S.06-87

# SIMON FRASER UNIVERSITY

## MEMORANDUM

**To:** Senate Committee on Agenda and Rules

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

**Subject:** Policy Revision – R20.01 Ethics Review of Research Involving Human Subjects

**Date:** 27 June, 2006

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The proposed revision to policy R 20.01 has now been received from Dr. Pinto and is ready to return to Senate for consideration.

The following motions should be considered by Senate:

**Motion**: "that Senate approve and recommend to the Board of Governors the revisions to Policy R 20.01 – Ethics Review of Research Involving Human Subjects

**Motion (approved by SCAR):** "that in the next REB elections of faculty members, University and community members, the terms of these members shall be staggered and shall range from one to three years.

Rationale: This is intended to provide more continuity for the Research Ethics Board. There are 12 members in this category. The terms of 10 members expire in 2007. The terms of 2 members expire in 2008. All these members have 3 year terms. If this motion is approved by Senate, the terms of 4 members each year would end.

Alison Watt

MEMORANDUM
OFFICE OF THE VICE-PRESIDENT, RESEARCH
SIMON FRASER UNIVERSITY

**TO:** Members of Senate Committee on Agenda and Rules (SCAR)

**FROM:** B. Mario Pinto
Vice-President, Research

**RE:** Policy Revision:
R20.01 Research Ethics Review

**DATE:** June 15, 2006

Further to the May 15th meeting of Senate, the above-noted policy has been revised to incorporate the two issues that were raised at that meeting:

(1) Section 1.7 has been revised and moved to 1.1 to provide a better introduction to the scope of research requiring review.

(2) The reference to "identifiable" communities has been removed in 8.2(f) and 7.3(e). Dr. Weeks, the Chair of the Review Committee, has confirmed with the DORE that sufficient latitude remains for the Research Ethics Board to define the scope of a community.

In addition, in consultation with the VP of Legal Affairs, I have clarified the wording of Section 3.7 regarding the constitution of the Research Ethics Board.

The revised policy is attached for your consideration and forwarding to Senate for approval.

**SIMON FRASER UNIVERSITY**
**Policies and Procedures**
University Research Ethics Review (R20.01)

**Date: October 1, 1992**

**Number: R 20.01**

**Proposed Revision Date: July 31, 2006**
**Revision No.: B**

**Ethics Review of Research Involving Human Subjects**

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 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 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** In general, all research involving human participants that proposes the systematic, controlled, empirical and objective inquiry into natural phenomena using currently accepted investigation procedures, the immediate product of which is evidence, with the objective of discovering how that aspect of the physical world works, requires ethics approval. This includes research conducted by any employee or student of Simon Fraser University, or Adjunct Faculty 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 regarding the potential need for ethics review.

**1.2** Research that utilizes human tissue may require review and approval by the Research Ethics Board before research is started, except as stipulated in **1.6** below. Research involving identifiable human remains, identifiable cadavers, primary tissue cultures, biological fluids, embryos, or foetuses must be reviewed by the Research Ethics Board. Any studies utilizing human tissue must first be reviewed by the Bio-Safety Committee who will provide the REB with a statement as to whether the proposed research meets these criteria and hence will require full REB review. Distinctions with respect to human tissue 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;
c. Biological Fluids which are fluids of human origin including blood, mucus, perspiration, saliva, semen, vaginal fluid, and urine.

**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 in the public domain 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 individual is approached directly for interviews or for access to private papers. The 'public domain' 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.

**1.5** All course-based research assignments involving living human subjects, including Directed Studies 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 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. research on ancient unidentifiable human remains.

**1.7** 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. 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.

**1.8** 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. When a graduate or undergraduate student is shown as the principal investigator on an application, the supervisor of the student is always the co-investigator.

**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 (REB)**

**3.1** 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.

**3.2** 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.

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

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

**3.5** 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.

**3.6** The REB provides an annual report of its activities in the previous year to Senate at its September meeting.

**3.7** There are at least twelve voting members of the REB 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. seven faculty members elected by faculty, with one from each of the Faculties of Applied Sciences, Business Administration, Education, Science, and Health Sciences and two from the Faculty of Arts and Social Sciences;

b. at least two 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. every two years, Senate will approve a list of individuals with medical degrees and/or law degrees qualified to serve on the REB;

f. in the event that a), b), or d) above does not produce a REB that includes a person with a law degree 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 Committee as required;

g. in the event that a), b), or d) above does not produce a REB that includes a person with a medical degree, the Chair of the REB will select the next available person from the approved list to serve on the Committee as required;

h. the term of office for voting members of the REB will be three years except for the student member who shall be elected for a two year term. No more than two consecutive terms will be allowed;

i. in the event that a member of the REB is unable to attend a meeting, the Chair of the REB has the authority to appoint a temporary replacement to act in place of the regular member until the regular member returns or until an election can be held.

**3.8** Prior to serving, all members of the REB 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. 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.

**3.9** On an annual basis, 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.

**3.10** The REB will normally meet at least once per month with no more than six weeks between meetings, unless there is no business to transact. Policy or procedural matters will be discussed at the open session of the meeting; ethics applications will be discussed in the closed session.

**3.11** A quorum of the REB 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 REB has the authority to establish its own procedures and internal policies that do not conflict with those established by Senate 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 REB has an obligation to provide, a reconsideration of a negative decision. Researchers may appeal decisions of the Research REB 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 REB.

**4.3** 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 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 REB would 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.

5. **Director of the Office of Research Ethics (DORE)**

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

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

**5.3** The duties and responsibilities of the DORE include, but are not limited to:

- **a.** being responsible for research ethics education programs at Simon Fraser University in conjunction with the REB;
- **b.** assisting researchers in the preparation of applications for submission to the REB;
- **c.** reviewing all applications submitted to the REB for the completeness of these applications and their compliance with this Policy;
- **d.** advising the REB 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 REB;
- **f.** acting in an ex officio non-voting capacity as Secretary to the REB;
- **g.** managing the Office of Research Ethics;
- **h.** undertaking other duties assigned by the REB, such as monitoring, data collection, and communication with other universities and granting councils.

6. **Review Process**

**6.1** Applications to the REB may be placed in one of three categories by the DORE. 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;
b. ***non-minimal risk***, which includes 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 the training or for assessment.

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

If the REB designates a project non-minimal risk it shall inform the applicant(s) in writing of its reasons and also shall give the applicant the opportunity to ask the REB to reconsider the designation of the project as non-minimal risk and propose a process, in consultation with the REB, that might assist the REB in its reconsideration.

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

Research proposals designated non-minimal risk must be externally 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 REB. A description of the project will be sent to two qualified reviewers by the DORE. 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

**6.4** 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 REB votes to approve the research protocol, approval will be granted and the research may be initiated;

**b.** when 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 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.

**6.5** An academic unit 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 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. 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.

Although the application of course approval may be submitted by the current instructor of the course it must be approved by the Chair, Director or Dean of the academic unit. When the DORE 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". If the course is designated minimal risk a summary of such approvals will be forwarded to a regular meeting 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). If the course is designated non-minimal risk it shall be forwarded to the REB for a decision.

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 or to be submitted to the REB for full review.

Course applications shall be considered in closed meetings of the REB. After approval the course application and approval shall be in the public domain.

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 potential risk of:

a. physical harm to the participants or third parties;
b. psychological harm to the participants or third parties;
c. injury to reputation or privacy of the participants or third parties;
d. breach of any applicable law;
e. harm to any community.

**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 REB 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 REB be.

**7.7** In a project involving more 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.

**7.8** 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.

8. **Informed Consent**

Informed consent may be obtained in different ways:

a. **expressed opt-in** by written, oral or by the conduct of the participant, such as returning a questionnaire. This type of consent must be voluntary, informed, unambiguous, obtained before beginning the research and may be withdrawn at any time, and unless there is explicit consent at the time of data collection, there will be no further collection of additional data, no further analysis of the data initially collected and there will be removal of the data from the database to the extent possible;

b. **implied**, which must be voluntary, with opt-out provisions where consent is assumed because the participant does not opt out. Participants may be notified of the research in writing by various means including, brochures, letters, media, announcements and advertisements of the research and of the provisions for opting out. Opt-out opportunities include written, oral or conduct, such as leaving the research site;

c. **oral**, which is acceptable where written documentation is culturally unacceptable, or where there are good reasons for not recording opt-in or opt-out in writing, using a form that the participant signs. An oral procedure should be managed and documented, indicating how the opt-in and opt-out provisions were conducted;

d. When research participants desire anonymity and personal data can be collected without the researchers present (such as the use of a self-administered questionnaire) individuals could indicate consent by filling out and mailing back an anonymous questionnaire to the researcher. Documentation of the consent should be done separately in order to prevent linking research participants to their data or the results of analyses.

**8.1** A mandatory condition of approval from the REB is that subjects, or authorized third parties, have given informed consent about participation in the research. The REB must approve methods of communication which are not in written form. The REB may approve consent procedures which do not include, or which alter, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

a. the research involves no more than minimal risk to the participants;

b. the waiver or alteration will not affect the rights and welfare of the participants;

c. the research could not be practically carried out without the waiver or alteration;

d. whenever possible and appropriate, participants will be provided with additional pertinent information after participation;

e. the waived or altered consent does not involve a therapeutic intervention;

f. if an approved protocol does not require written consent, the researcher has kept a record of who has been interviewed or who has participated.

**8.2** Normally, researchers must provide the following information to participants 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 goals, 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 participants 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. 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;

g. methods for data archiving, and provisions for ensuring security and confidentiality of data;

h. when intentional deception is a necessary component of initial instructions and information to participants, participants must be de-briefed immediately after their participation and given the opportunity to opt-out. Opting out will mean that the data collected cannot be used for analysis or retained, and that the individual's participation and decision to opt-out will remain confidential;

i. when students are to be approached or tested on school grounds, permission of the school district is required;

j. prior to conducting research activities and where applicable, participants must be advised whether employers, and/or government agencies have *given permission*, *denied permission*, or *have not been approached for permission*, to include their employees to take part in the study.

**8.3** Individuals who are not legally competent, or who are under legal guardianship , or who are members of a captive population may be asked to become research subjects only if all the following conditions are satisfied:

a. the research requires the participation of such individuals;

b. free and informed consent will be obtained from participants competent to do so and for those who are not, from their legally 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 participant, should they become legally competent during the course of the research;

f. provision must be made for participants who are legally incompetent or subject to legal guardianship 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;

g. the age of majority in British Columbia is 19 years of age 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. Consistent with 8(f), 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 guardian consent will generally only be required if the research study is deemed non-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.).

9. **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 the Tri-Council statement 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 Tri-Council or similar policy, as determined by the REB.