S.00-19

SIMON FRASER UNIVERSITY

Memorandum

To: Senate

From: Alison Watt
Director, University Secretariat

Date: January 25, 2000

Subject: Research Ethics Policy Revisions

The attached paper on proposed revisions to the Research Ethics Policy was considered by SCAR on January 25, 2000 and is now forwarded to Senate for discussion.

Following consideration by Senate, B. Clayman and the Task Force will determine what changes are necessary and the revised policy will come back to Senate for further consideration in the near future.

SIMON FRASER UNIVERSITY

OFFICE OF THE VICE-PRESIDENT, RESEARCH

Memorandum

TO: President J.P. Blaney

FROM: Bruce P. Clayman
Vice-President, Research

SUBJECT: Proposed Ethics Policy Revisions

DATE: January 18, 2000

As you are aware, Dr. Ellen Gee, Chair of the President's Task Force for Revision of the Research Ethics Policy, has provided with her letter of January 12, 2000 the final report of the Task Force comprising the recommended revision of the present research ethics policy, R20.01.

I am very appreciative of the difficult task accomplished by the Task Force and the extensive consultation that provided input to their deliberations. In large measure, the draft Policy is appropriate, well-constructed and compliant with the Tri-Council Policy Statement (TCPS) on Research Involving Human Subjects - as required by the Presidents of the Granting Councils.

There are three largely administrative areas where I believe improvements are required:

Article 5.6 provides for election of the Chair and seven of the eight other members of the REB. This is proposed by the Task Force through nomination by the university community, followed by a Senate election wherein a ranked ballot method winnows the pool of candidates such that the full membership of the REB satisfies the requirement that they are knowledgeable about ethics and research and collectively provide substantial expertise in the methods and areas of research involving [human] subjects, in the opinion of the continuing members of the REB [Article 5.3 of the draft Policy].

Unfortunately, this approach to an election is impossible to implement administratively and the expected results can be inconsistent with the requirements of the TCPS in that the process does not assure that "...members have broad expertise in the methods or in the areas of research that are covered by the REB" and "at least one member is knowledgeable in ethics" (TCPS Article 1.3). At SFU, research involving humans occurs in a wide variety of disciplines, ranging from biomedical and clinical areas to psychology and the social sciences. The process of nomination and ranked ballot election could result in lack of coverage of one or more important research areas. In addition, the requirement in Article 5.3c that members be "knowledgeable about ethics and research" misses the intent of the TCPS that at least one member be "knowledgeable in ethics," where ethics is considered to be a field of scholarship.

On the assumption that the goal remains election of REB Chair and members by Senate, I propose the following revisions:

- The creation, in consultation with the Chair of the Task Force, of three broad disciplinary categories of research involving humans. These categories would be specified in the Policy.
- The addition of a separate category for a member who is knowledgeable in ethics; this would result in the addition of one member to the REB.

Then, every two years, there would be nomination by the university community of slates of candidates within the categories of members whose terms expire in that year. This would be followed by simple elections by Senate from those slates. This is parallel to the election of the member described in Article 5.3d in a different category: ("one member of the community served by the University who is not otherwise affiliated with the University").

I also recommend that the Chair be elected through a similar process of simple nomination and election.

Article 5.7 and point 3 of the covering letter has the Research Ethics Officer (REA) under the supervision of the Chair of the REB. The Chair is a faculty member elected by Senate. The rationale for this approach is the need for the REB to be independent of the administration of the university, in view of the delegation to the REA of the authority to approve minimal risk applications. Unfortunately, this approach is not feasible administratively, for two main reasons:

- The Chair of the REB would be the person to develop the position description for the REA, and appoint, supervise, evaluate and possibly terminate him/her. However, the Chair should be selected for her/his qualifications related to research ethics, not administrative experience and abilities and may lack familiarity with Human Resources Policies and Procedures and/or lack management/supervisory skills.
- The Chair of the REB would not occupy a place in the administrative and budgetary structure of the university. While in theory a place could be created, in that case the lines of authority and budget would logically flow through Senate, which itself is not equipped to provide the needed administrative supervision and accountability.

I propose instead that the Office of Research Ethics report to either the Vice President, Academic or the Vice President, Research whose office would provide the necessary administrative expertise and support (and access to budgetary resources). In most other Canadian universities, the office of the Vice President, Research is responsible for the REB and this is acceptable to the Tri-Council group.

If there are concerns that the independence of the process of ethics review would be compromised by this approach, I would point out that the REA is not delegated the authority to reject applications, so that any minimal risk application that is not approved by the REA would go to the REB automatically. This model has been in place successfully for many years at the University of Waterloo. It is also the case that the SFU internal auditor, who reports in confidence to the SFU Board of Governors, holds an appointment in Financial Services, but the Board accepts his/her independence from the administration.

If concerns about independence remain, I would propose that the REA simply not be a voting member of the REB and not be delegated the authority to approve applications, but only to recommend approval to the REB Chair, although this would increase the workload of the Chair substantially.

Article 10.4 provides for appeals to be heard by the REB of another Canadian university. Because of differences in protection of privacy and freedom of information legislation among the Provinces, it would be far preferable to restrict the appeals to being heard by universities within the Province of British Columbia, so I recommend that the draft Policy be changed to reflect this.

I would be pleased to discuss these points with you.

Bruce Clayman

SIMON FRASER UNIVERSITY

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12 January 2000

Dr. Jack Blaney
President
Simon Fraser University

Dear President Blaney:

Please find attached a copy of the new Research Ethics Policy. I am also sending a copy to Dr. Clayman, VP-Research, who will be responsible for distribution prior to consideration by Senate.

The Task Force requests that this letter be attached to all copies of the policy that are distributed at this time. It contains information that is not included in the new policy *per se* and amplifies some of the provisions of the policy.

For ease of reading, I am listing the points that the Task Force wishes to bring to your attention.

1. This policy should be reviewed in two years (i.e., semester 2002-1). It changes the ethics review process in many ways, and it is crucial that any unforeseen problems be corrected quickly. The review could be performed by the National Council for Ethics in Human Research (NCEHR), the Research Ethics Board (REB) of another university, or by the REB Chairs of two or three universities. The REB of SFU should provide input into this review. In addition, during this two-year period, researchers who undergo ethics review (either expedited or full review) should be given a short questionnaire (prepared by the REB) to provide their feedback on the review process. These surveys will be anonymous, and submitted to the Secretary of Senate or Alison Watt.

2. The policy calls for an affiliative relationship to be established with one or more universities (preferably in BC, for cost reasons) for handling appeals and for information sharing. These relationships have not yet been established. Once SFU's REB is in place, it should make the necessary affiliative arrangements.

3. The Task Force, in accordance with the Tri-Council Policy Statement, stresses that the REB is a body independent of the administration of the university, except in the sense that it is a committee of Senate. We suggest establishing an Office of Research Ethics, reporting to Senate, that consists of the REB Chair, other members of the REB including the Research Ethics Advisor (REA), and a clerical position (reporting to the REA).

4. The ethics review process at SFU will involve considerably more work for the REB (now URERC), its Chair, and the Research Ethics Advisor. The faculty member who assumes the position of REB Chair should have, in the first year of operation of the new policy, a complete release from teaching duties. In subsequent years, normally a two-course release per year will be needed. Faculty members who sit on the REB should normally have a one-course release per year. The REA is a new position at the university, requiring a PhD. The REA will need clerical assistance, and at least a half-time position should be created. In some larger units with a considerable amount of undergraduate research requiring ethics review, course release may be needed for the faculty member responsible for the LERP. All in all, then, the new policy incurs a considerable financial outlay for the university.

5. The Task Force wishes to stress that Local Ethics Research Panels (LERPS) will institute ethics review procedures that work best for each unit. The use of pre-approved ethics protocols in some cases, e.g., course research projects, is acceptable.

6. The issue of Confidentiality Certificates for research subjects was brought to the attention of the Task Force (such certificates have been used in certain times and places in the United States). We recommend that an ad hoc Committee be established to investigate the possibility of using Confidentiality Certificates at SFU.

7 The current URERC has requested that the Task Force provide guidelines for implementation of the policy. We do not feel that it is possible for us to do this in advance. However, we recommend the secondment, or partial secondment, of Ian Forsyth to assist in this task. One possibility is to include a small group of past, experienced URERC members to assist in articulating and making available these specific guidelines. Also, we emphasize that one of the tasks of the REB is posting its interpretations of ethics issues on its web site, based on its evolving experience.

8. The Task Force is not happy with the policy stipulation that research involving human subjects in graduate courses must be reviewed at the REB level, which is in compliance with the Tri-Council Policy Statement as we read it. We request that the REB explore the possibility that such graduate course research could be handled at the local level.

9. Research done by students in co-op education during a work semester is subject to ethics review since during a work semester, a co-op student is enrolled in an SFU course. The review will be done by the LERP of the unit offering the course in which

the student is enrolled (see Section 6). However, the Office of Co-op Education will play an intermediary role in this process. The additional workload for the Office of Co-operative Education may require additional staff.

Respectively submitted,

The President's Task Force for Revision of the Research Ethics Policy

Ellen Gee, Chair
Christine MacKenzie
Phil Winne
Michelle McGinn, graduate student representative

cc. Dr. Bruce Clayman, VP, Research

Policy and Practices for Ethics Review of Research Involving Subjects

1. Purpose

The purpose of this policy is to promote and facilitate ethical *research*[1] involving *subjects*, while protecting and promoting the interests of subjects, safeguarding *researchers'* and the University's academic freedom, and affording benefits to society that ensue from research. To achieve these goals, principles for the ethical conduct of research are needed, as well as appropriate and flexible procedures.

The policy and its procedures pertain to faculty, post-doctoral fellows, graduate and undergraduate students, visiting researchers, employees of the University, and those employed or supervised by any of the foregoing, who are engaged in research under the aegis of the University. This policy applies regardless of citizenship of researcher and subjects, and regardless of the location of the research.

Also, this policy pertains to any research involving subjects that uses University resources or facilities, including rented space.

2. Rationale

This policy and its procedures are consistent with THE TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS (1998), which outlines general principles and practices regarding ethical research conduct for both individual researchers and universities. The University and its researchers are responsible for ensuring that research practices conform to this policy.

3. Principles For Ethical Conduct Of Research Involving Humans

This policy is guided by the following ethical principles. Conflicts may arise in applying these principles in isolation. In such cases, researchers, the University's Research Ethics Board (REB; see Section 5), and the Local Ethics Review Panel (LERP; see Section 6) must weigh the principles to reach a reasoned conclusion.

3.1 In all research, subjects have a right to be protected from *risk* or *harm*. This means that the multiple interests relating to the dignity, health and well-being of the subject—physical, biological, psychological, and cultural—normally must be protected (cf. Section 3.3). Other principles flow from this overarching one.

a. Subjects are normally presumed to have the capacity and right to provide *free and informed consent* regarding their participation in research.

b. *Vulnerable persons* and members of any *captive population* have the right to special protections against possible risks from involvement in research.

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[1] All italicized terms are defined in Appendix A at the end of this policy.

c. Subjects normally have the right to privacy and *confidentiality*.

d. Subjects have the right to *anonymity* if the research procedure allows it. If they desire and so declare, however, subjects may request they be identified and recognized in reports of research provided this does not compromise any other subject's right to privacy and confidentiality. The researcher will honor the subject's request to the best of his/her ability.

e. Ethical research involves a favourable balance of risks and benefits; foreseeable risks should not outweigh anticipated benefits for subjects, other individuals, society as a whole, and/or the advancement of knowledge.

f. Ethical research upholds the values of justice and inclusiveness. This means that:

- the ethics review process is conducted in a fair and independent manner,
- no segment of the population is unfairly burdened with the risks of research, and
- individuals and groups who may benefit from research are neither neglected nor discriminated against.

3.2 In some research (e.g., with community groups, First Nations bands), subjects are research collaborators. Such research may present complex ethical considerations, for example, regarding ownership of *data*, framing of research questions and results, and differing perspectives of the researcher(s) and subjects on risks and benefits of the research. The ethics review process and the researchers' implementation of research procedures must recognize and reflect both the value and the ethical complexities of such research.

3.3 Some research on *corporate entities* and public figures (e.g., elected officials, artists, authors, CEOs) may be at odds with their interests. Such research may have scholarly merit or serve the public interest in a free and democratic society. It should not be prevented solely because it entails non-collaboration or by applying a context-insensitive risks/benefits analysis to the researcher, subject(s) and/or the University.

3.4 Academic freedom is coupled with the responsibility of the researcher to ensure that research meets high scholarly and ethical standards.

3.5 The legal context for research involving subjects is evolving. Sometimes ethical and legal principles diverge. Researchers and the University share an obligation to ensure that research is designed, approved, and carried out in a manner that provides the greatest degree of protection for subjects so that the highest ethical standards can be maintained. Researchers should be familiar with and understand the law that pertains to their research. Researchers and the University have a role in the development of legal principles that take into account the goals, interests, and values of research. Accordingly, researchers and the Research Ethics Board will have recourse to legal expertise where necessary. The University is committed to providing legal advice (and representation or indemnification, if necessary) to researchers who, in good faith, encounter problems when planning their research or when conducting research approved under this policy.

3.6 If there is any conflict among the interests of subjects, researchers, and the University, primary consideration is for the protection of subjects.

In applying the foregoing principles, a formulaic approach is to be avoided. Flexibility and sensitivity to context must be preserved. However, any researcher(s) who seeks a modification regarding a principle is responsible for demonstrating the need.

4. Research Requiring Ethics Approval

Anyone who plans research that involves data about subjects in any setting, including a *public setting* (see Section 9.2), or data not in the *public domain* must receive ethics approval before gathering data. Ethics review is performed either by the University Research Ethics Board (REB; see Section 5) or by a Local Ethics Review Panel (LERP; see Section 6).

4.1 Researchers who require ethics approval include:

a. undergraduate students doing research in courses, including honours essays/projects courses and practicum courses taken as part of co-operative education (see Section 6).

b. graduate students conducting research as part of a graduate course, including practicum courses taken as part of co-operative education, or program.

c. graduate students doing research contributing to a thesis, research project, or extended essay.

d. undergraduate and graduate students doing research under the aegis of the University that is not a requirement of course work, their thesis, research project, or extended essay, e.g., a student who carries out research for an agency off-campus, but uses university resources for that research.

e. faculty members and visiting researchers, and their employees.

f. other employees of the University, and their employees.

4.2 Normally, review of undergraduate student research is conducted by a LERP. Review of all other research is done by the University REB.

4.3 Types of research that must be reviewed according to this policy include research:

a. in which the researcher collects data about subjects and/or from documents not in the public domain, on- or off-campus.

b. based on data in hand when the identity of individuals could be determined.

c. using data acquired from another person or institution when the identity of individuals could be determined.

d. that is part of a multi-institutional project in which a University researcher gathers or analyses data, unless those data are of the type described in 4.4 e.

e. in which data are collected in support of creating an artistic work.

f. that has been already approved and in which, subsequently, there are significant changes in collecting, storing, analyzing, or reporting data.

g. where, in the context of an unforeseen and fleeting opportunity, a researcher acts in accord with ethical principles and practices (see Section 7.1 a, b) to gather or receive data before the REB or a LERP reviews and approves an application (see Section 8.3) specifically pertaining to research that uses these data. See also Section 7.1 d.

4.4 Types of research that do not require review are listed below. In the event of uncertainty, the REA should be consulted.

a. performance reviews of University employees.

b. assessments of students carried out within normal educational parameters.

c. scholarly work in the form of artistic expression (but see Section 4.3 e).

d. data collected by the University that relate directly to and are necessary for administering, evaluating, or seeking to improve an operating program or activity of the University (e.g., University Industry Liaison Office survey of company contacts).

e. data acquired previously from the University, another person or institution in which the identity of persons could not be determined (e.g., secondary data sets acquired from Statistics Canada).

f. *contract research* or research covered by the Outside Activities policy (A 30.04) that is conducted independently of the University, makes no use of University resources or facilities, and will be disseminated with no affiliation with the University.

g. forensic case investigations or identifications carried out to aid a law enforcement agency.

5. University Research Ethics Board (REB)

The University Research Ethics Board is responsible for the ethics review of all research involving subjects and documents not in the public domain, except for research specifically assigned for review by a Local Ethics Review Panel (see Section 6), and research that is excluded from ethics review (see Section 4.4).

5.1 The University Research Ethics Board:

a. is responsible for ensuring that researchers are aware of the principles and practices of ethical conduct of research.

b. works cooperatively with researchers in pursuit of ethical conduct in research.

c. assists researchers in preparing and revising applications for ethics approval of research (hereafter, the application).

d. may establish its own operating procedures as needed. These will be communicated immediately to University researchers by notice posted on the REB's web site.

e. adjudicates applications and supporting documentation. Decisions will be: approved, not approved, or requires further clarification. In the latter two cases, written reasons will be provided.

f. if the research involves more than *minimal risk* to subjects and has not been peer-reviewed, is responsible for weighing risks and benefits. This may be informed by its own or an external *scholarly review* of the research.

g. records its interpretations of and researchers' submissions on the principles of ethical conduct of research, and makes these interpretations available to University researchers.

h. liaises with the University Research Office, LERPs, other Universities' REBs, governments, and institutions.

i. assists LERPs in creating procedures for adjudicating applications by undergraduate students within Faculties, Schools, Departments, research centres, programs, etc.

j. approves the composition and procedures of LERPs.

k. audits the procedures and records of LERPs, and makes recommendations for improvement.

l. adjudicates appeals by undergraduate students of negative decisions made by a LERP.

m. audits the records of individual research projects, including those approved by a LERP.

n. forwards appeals for ethics approval to Canadian universities with which a formal agreement is in place.

o. adjudicates appeals for ethics approval from Canadian universities with which a formal agreement is in place.

5.2. If a researcher or a member of the REB is or appears to be in a conflict of interest, this must be communicated to the REB. The REB will make special arrangements to deal with such situations.

5.3 The REB consists of nine voting members, both men and women, including:

a. the Chair of the REB (see Section 5.5).

b. the Research Ethics Advisor (see Section 5.7).

c. six faculty members, knowledgeable about ethics and research, who collectively provide substantial expertise in the methods and areas of research involving subjects.

d. one member of the community served by the University who is not otherwise affiliated with the University.

5.4 The REB may draw upon advisors of its choosing, including the Director of Health Services, the Director of Occupational Safety, faculty members, and community members, for ethics review of applications. These advisors may provide written assessments, be invited to attend relevant REB meetings, or both.

5.5 The Chair of the REB is a tenured Associate Professor or Professor who normally has been a member of the REB. The Chair of the REB:

a. convenes regularly scheduled and extraordinary meetings.

b. supervises the Research Ethics Advisor (REA) per Policy R 50.01, University Research Associates.

c. circulates to the REB applications involving more than minimal risk for detailed consideration.

d. on behalf of the REB, gives final written approval to applications for a specific time period and specifying records the researcher is obliged to keep.

e. may require clarification or submission of additional material from an applicant.

f. in collaboration with the REB, decides if an application will be distributed to an advisor(s) for review and recommendation.

g. oversees appeals of negative decisions made by LERPs.

h. forwards a researcher's appeals of a negative decision to a Canadian university with which a formal agreement is in place.

i. establishes formal relations with other universities' REBs for purposes of appeal (see Section 10).

j. receives appeals from other Canadian universities with which a formal agreement is in place and forwards them to the REB for adjudication.

5.6 The REB is a committee of the University Senate.

a. The Chair of the REB is nominated by the University community and elected by Senate using a ranked ballot method that successively winnows the pool of candidates. Normally the Chair will have previously served on the REB, and may serve as Chair for a total of six years, normally in two consecutive three year terms.

b. Members other than the Research Ethics Advisor (see Section 5.7) are nominated by the University community and elected by Senate using a ranked ballot method that successively winnows the pool of candidates such that the full membership of the REB satisfies Section 5.3, as determined by the continuing members of the REB. Members normally serve three year terms that will be staggered at the start of this policy. Except for the Research Ethics Advisor, members serve for a maximum of six years.

c. The REB normally meets once monthly.

d. A quorum consists of six voting members who, in the judgment of the REB Chair, constitute a committee with expertise in the method(s) or area(s) of research to be reviewed.

e. The REB maintains records of its operations and decisions according to the University's Information Policy (10.01). Records are maintained and disposed in accordance with approved Records Retention Schedules and Disposal Authorities.

5.7 The Research Ethics Advisor (REA),who may be a seconded faculty member, is a University Research Associate per Policy R 50.01, University Research Associates. The REA supervises the Office of Research Ethics and its staff, and reports to the Chair of the REB (see Section 5.5 b). He/she has a doctorate, is experienced with a variety of research methods involving subjects, and is knowledgeable about research ethics. The REA:

a. is responsible for research ethics education programs on campus.

b. assists researchers in preparing applications.

c. examines the completeness of all applications.

d. may require clarification or submission of additional material from an applicant.

e. reviews all applications submitted to the REB, including written submissions from researchers regarding changes in previously approved research plans (see Section 7.1 e), regarding risks to subjects and benefits.

i. The REA is delegated authority to approve applications on behalf of the REB that are judged to involve no risk or minimal risk to subjects and that comply with this policy, thereby providing an *expedited review*.

ii. The REA forwards applications judged to involve more than minimal risk to subjects to the REB Chair for detailed consideration by the REB (see Section 5.5 c).

f. processes applications, revisions, approvals, annual updates, project terminations, audits, and appeals for the REB.

g. records minutes of REB meetings.

h. is the custodian of REB records, which are maintained in accordance with the University's Information Policy (10.01). Records are retained and disposed in accordance with approved Records Retention and Disposal Authorities.

i. is an ex-officio member of all LERPs.

5.8 The University REB will liaise, as possible, with other universities' REBs to:

a. develop and enhance interpretations of principles and practices regarding ethics in research.

b. collaborate in developing responses to changes in policies and law that govern or influence ethics in research.

c. share information about processes and practices for adjudicating applications.

d. forward appeals to and receive appeals from other Canadian universities with which the University has a formal agreement.

6. Local Ethics Review Panels (LERP)

Students' research carried out as part of coursework requirements in undergraduate courses, including undergraduate honours essays/projects/theses courses and practicum courses taken as part of co-operative education, requires ethics approval. Each Department, School and non-departmental Faculty in which undergraduate students may conduct research with subjects as part of coursework requirements will form a Local Ethics Review Panel (LERP).

6.1 The composition and operating procedures of each Department's, School's and non-departmental Faculty's LERP will be created in collaboration with and approved by the REB. The REA is an ex-officio member.

6.2 Each LERP will develop a checklist to be completed by prospective employers of students taking co-operative education practicum courses regarding the possibility and nature of research in which a student may be involved during a practicum course. The Office of Co-operative Education will issue that checklist to every student's prospective employer and transmit it to be received by the LERP at least two weeks prior to commencement of the student's employment. Based on this information, the LERP, as it deems appropriate, will direct the employer and/or student to prepare and return to the LERP a proposal for ethics review of research.

6.3 If a student researcher, instructor, or a member of the LERP is or appears to be in a conflict of interest, this must be communicated to the LERP. The LERP will make special arrangements to deal with such situations.

6.4 If the research involves more than minimal risk to subjects, the LERP will deny approval, appealable per Section 10, or refer the application to the REB for review.

6.5 The Chair, Director or Dean (or his/her designate) is the custodian of LERP records, which are maintained in accordance with the University's Information Policy (10.01). Records are retained and disposed in accordance with approved Records Retention and Disposal Authorities.

7. Responsibilities Of Researchers

7.1 Researchers have the responsibility to:

a. conduct research in accord with ethical principles and practices.

b. be aware of principles and practices of ethical research consistent with their discipline(s). If any principles or practices diverge from this policy and are essential to the proposed research, researchers must include in the application a citation to the publication(s) presenting the disciplinary principle(s) or practice(s) plus a justification for diverging from this policy.

c. investigate thoroughly when doing research about an organization (e.g., business, hospital, school, social service agency, society), either on its premises, using its documents, or involving persons affiliated with it (e.g., customers and employees, patients and doctors, students and teachers, clients and therapists, members), whether the organization has its own policies concerning research. In the application, researchers must document their investigation and its results. If the proposed research contravenes an organization's policies concerning research, researchers must explain in their application how their proposed research preserves the principles of Section 3.

d. obtain written ethics approval from the REB or LERP before gathering or analyzing data about subjects. There is one exception. In the context of an unforeseen and fleeting opportunity, a researcher, acting fully in accord with Section 7.1 a, may gather or receive data for research before an application specific to that research has been reviewed and the researcher has received written approval according to this policy. In this rare circumstance, until the REB or LERP reviews a re-application or first application specific to such research, and until the researcher receives written approval from the REB or LERP regarding that application, the researcher may neither further examine nor analyze those data, and may not disseminate in any medium any observation, information or result relating in any way whatsoever to those data.

e. inform the REA or LERP of any significant change in a previously approved research plan. In this rare circumstance, until the REB or LERP reviews a re-application specific to such research, and until the researcher receives written approval from the REB or LERP regarding that re-application, the researcher may neither further examine nor analyze those data gathered or received, and may not disseminate in any medium any observation, information or result relating in any way whatsoever to those data.

f. obtain written approval under the Freedom of Information and Protection of Privacy Act (FOI/POP) before collecting data about subjects held in University record-keeping systems.

g. provide an annual update to the REB or LERP, according to its procedures, for research approved for more than a 12 month period.

h. request in writing and receive an extension from the REB or LERP before continuing research activities beyond the date specified in the approved application.

i. keep records, as specified in the REB's or LERP's approval, for a minimum of three years after the termination of the period approved for the research so that an audit could determine whether ethical practices in research have been upheld.

j. provide means for any subject to inquire about the research.

k. provide information to every subject about how to register a complaint with the REA about research practices or a researcher's conduct in activities relating to the research.

7.2 When the researcher is a student, the student's supervisor is responsible for educating the student about ethical issues pertaining to the proposed research and reviewing the student's submission for ethics approval, before it is transmitted to a LERP or the REB, to ensure it complies with this policy.

8. Procedures For Researchers To Obtain Ethics Approval

8.1 Researchers except undergraduate students conducting research as part of coursework requirements are encouraged to consult with the REA about ethical practices in research, procedures for making an Application for Ethics Approval of Research (hereafter, the Application), and any concerns about the process of ethics review of research. Undergraduate students conducting research as part of coursework requirements are encouraged to consult on these matters with their instructor(s) or supervisor(s) and the LERP of the Department, School, or Faculty where they enroll in a course involving research with subjects.

8.2 All researchers except undergraduate students conducting research as part of coursework requirements submit applications for ethics approval to the REA. Undergraduate student researchers conducting research as part of coursework requirements submit applications for ethics approval as stipulated by the LERP of the unit offering the course.

8.3 The Application is completed by the researcher. Appendix B contains forms for applications submitted to the REB. [*Note: Forms will be created by the REB, per Section 5.1 d, and are not included in this policy.*] In addition to these forms, a complete application must be filed that includes descriptions of, at least, the following:

a. purpose(s) of the project;

b. framework for the project in prior research, theory, and/or professional or social practice(s);

c. method(s), protocol(s) or methodology to be applied in gathering data about subjects (see also Section 9);

d. research instrument(s) to be used to gather data about subjects, with copies whenever possible, for example: observation protocol, interview schedule, questionnaire, tests and measurements;

e. procedures for securing and recording free and informed consent from each subject, including whenever possible copies of the Statement(s) of Information about the Research for Subjects and Informed Consent (see also Section 9). Signed informed consent forms are not mandatory, but researchers who do not use them must explain why they are not appropriate.

f. measures to protect *confidential information* in recording and storing data, and in reporting or publishing the research (see also Section 9);

g. risks to subjects (see Section 9);

h. benefits for subjects, other individuals, society as a whole, and/or the advancement of knowledge;

i. method(s) for obtaining feedback from each subject, except those not capable of providing it (e.g., young children, people with certain disabilities), when the research exposes a subject to more than minimal risk;

j. written agreement from an external agency or institution under whose auspices the research will be conducted, when the agency requires a written agreement, except as excluded in Section 3.3. If the agency or institution requires prior approval by the REB or LERP as a condition of agreement, this should be so stated in the Application. Conditional approval by the REB or LERP may be granted contingent on its subsequent receipt of written agreement from the external agency or institution;

k. prior written agreement from the University's Archives and Record Management Department that confirms compliance with provincial privacy law, the Freedom of Information and Protection of Privacy Act, when using university records that disclose personal information for a research purpose, including statistical research;

l. any other information the REB or LERP may require (see Sections 5.5 e and 5.7 c, d).

9. Special Considerations In Research With More Than Minimal Risk To Subjects

Some research with potential to advance knowledge or benefit society exposes subjects participating in the research to more than minimal risk when data are gathered, stored, or published. In these cases, extraordinary care and consideration is warranted to protect every subject's dignity, health, and well being, and to protect the confidentiality of data about every

subject. The following subsections illustrate some areas of special consideration for the researcher. In all cases, the researcher should thoroughly address in the Application steps taken to protect subjects from risk.

9.1 Research Confidentiality and the Law

In obtaining informed consent from subjects under the jurisdiction of Canadian law, researchers should include a statement that there are limitations on the extent to which absolute confidentiality can be assured under existing Canadian law. Child protection legislation provides for mandatory reporting of information that relates to the abuse of a child and no exception is made for researchers. A university researcher may also become involved in legal proceedings in which information obtained under the promise of confidentiality is sought under a court order. Although university researchers do not have any legislative protection to withhold confidential information in the face of a court order, the common law (that is, the law developed by judges) has developed a set of tests known as the *Wigmore criteria*—after the name of the law professor who first proposed them—that allows, on a case by case basis, for a claim of privilege that may enable a university researcher to maintain confidentiality. The overall probability of any single researcher being subject to such action is small but it can occasionally happen to researchers in a broad spectrum of disciplines and areas of research. Nonetheless, researchers should design their research to enhance their ability to legally protect confidential information. In particular:

a. The informed consent statement should include the statement that the researcher and the University will do everything possible to maintain confidentiality as promised by the researcher. This includes challenging any subpoena or other legal process that seeks disclosure, exhausting all avenues of legal appeal, and stating that the university is committed to covering reasonable legal costs associated with any challenge and appeal.

b. The application should include an explanation of why the researcher believes that research confidentiality is necessary to acquire valid data in the proposed study, together with an articulation of the benefits that might be reasonably derived from the research for subjects, other individuals, society as a whole, and/or the advancement of knowledge.

In applying these guidelines, flexibility and sensitivity to context must be preserved.

9.2 When data about a subject are gathered in a public setting, the subject may be invited to reveal data that normally would not be revealed in that setting. In this instance, three considerations must be addressed:

a. The subject must be made aware that other individuals in the public setting or devices in that setting may have access to confidential information.

b. The subject must understand that he/she can withdraw from participation in the research at any time without penalty.

c. There must be a record of the subject's informed consent regarding 9.2 a and 9.2 b.

9.3 Some research proposes to gather data about or from subjects under circumstances in which they are deceived. That is, in securing a subject's free and informed consent, information is withheld or misinformation is provided about the purposes and/or methods of the research. In research that involves deceiving a subject, five considerations must be addressed:

a. The subject must understand that he/she can withdraw from participation in the research at any time without penalty.

b. There must be a record of the subject's free and informed consent regarding 9.3 a.

c. The research must include a procedure for debriefing the subject that can be reasonably expected to eliminate any harm to the subject directly or indirectly caused by the deception or participation in the research.

d. The research must include a follow-up procedure that eliminates or redresses harm the subject may experience if debriefing is unsuccessful.

e. There must be a record of the subject's understanding of 9.3 c and 9.3 d.

9.4 When risk to a subject has potential to occur after the completion of data gathering, the researcher must propose a method by which to counter that risk. In debriefing every subject, the researcher must make clear:

a. how the researcher will monitor the subject's condition with respect to the risk;

b. resources or methods known to be valid in eliminating, reducing or redressing the risk; and

c. the availability of those resources or methods to the subject.

10. Appeals

Researchers, the REB and the LERP should make every effort to work together to achieve ethics approval of proposed research.

10.1 In the event of a negative decision by the LERP or REB, a researcher has the right to appeal that decision.

10.2 Appeals must be made in writing and include all supporting materials. Except in extenuating circumstances, the appeal must be forwarded within 14 days of the date of issuance of the negative decision.

10.3 The researcher has a right to appear before the REB or LERP adjudicating the appeal. In some circumstances, telephone or video-conference may be appropriate media for the researcher's presence at an appeal. If there are travel costs to the researcher in pursuing an appeal, receiptable expenses for travel from the University to the site of the appeal will be reimbursed by the University, per Policy AD 3.2, Travel and Business Expenses.

10.4 Appeals are heard as follows:

a. Appeals by undergraduate students of negative decisions by a LERP will be submitted to the University REB, who will consider the appeal within 14 days of its receipt. In such cases, the REA will be considered in a conflict of interest and Section 5.2 will apply. The University REB's decision will be final.

b. Appeals of negative decisions by the University's REB will be submitted to the REB of another Canadian university with which the University has a formal agreement. The decision of the other university's REB will be final.

Appendix A. Definitions

Anonymity. A condition such that a subject's identity is unknown to the Researcher.

Captive population. A person(s) required by law to (a) inhabit a specific setting (e.g., prison, school) or (b) participate in activity (e.g., community service, driving test).

Confidential information. Information about a subject or that a subject provides to a Researcher for use exclusively in a research project that should not be disclosed to anyone.

Confidentiality. Keeping information confidential.

Contract research. Research commissioned and partly or fully paid for by a person or Corporate entity external to the University involving a legally enforceable agreement which may include conditions setting forth specific terms governing the conduct, direction and scheduling of the tasks to be performed; designating ownership of proprietary rights to the research results; laying out the financial regimen to be followed; and other restrictions required by the research sponsor.

Corporate entity. An entity constituted of more than one person that legally may act as a single person (e.g., business, non-profit society, trade union, school district, royal commission).

Data. Information or an artifact(s) gathered for Research that originates with, reflects on, or is about a subject. Data may be in one or more forms, including but not limited to records of oral expression, written material, or behavior; deposits or erosions of physical kinds (e.g., lost personal articles, wear on a floor tile); and bodily tissue(s) or fluid(s), including human remains. Data may be recorded in one or several media including but not limited to the researcher's memory, written records, audio records, video records, electronic records, or an artifact per se.

Expedited review. An examination of proposed research by the Research Ethics Advisor yielding a recommendation to the Chair of the Research Ethics Board that the research be approved on ethical grounds. Because the research is judged to expose subjects to no or Minimal risk, detailed consideration by the Research Ethics Board is not required.

Free and informed consent. Written or oral agreement to participate in Research given by a subject or by a person legally authorized to make such agreements for a subject under all of the following conditions:

a. The subject or person legally authorized to make agreements for a subject experiences no undue coercion, either a reward or penalty, to participate in the research.

b. The subject or person legally authorized to make agreements for a subject is competent to understand the risks, benefits, and conditions of the research.

c. The subject or person legally authorized to make agreements for a subject is explicitly told the risks, benefits, and conditions of the research.

d. The subject or person legally authorized to make agreements for a subject, by consenting to participate in research, neither conditionally, implicitly, nor explicitly waives any legal right.

Whenever a subject is competent to understand the risks, benefits, and conditions of the research, the subject's agreement or denial to participate in research supercedes that of anyone legally authorized to make such agreements for a subject.

Harm to individual. See Risk.

Informed consent. See Free and informed consent.

Minimal risk. A potential harm or danger that may be experienced as a result of participating in research to which a reasonable subject, with full knowledge of the harm or danger and without undue enticement or coercion, would agree to be exposed because the harm or danger is transitory, minor, or easily reversed (e.g., by a brief conversation), or because the harm or danger is neither more significant nor more likely to occur as a result of participating in the research than in the subject's everyday life.

Public domain. Information that is publicly available in the form of documents, records, works, performances, archival materials or third-party interviews, in any medium (written, electronic, or otherwise) that is free for anyone to use without permission, whether copyrighted, patented, or pending application for same.

Public setting. A setting in which a reasonable person would understand that (a) anonymity may not be preserved and (b) activities may be observed by another person or device (e.g., videotape, turnstile counter).

Research. Investigating that involves gathering or receiving data with intent to: share credible observations; or, establish facts, principles or generalizable knowledge which the Researcher(s) intends or is required by prior agreement to disseminate to others in any form, including oral, written, video, or electronic; or, use the data as input or background to creating a subsequent artistic work. Inquiries concerning professional practice that are carried out in a supervised practicum course by a teacher-in-training or by a clinician-in-training are not research.

Researcher. Anyone under the aegis of the University, including students, employees of the University, or their employees who engage in Research.

Risk. A potential or actual condition of mind or body that a subject would not normally seek to experience because it is or perceived to be unpleasant, harmful, or threatening; or a potential or actual condition judged by a reasonable person or designated in law to have such features. See also Minimal risk.

Scholarly review. An examination of methodological soundness and potential theoretical contribution of the proposed Research. If the proposed research entails more than Minimal risk, scholarly review includes a judgment of the balance between risks and benefits. A

scholarly review may include suggestions for improving the research, increasing benefits, and minimizing risks.

Subject. A living person who is, or the remains of a person which are, the source of Data for Research.

Vulnerable person. A subject whose freedom to grant or deny consent to participate in research, or whose capability to be fully informed about the risks and benefits of research is constrained by physical, psychological, social, cultural, legal or other circumstances. Any member of a Captive population is a vulnerable person.

Wigmore criteria. Four conditions that courts consider in judging whether communications between two parties, such as subject and a researcher, are legally privileged such that one party will not be required to disclose the content of the communication under subpoena or in legal testimony. The conditions are:

a. Communications must originate in a confidence that they will not be disclosed.

b. Confidentiality must be essential for the maintenance of the relationship between the parties.

c. The relationship must be one in which the opinion of the community ought to be sedulously (i.e., with careful perseverance and without guile) fostered.

d. There must be balance between the injury to the relationship caused by disclosure with the benefits gained from the correct disposal of the litigation.