

Simon Fraser University

S.01-18

Memorandum

To: Senate

From: Alison Watt, Secretary
Senate Committee on Agenda and Rules

Date: February 21, 2001

Subject: Proposed Policy and Procedures for Ethics Review of
Research Involving Human Subjects

Action undertaken by the Senate Committee on Agenda and Rules, at its meeting of February 20, 2001, gives rise to the following motion:

MOTION: ~~"that Senate approve and recommend approval to the Board of Governors the proposed Policy and Procedures for Ethics Review of Research Involving Human Subjects as set forth in S.01-18"~~

Motion withdrawn - presented for information



SIMON FRASER UNIVERSITY

DEAN OF SCIENCE



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February 16, 2001

To: Secretary of Senate
From: Willie Davidson, Chair, ad hoc Committee to Review Revisions to the Research Ethics Policy
Re: Report

Please find attached the recommended Policy and Procedures for Ethics Review of Research Involving Human Subjects for consideration by Senate. The process to get to this recommendation has involved considerable formal and informal input from interested faculty. Our aim was to develop a policy that reflects the values of Simon Fraser University while conforming to the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans".

Sincerely

A handwritten signature in cursive script that reads "Willie Davidson".

William S. Davidson

**PROPOSED POLICY & PROCEDURES
FOR
ETHICS REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

February 16, 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 where these do not conflict with ethical standards. 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. No more than three years after the implementation of this Policy, and no more than every five years thereafter, Senate should 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:

- 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 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 for any active project, funded or not, involving human subjects and to submit that project with complete documentation to the Director of Research Ethics 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 authority 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 to Senate at its September meeting.
- 3.7 There are twelve voting members of the Research Ethics Board plus the Director of Research Ethics who will be *ex officio* and serve as secretary. Membership qualifications 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, from the faculty at large,
 - b) four others to be elected by Senate, from the university community at large (these may include faculty, staff, and students),
 - c) two members elected by Senate, from the community outside of the university,
 - d) the term of office for voting members of the Research Ethics Board will be three years with no more than two consecutive terms allowed. These terms will be staggered with four members being elected each year.
- 3.8 Prior to serving, all members of the Research Ethics Board will attend a workshop or orientation session, organized by the Director 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 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 an ad hoc committee of Senate, established as required by the Senate Committee on Agenda and Rules. The decisions of the Board 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 Research Ethics

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

- 5.2 The appointment of the Director of Research Ethics will be made by the Vice President (Research) after receiving advice from a search committee comprising the Research Ethics Committee.
- 5.3 The duties and responsibilities of the Director 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) acting in an *ex officio* capacity as Secretary to the Research Ethics Board, recording minutes of Research Ethics Board meetings, and transmitting decisions made by the Research Ethics Board, or the Chair or the Deputy Chair on behalf of the Research Ethics Board, to researchers,
 - f) managing the Office of Research Ethics.

6. Review Process

- 6.1 Applications to the Research Ethics Board may be placed in one of three categories by the Director 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 Applications that are categorized by the Director of Research Ethics as minimal risk will be reviewed by a member of the Research Ethics Board. If the member of the Research Ethics Board is satisfied that this application does indeed fall under the category of minimal risk, then she/he recommends to the Chair or Deputy Chair of the Research Ethics Board that the application be approved. The Chair or Deputy Chair has the power to grant immediate approval for minimal risk proposals without a meeting of the Research Ethics Board. If, however, the member is not satisfied that the application fall under the category of minimal risk, she/he will so inform the Director of Research Ethics and the application will either be returned to the applicants to be modified or else be treated under the category of non-minimal risk (see section 6.4).
- 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 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 Research Ethics is satisfied that this course poses only minimal risk to research subjects and student participants, she/he will submit the material to a member of the Research Ethics Board and the Chair or Deputy Chair for review. If the member of the Research Ethics Board and the Chair or Deputy Chair consider that the type of projects that students will carry out as part of the course is indeed minimal risk, then they may grant immediate approval for the course to be designated as a "Research Ethics Board approved course". This designation will remain with the course as long as the course description and the general method of teaching the course does 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 by either the member of the Research Ethics Board or the Chair or Deputy Chair, then 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(s) of the course must sign a statement to the effect that she/he/they will take responsibility for teaching the ethical issues related to the research projects and take responsibility for the actions of the students as they relate to the research projects. In particular, if the instructor(s) deem(s) a research project to involve an element of greater than minimal risk, it is the responsibility of the instructor(s) 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 before submission to the Research Ethics Board. Proposed research that has not been approved by a recognized granting agency (e.g., SSHRC, CIHR) using peer review, will be sent to two qualified reviewers by the Director 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. 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 appropriate to the disciplinary standards of the researchers and the proposed project.

6.5 When an application has been reviewed for 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.