFU's policy revision followed these steps:

October 1998	President's Task Force for Revision of the Research Ethics Policy was established
January 2000	President's Task Force for Revision of the Research Ethics Policy forwarded a draft revision of the policy
February 2000	Discussion at Senate with a decision that the Task Force's report should be referred to an ad hoc committee.
February 2000	Ad hoc committee established and started work
January 2001	New revision circulated
January 2001	Open meeting to discuss the revision, followed by further revisions.
March 2001	Senate discussed proposed revision and comments were referred to the committee
June 2001	Final revision circulated to University community

Motion

That Senate approve and recommend to the Board of Governors the attached Policies and Procedures for Ethics Review of Research Involving Human Subjects - June 5, 2001

Attachment

POLICY AND PROCEDURES FOR ETHICS REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

June 5th, 2001

Preamble:

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

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 subjects 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 and 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.

Policy:

This Policy provides a mechanism for ethics review of research involving human subjects to protect those subjects, 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 subjects. 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 Subjects, and make amendments should they be deemed necessary.

1. Requirement for Ethics Review

1.1 All research involving living human subjects, conducted by any employee or student of Simon Fraser University, requires review and approval by the Research Ethics Board before research is started, except as stipulated in **1.6**, **1.7** and **1.8** below.

1.2 Research involving human remains, cadavers, tissues, biological fluids, embryos, or foetuses must be reviewed by the Research Ethics Board.

1.3 Research involving living human subjects 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),

c) identifiable private information about a living individual.

1.4 Research about a living individual, based exclusively on publicly available information, documents, records, works, performances, actuarial materials, or third party interviews, is not required to undergo research ethics review. However, such research requires ethics review if the subject is approached directly for interviews or for access to private papers.

1.5 All course-based research assignments involving living human subjects require ethics review and approval (see section 6.3).

1.6 Certain classes of research involving human subjects are excluded from the requirement of ethics review by the Research Ethics Board at SFU:

a) research conducted by a member of the academic staff as an ***Outside Professional Activity (see 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 on ancient unidentifiable human remains.

1.7 Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to Research Ethics Board review unless there is an element of research in addition to the assessment.

1.8 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.

1.9 The opinion of the Director of the Office of Research Ethics should be sought whenever there is doubt whether or not a particular research project requires ethics review.

2. Researchers' Procedural Responsibilities

2.1 In supervised research, the term "researcher" is defined as including both the supervisor and the individual(s) being supervised.

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

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

2.4 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.

3. Research Ethics Board

3.1 The Research Ethics Board 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.

3.2 The Research Ethics Board 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.

3.3 The Research Ethics Board has the responsibility to monitor on-going research and to terminate any project that does not conform to ethical standards.

3.4 The Research Ethics Board is responsible for responding to inquiries from external agencies with responsibility to monitor ethics review procedures at universities.

3.5 The Research Ethics Board 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.

3.6 The Research Ethics Board provides an annual report of its activities in the previous year to Senate at its September meeting.

3.7 There are twelve voting members of the Research Ethics Board plus the Director of the Office of Research Ethics who will be *ex officio* non-voting and will serve as Secretary. Membership qualifications shall comply with the specifications of Article 1.3 of the TCPS. The specific membership and the terms of members will be as follows:

a) six faculty members elected by faculty, with one from each of the Faculties of Applied Sciences, Business Administration, Education, and Science, and two from the Faculty of Arts,
b) three members to be elected by Senate, from the university community at large (these may include faculty and staff),
c) one student member to be elected by Senate,
d) two members elected by Senate, from the community outside of the university,
e) the term of office for voting members of the Research Ethics Board will be three years except for the student member who may serve for a one or two year term. No more than two consecutive terms will be allowed.

3.8 Prior to serving, all members of the Research Ethics Board will attend a workshop or orientation session, organized by the Director of the Office of Research Ethics, to ensure that they have an understanding of the principles and practices of ethical review.

3.9 On an annual basis, the Research Ethics Board 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 Research Ethics Board previously, normally for at least two years.

3.10 The Research Ethics Board will normally meet at least once per month with no more than six weeks between meetings, unless there is no business to transact.

3.11 A quorum of the Research Ethics Board for meetings at which applications involving non-minimal risk will be considered, is the Chair or Deputy Chair plus six of the voting members (i.e., seven in total).

3.12 The Research Ethics Board has the authority to establish its own procedures and to make recommendations to Senate for revisions to the Policy.

4. Research Ethics Appeal Board

4.1 Researchers have the right to request, and the Research Ethics Board has an obligation to provide, a reconsideration of a negative decision. Researchers may appeal decisions of the Research Ethics Board to the Research Ethics Appeal Board within 15 working days.

4.2 The Research Ethics Appeal Board will be the University of Victoria's Human Research Ethics Committee (HREC). The decisions of the HREC shall be final and binding in all respects for any appeal lodged against a decision of the Research Ethics Board.

4.3 Appeals may only be heard on the basis of a procedural error that materially and adversely influenced the decision of the Research Ethics Board, including real or reasonably apprehended bias, including epistemological bias, or undeclared conflict-of-interest on the part of one or more members of the Research Ethics Board. The Research Ethics Appeal Board will first determine whether a procedural error, bias or a conflict of interest (as described above) occurred, and if so, the Research Ethics Appeal Board would then proceed to hear the case and make a final determination on the research proposal.

5. Director of the Office of Research Ethics

5.1 The Director of the Office of Research Ethics reports to the Vice-President (Research).

5.2 The appointment of the Director of the Office of Research Ethics will be made by the Vice-President (Research) after receiving advice from a search committee comprising the Research Ethics Board. The Director of the Office of Research Ethics will have experience in research involving human subjects and will hold a doctoral degree.

5.3 The duties and responsibilities of the Director of the Office of Research Ethics include, but are not limited to:

a) being responsible for research ethics education programs at Simon Fraser University in conjunction with the Research Ethics Board,
b) assisting researchers in the preparation of applications for submission to the Research Ethics Board,
c) reviewing all applications submitted to the Research Ethics Board for the completeness of these applications and their compliance with this Policy,
d) advising the Research Ethics Board with respect to the category of risk (i.e., minimal, in-course student, or non-minimal) of an application,
e) approving minimal risk applications, and providing summaries of such approvals to the Research Ethics Board,
f) acting in an *ex officio* non-voting capacity as Secretary to the Research Ethics Board
g) managing the Office of Research Ethics,

h) undertaking other duties assigned by the Research Ethics Board, such as monitoring, data collection, and communication with other universities and granting councils.

6. Review Process

6.1 Applications to the Research Ethics Board may be placed in one of three categories by the Director of the Office of Research Ethics. These categories are:

a) ***minimal 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 subject in those aspects of his or her everyday life that relate to the research,

b) ***in-course student;*** which applies to undergraduate and graduate courses that require or allow students to participate in research projects as part of the training or for assessment,

c) ***non-minimal risk***; which includes applications not covered by a) and b) above.

All studies designed to determine the consequences for individuals and communities of specific preventative or therapeutic measures and/or invasive procedures, and studies concerning human health-related behaviour and/or experiences in a variety of circumstances and environments are considered non-minimal risk.

6.2 An application that is categorized by the Director of the Office of Research Ethics as minimal risk will be reviewed by the Director. If the Director is satisfied that the application meets the standards established in this policy, the Director shall approve the application on behalf of the Research Ethics Board. If the Director is not satisfied that the application meets the standards of this policy, the application may be returned to the applicant for revisions, or forwarded to the Board for consideration. If forwarded to the Board, the Chair or Deputy Chair has the authority to grant approval for minimal risk proposals without a meeting of the Research Ethics Board, or to refer it to the next meeting of the Research Ethics Board. Summaries of all approvals by the Director, Chair or Deputy Chair will be brought to the next regular meeting of the Board. The Board may review and amend any decisions made independently by the Director, Chair or Deputy Chair.

6.3 A department wishing to offer an undergraduate or graduate course that requires or allows students to participate in research projects involving human subjects will submit to the Director of the Office of Research Ethics:

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) the means by which the students in the course are made familiar with appropriate ethical standards, with copies of printed materials,
e) the means by which students submit their research plans to the instructor(s),
f) the means by which those plans are assessed and approved by the instructor(s),
g) the means by which the conduct of the in-course student research projects is monitored,
h) and other relevant information.

When the Director of the Office of Research Ethics is satisfied that this course poses only minimal risk to research subjects 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". A summary of such approvals will be forwarded to a regular meeting of the Research Ethics Board. 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).

If approval is not given, the application will be returned to the department with an explanation and appropriate suggestions. 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 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 or to be submitted to the Research Ethics Board for full review.

6.4 Research proposals designated non-minimal risk must be reviewed for scholarly merit. Scholarly merit involves a global assessment of the degree to which the research might further the understanding of the phenomenon being studied. 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. Projects that are not approved for funding through peer review must be reviewed locally for scholarly merit before submission to the Research Ethics Board. A description of the project will be sent to two qualified reviewers by the Director of the Office of Research Ethics. One reviewer will be chosen by the applicant(s) and the other by the Chair or Deputy Chair of the Research Ethics Board in consultation with members of the Research Ethics Board who have experience in the discipline of the applicant(s) or the project. If the decision of the two reviewers is not unanimous, the Chair of the Research Ethics Board will consider the views of the two reviewers and cast the deciding vote.

6.5 When a project has been determined to have scholarly merit, it will be reviewed by the Research Ethics Board. Normal outcomes of the review process are:

a) when a majority of the Research Ethics Board votes to approve the research protocol, approval will be granted and the research may be initiated,

b) when the Research Ethics Board 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 Research Ethics Board 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.

7. Risk Analysis

7.1 Researchers should assess all reasonably foreseeable risks involved in, and benefits expected to arise from research projects. Researchers involved in greater than minimal risk research projects should be prepared to document reasonably foreseeable risks and benefits.

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

7.3 Researchers should consider possibilities that exist with respect to possible:
a) physical harm,
b) psychological harm,
c) injury to reputation or privacy,
d) breach of any relevant law.

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

7.5 Benefits include specific advantages to subjects, 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).

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

7.7 The Research Ethics Board 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.

7.8 The Research Ethics Board 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 this section is intended to diminish researchers' rights to engage in critical inquiry and disseminate that information, even though analysis of this sort of might be considered "harmful" to the interests involved.

8. Informed Consent

8.1 A mandatory condition of approval from the Research Ethics Board is that subjects, or authorized third parties, have given informed consent about participation in the research. Normally, all communication with research subjects will be in writing, unless circumstances of the research prevent this. The Research Ethics Board must approve methods of communication which are not in written form.

8.2 Normally, researchers must provide the following information to subjects or authorized third parties:

a) information that the subject is being invited to participate in a research project,
b) an understandable description of the research, the identity and institutional affiliation of the researcher, contact information, the duration, the nature of participation, and a description of research procedures,
c) an understandable description of reasonably foreseeable harms and benefits that may result from participation as a research subject; in research which involves treatment procedures, this description must include an assessment of potential harms and benefits of not undertaking the treatment,

d) an assurance that subjects are free to avoid participation or to withdraw from participation at any time,
e) an understandable description of the type(s) of data to be collected, the method(s) of data collection (e.g. interview, video recording), the purpose(s) for which the data will be used, and limits on the use, disclosure and retention of data,
f) anticipated secondary uses of identifiable data collected during the research, and anticipated linkages of data with other data about research subjects,
g) methods for data archiving, and provisions for ensuring security and confidentiality of data.

8.3 Individuals who are not legally competent may be asked to become research subjects only if all the following conditions are satisfied:

a) the research requires the participation of individuals who are not legally competent (e.g., studies of children),
b) free and informed consent will be obtained from authorized representatives, following procedures outlined under **8.2a** through **8.2g** (above),
c) research is in the "minimal risk" category, or has the potential to provide distinct benefits to the research subjects,
d) the researcher can show how the subjects' best interest will be protected,
e) the same provisions defined in **8.2a** through **8.2g** (above) will be extended to the research subjects, should they become legally competent during the course of the research,
f) provision must be made for subjects who are legally incompetent to express their opinions about participation in the research; dissent on the part of a research subject must preclude further participation in the research, regardless of his/her legal competency.

S.01-55
Addendum

Social Sciences and Humanities Research Council of Canada
Conseil de recherches en Sciences humaines du Canada

July 6, 2001

Dr. Bruce P. Clayman
Vice-President Research
Simon Fraser University
BURNABY BC V5A 1S6
Fax: (604) 291-4860

Dear Dr. Clayman:

Thank you for sending us the revised policy governing the ethics review of research involving humans at Simon Fraser University (SFU), which we understand will be presented to Senate for approval on July 9, 2001.

The revised SFU policy meets the general requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) and the expectations of the federal funding Agencies. Enclosed are some observations that could be taken into account in future revisions of the SFU policy.

The federal funding Agencies are committed to promoting research that is ethically sound, and intend to continue to work closely with research institutions on this matter.

Sincerely,

Thérèse De Groote
Policy Analyst

c.c. CIHR/Benoit Morin
c.c. NSERC/Anne-Marie Monteith

Enclosure

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Canada

July 7, 2001

SIMON FRASER UNIVERSITY
ETHICS REVIEW OF RESEARCH INVOLVING HUMANS

The following comments are based on the revised "Policy and Procedures for Ethics Review of Research Involving Human Subjects" dated June 1, 2001.

The policies and procedures for ethics review meet the federal funding Agencies' requirements described in Section 1 and 2 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

Some of the comments that were provided on an earlier version (see below) have not been addressed by the institution, but could be taken into account in future revisions:

Article of TCPS	Comment
1.1	SFU Policy 1.6 c) exempts research on ancient unidentifiable human remains from ethics review. Following the advice of the Tri-Council Advisory Group on this matter (ref. our letter of March 29, 2001), researchers should seek the REB's opinion on whether ethics review is required for a particular project, e.g., in accordance with SFU Policy 1.9.
1.1	SFU Policy 1.8 specifies that research on public policy issues and public institutions, among other matters in the public domain, is not required to undergo ethics review, even when it involves interviewing individuals. However, TCPS Article 1.1 c) requires research to undergo ethics review if any person is approached directly for interviews or access to private papers. Individuals who are approached to participate in a research project about their organisation, whether a corporation or a government, have a right to give free and informed consent (see also discussion on TCPS pages 2.2 and 2.4). The purpose of the ethics review for such research is only to ensure that the interviews are conducted according to professional protocols.
1.7	SFU Policy 3.11 defines a quorum as the Chair (or Deputy Chair) plus six of the voting members. The quorum rule should also take into account the range of expertise and background stipulated in Article 1.3: members present should have expertise in the methods or areas of research; knowledge in ethics; include a representative of the community who has no affiliation with the institution; and for biomedical research, knowledge in the relevant law.
1.11	The agreement with the University of Victoria to have their REB serve as SFU's appeal committee (ref. SFU Policy 4.2) should be documented.
1.12	SFU Policy 4.3 makes reference to "undeclared conflict-of-interest on the part of one or more members of the Research Ethics Board". It would be useful to clarify what constitutes a conflict of interest for an REB member. Alternatively, if guidelines on conflicts of interest are described in another institutional policy, it could be a cross-referenced.
1.14	The SFU Policy could address the requirements for multi-centred research and research that is conducted outside the jurisdiction or country of the institution.