ST. STEPHEN'S COLLEGE

ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS

Adapted from the Tri-Council Policy Statement of the Medical Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, August 1998 and from the University of Alberta Policy regarding Human Research (University Secretariat Article 66).

A. INTRODUCTION

In keeping with the University of Alberta motto, St. Stephen's College researchers are encouraged to search for and disseminate "whatsoever things are true" (Philippians 4:8 – KJV). The purpose of the ethical standards embodied in this policy is not to limit research activities, but to promote and facilitate the conduct of all research in ways that respect the dignity and preserve the wellbeing of human research participants. These ethical principles and ethics review procedures reflect the commitment of St. Stephen's College and its members to Canadian and international norms that have developed across a wide variety of fields, including the humanities, the arts and the natural, medical and social sciences.

B. GUIDING ETHICAL PRINCIPLES

Researchers contribute to human welfare by acquiring knowledge and applying it to human problems. They simultaneously consider two types of obligations in the design and conduct of research. One of these obligations is to conduct research as capably as their knowledge permits, and another is to protect the dignity and preserve the well being of human research participants.

a. Respect for Human Dignity

The cardinal principle of modern research ethics is respect for human dignity. Such respect requires that researchers protect the multiple and interdependent interests of the person, from bodily to psychological to cultural integrity, as they may be affected by the research. This principle forms the basis of the remaining ethical principles described in the following subsections. Conflicts may sometimes arise from the application of these principles in isolation from one another. Researchers and Research Ethics Committee Panels must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

b. Respect for Free and Informed Consent

Individuals are generally presumed to have the capacity and right to make free and informed decisions. Thus, respect for persons means respecting the exercise of individual consent. In practical terms, within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research participant.

c. Respect for Vulnerable Persons

Respect for human dignity entails high ethical obligations towards vulnerable persons—to those whose lack of competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

d. Respect for Privacy and Confidentiality

Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity respected.

e. Respect for Justice and Inclusiveness

Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research proposals, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

f. Balancing Harms and Benefits

The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance, that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefit analysis thus affects the welfare and rights of research participants, the informed assumption of harms and benefits, and the ethical justification for competing research paths.

This is not to say that harm may not result from research. In some areas of research such as political science, economics or modern history, there may be occasions in which research ethically results in harm to the reputations of organizations or individuals in public life. There is often uncertainty about the magnitude and kind of benefits or harms that may result from proposed research and a resultant uncertainty about the balance of benefits and harms. This uncertainty imposes an obligation to conduct research at a high level of competency in order to maximize the potential benefits of the research.

g. Minimizing Harm

A principle related to achieving a favorable harms-benefit balance is that of **non-maleficence**, or the duty to avoid, prevent or minimize harm. Research procedures which might cause serious or lasting harm to a participant must not be used unless their absence would expose the participant to a risk of even greater harm. Research participants must not be subjected to unnecessary risks of harm. Their participation must be essential to achieving scientifically and societally important aims that cannot otherwise be realized. Minimization of harm also requires that research involve the smallest number of human participants and the smallest number of tests on them that shall ensure scientifically valid data. Should adverse effects result from research procedures, the researcher has an obligation to assist the participant in reducing or eliminating those effects.

h. Maximizing Benefit

Another principle related to the harms and benefits of research is **beneficence**. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize benefits. The principle has particular relevance for researchers in areas such as social work, education, health care and applied psychology. Benefits of research may accrue to the research participants themselves, to other individuals or to society as a whole, or to the advancement of knowledge. In most research, the primary benefits are for society and for the advancement of knowledge.

C. RESEARCH ETHICS POLICIES AND PRINCIPLES

Article 1.1

a. All research by St. Stephen's College faculty and students that involves living human subjects requires review and approval by a Research Ethics Committee Panel in accordance with this Policy Statement before the research is started, except as stipulated below.

b. Research about a living individual involved in the public area, or about an artist, based exclusively on publicly available information, documents, records, works performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy.

c. Quality assurance studies, performance reviews of an organization, or its employees or students within the mandate of the organization, or testing within normal educational requirements, are not subject to Research Ethics Committee review unless they contain an element of research in addition to assessment. Researchers shall seek the advice of the Research Ethics Committee whenever there is any ambiguity or doubt about the applicability of the St. Stephen's College Standards to a particular project.

d. Researchers are primarily and ultimately responsible for the protection of human research participants. In order to fulfill this responsibility, researchers must be competent in their areas of inquiry. They must be familiar with and comply with the St. Stephen's College Standards and with other ethics guidelines relevant to their disciplines. Researchers must ensure that all individuals under their supervision have the training and competence needed to carry out their responsibilities. Principal investigators must ensure that all research personnel are familiar with and comply with the St. Stephen's College Standards and other applicable ethics guidelines.

e. Instructors who include research components in their courses must ensure that their students are competent to conduct the assigned research and that they are familiar with and comply with the St. Stephen's College Standards and other applicable ethics guidelines. Adequate supervision of student research must be ensured, with greater care required as risk of harm to participants increases. Assistants, students, and others who conduct research under the supervision of others should understand that they are themselves researchers and therefore also bear personal responsibility for the ethical conduct of research with human participants.

f. Researchers have an ethical obligation to protect the welfare of their assistants, employees, and students by not exposing them to unsafe equipment, materials, and environments during the course of research.

Article 1.2

St. Stephen's College, Edmonton mandates its Research Ethics Committee to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of, this institution, using the considerations set forth in this Policy as the minimum standard.

Article 1.3

a. The Research Ethics Committee consists of at least nine persons, with the Academic Dean as Chair.

b. At least three members have broad expertise in the methods or in the areas of research that are covered by the Research Ethics Committee.

c. At least three members are knowledgeable in ethics.

d. At least three members have no affiliation with St. Stephen's College, but are recruited from the community.

e. Normally, the review of Research Proposals is conducted by a 3-person panel that includes the expertise described in ss. a., b., and c. immediately above. The Dean does not serve on these panels.

Article 1.4

a. The Research Ethics Committee Panel satisfies itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

b. Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

c. The use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular patient population. Consistent with clinical equipoise, a placebo may be used as the control treatment in a clinical trial in the following circumstances:

    i. There is no standard treatment.

    ii. Standard therapy has been shown to be no better than placebo.

    iii. Evidence has arisen creating substantial doubt regarding the net therapeutic advantage of standard therapy.

    iv. Effective treatment is not available to patients due to cost constraints or short supply. (This may only be applied when background conditions of justice prevail within the health care system in question; for example, a placebo-controlled trial is not permissible when effective but costly treatment is made available the rich but remains unavailable to the poor or uninsured.).

    v. In a population of patients who are refractory to standard treatment and for whom no standard second-line treatment exists.

    vi. Testing add-on treatment to standard therapy when all participants in the trial receive all treatments that would normally be prescribed.

vii. Patients have provided an informed refusal of standard therapy for a minor condition for which patients commonly refuse treatment and when withholding such therapy shall not lead to undue suffering or the possibility or irreversible harm of any magnitude.

When a clinical trial involving a placebo control is undertaken, the researcher and the Research Ethics Committee Panel must ensure that patients or authorised third parties are fully informed about any therapy that shall be withdrawn or withheld for purposes of the research, about the anticipated consequences of the withdrawing or withholding of the therapy, and the reasons why the investigator deems a placebo-controlled trial to be necessary.

Article 1.5

The Research Ethics Committee, in assessing proposals, takes a proportionate approach, based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

Article 1.6

The Research Ethics Committee meets in plenary session at the call of the Chair only when there is reason to do so. Normally, its functions are assigned to panels, with a Panel Coordinator appointed to facilitate achievement of consensus.

Article 1.7

Records of all Research Ethics Committee Panel processes and of the Research Ethics Committee meetings are maintained by the Dean's office. The records clearly document the Research Ethics Committee/Panel's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the records are accessible to authorized representatives of St. Stephen's College, institutional accreditors, and funding agencies.

Article 1.8

In the usual course of events, the work of the Research Ethics Committee is conducted by three-member Panels, each comprising one methodologist, one ethicist and one member-at-large. The Academic Dean, as Chair of the Research Ethics Committee, appoints one member of each Panel to act as Coordinator for that Panel, whose responsibility it is to:

a. convene the Panel for the purposes of deliberation as required
b. facilitate the reaching of consensus regarding the Panel's recommendations
c. report the findings and consensus recommendations of the Panel to the Dean.

The work of the Panels is usually carried out by e-mail, telephone, and fax. If, in exceptional circumstances, a meeting of the Panel is deemed necessary or desirable, it occurs at the call of the Coordinator. If, in exceptional circumstances, a meeting of the whole or any part of the Research Ethics Committee is deemed necessary or desirable, it occurs at the call of the Research Ethics Committee Chair.

The usual process for ethical review of a Proposal is as follows.

a. Independent review of the Proposal by each member of the Panel, who prepare their written response to the Proposal on the form provided
b. Internal discussion of the Proposal and the independent reviews by the Panel members, with a view to reaching consensus

c. Communication of that consensus response (including any recommendations for revision to the Proposal) to the Dean
d. Communication of that consensual decision by the Dean to the student and his/her Thesis Supervisor, with a copy to the student's Program Coordinator for inclusion in the student's file

Research Ethics Committee reviews are based upon fully detailed research proposals or, where applicable, progress reports. The Research Ethics Committee Panel functions impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. The Research Ethics Committee Panel accommodates reasonable requests from researchers to participate in discussions about their proposals, but researchers are not be present when the Research Ethics Committee Panel is making its decision. When an Research Ethics Committee Panel is considering a negative decision, it provides the researcher with all the reasons for doing so and gives the researcher an opportunity to reply before making a final decision.

Article 1.9

Researchers have the right to request, and Research Ethics Committee Panels have an obligation to provide reconsideration of decisions affecting a research project.

Article 1.10

When researchers and Research Ethics Committee Panels cannot reach agreement through discussion and reconsideration, the Dean assigns a second Research Ethics Committee Panel to review the proposal. The decision of the second Panel is final.

Article 1.11

If the Research Ethics Committee is reviewing a research proposal and a member of the Research Ethics Committee has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that that member not participate in a Panel reviewing that proposal.

Article 1.12

a. Ongoing research is subject to continuing ethics review. The rigour of the review is in accordance with a proportionate approach to ethics assessment.

b. When submitting an proposal involving ongoing research, the researcher proposes to the Research Ethics Committee the continuing review process deemed appropriate for that project.

c. Normally, continuing review consists of at least the submission of a succinct annual status report to the Research Ethics Committee. The Research Ethics Committee shall be notified promptly when the project concludes.

Article 1.13

When the research is to be performed in an Institution that has a its own Research Ethics Review Policy, the researcher must document that s/he has submitted their proposal to that process. The Institution's certification that its Research Ethics Review Policy has been satisfied is sufficient authorization for the research to proceed without further review by the St. Stephen's College Research Ethics Committee, provided the Institution's Research Ethics Review Policy follows the guidelines of Tri-Council Policy Statement of the Medical Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

Article 2.1

a. Research governed by this Policy (see Article 1.1) may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).

b. Evidence of free and informed consent by the subject or authorized third party is ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent are documented.

c. The Research Ethics Committee may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the Research Ethics Committee finds and documents that

   i. The research involves no more than minimal risk to the subjects;

   ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

   iii. The research could not practicably be carried out without the waiver alteration;

   iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and

   v. The waivered or altered consent does not involve a therapeutic intervention.

d. In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

Article 2.2

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

Article 2.3

Research Ethics Committee review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require Research Ethics Committee review since it can be expected that the participants are seeking public visibility.

Article 2.4

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given

adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective subjects with the following:

a. Information that the individual is being invited to participate in a research project;

b. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

d. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and

e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

In light of (b) and (c), Research Ethics Committees may require researchers to provide additional information as delineated in Table 1.

Table 1

Additional information that may be required for some projects

1. An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;
2. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;
3. Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;
4. An indication as to who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of data;
5. An explanation of the responsibilities of the subject;
6. Information on the circumstances under which the researcher may terminate the subject's participation in the research;
7. Information on any costs, payments, reimbursement for expenses or compensation for injury;
8. In the case of randomized trials, the probability of assignment to each option;
9. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

Article 2.5

Subject to applicable legal requirements, individuals who are not legally competent are only asked to become research subjects when:

a. the research question can only be addressed using individuals within the identified group(s);

b. free and informed consent can be sought from their authorized representative(s); and

c. the research does not expose the subjects/co-researchers to more than minimal risks without the potential for direct benefits for them

Article 2.6

For research involving persons who are not legally competent, the Research Ethics Committee ensures that, as a minimum, the following conditions are met.

a. The researcher shows how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected.

b. The authorized third party is not the researcher or any other member of the research team.

c. The continued free and informed consent of an appropriately authorized third party is required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.

d. When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent is sought as a condition of continuing participation.

Article 2.7

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the person who is not legally competent understands the nature and consequences of the research, the researcher seeks to ascertain the wishes of the individual concerning participation. The potential subject's dissent precludes his or her participation.

Article 3.1

Subject to the exceptions in Article 1.1(c), researchers who intend to interview a human subject to secure identifiable personal information shall secure Research Ethics Committee approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in Article 2.4. As indicated in Article 1.1, Research Ethics Committee approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

Article 3.2

Subject to Article 3.1 above, researchers shall secure Research Ethics Committee approval for obtaining identifiable personal information about subjects. Approval for such research shall include such considerations as:

a. The type of data to be collected;

b. The purpose for the which the data will be used;

c. Limits on the use, disclosure and retention of the data;

d. Appropriate safeguards for security and confidentiality;

e. Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular subjects;

f. Any anticipated secondary uses of identifiable data from the research;

g. Any anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records; and

h. Provisions for confidentiality of data resulting from the research.

Article 3.3

If identifying information is involved, Research Ethics Committee approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the Research Ethics Committee that:

a. Identifying information is essential to the research; and

b. They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects;

c. Individuals to whom the data refer have not objected to secondary use.

Article 3.4

The Research Ethics Committee may also require that a researcher's access to secondary use of data involving identifying information be dependent on:

a. The informed consent of those who contributed data or of authorized third parties; or

b. An appropriate strategy for informing the subjects; or

c. Consultation with representatives of those who contributed data.

Article 3.5

Researchers who wish to contact individuals to whom data refer shall seek the authorization of the Research Ethics Committee prior to contact.

Article 3.6

The implications of approved data linkage in which research subjects may be identifiable shall be approved by the Research Ethics Committee.

Article 4.1

Researchers and Research Ethics Committee members disclose actual, perceived, or potential conflicts of interest to the Research Ethics Committee.

Article 5.1

a. Where research is designed to survey a number of living research subjects because of their involvement in generic activities (e.g., in many areas of health research or in some social science research such as studies of child poverty or of access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, gender or age, unless there is a valid reason for doing so.

b. This article is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one gender, colour, or religion, or of a religious order which is restricted to one gender).

Article 5.2

Women shall not automatically be excluded from research solely on the basis of gender or reproductive capacity.

Article 5.3

Subject to the provisions in Articles 2.6 to 2.7, those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals, or to the group that they represent.