

Policy:	E-3.2
Approved By:	College Executive Team
Approval Date:	May 24, 2006
Amendment Date:	
Policy Holder:	President

ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN SUBJECTS

Purpose / Rationale

The purpose of this policy is to establish principles and guidelines for maintaining quality and ethical standards and principles for the conduct of research on human subjects, and for reviewing such research activities that are undertaken, sponsored by, or involve Camosun College.

Scope / Limits

- 1. This policy applies to researchers engaged in any research activities that include human subjects and involve the College through
 - a) inclusion of College employees and/or students, either as researchers or participants;
 - b) affiliation between the College and other institutions and/or members of the public (including, but not limited to, partnerships and/or sponsorships); **and/or**
 - c) non-college individuals or organizations using the College name or its resources and/or conducting research on College students and/or employees.
- 2. This policy does *not* apply to ongoing information gathering activities deemed to be of minimum risk that are sanctioned by the College, are in accordance with its core mandate, and are related directly to the normal administering, evaluating, or improving of an operation, program, service or activity within the College. Commonly, such activities include, but are not limited to, quality assurance studies, performance reviews or testing within normal educational requirements.

Principles

- 1. The College is committed to safeguarding the rights and well-being of human subjects of research activities in which the College is involved by adhering to quality and ethical standards and principles for research involving human subjects stipulated in this and other Camosun College policies and guidelines. (See links.)
- 2. Researchers, the College, and the College's Research Ethics Board (REB) are jointly responsible for safeguarding the rights and well-being of human subjects of research activities in which the College is involved. Regardless, the primary responsibility for adhering to the principles and guidelines stated in this policy and for ensuring high standards of conduct in research involving human subjects rests with the principal researcher(s). (See definition.)

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- 3. The College will establish a Research Ethics Board (REB) with the primary responsibility to evaluate and monitor the quality and ethical standards and principles of College research activities that involve human subjects. This body will have the authority to cease research activity that has not been approved through the Proportionate Ethics Review process. (See Section B.)
- 4. No research involving human subjects is to commence until an ethics review, based on a Proportionate Ethics Review process, has been completed.
- 5. A Research Appeal Board will be made available to hear appeals of REB decisions. (See Guideline E-3.2.1, Section E.2)
- 6. Research activities that have the potential to cause damage to the College's reputation will not be approved.

A. DEFINITIONS

- 1. Ethics Review means the processes and guidelines by which research proposals are evaluated to determine if they meet the quality and ethical principles and standards for research involving human subjects.
- **2. Principal Researcher(s)** means the person(s) primarily responsible for conducting a particular research activity.
- **3. Risk** means the likelihood that something harmful might occur and the magnitude of the harm.
- **4. Minimal Risk** means risk that is considered to be within the range normally encountered by, and acceptable to, the human subject in his/her everyday life.

B. Proportionate Ethics Review

All research proposals and activities that involve human subjects will be reviewed through a Proportionate Ethics Review process which is based on the ethical principle that, while all research involving human subjects must be reviewed adequately to ensure protection for the subjects, the greater the potential for risk or harm to the subjects, the greater the scrutiny required in reviewing the research. In accordance with this principle, research proposals will be reviewed through one of the following three levels as appropriate:

- 1. Full REB Review of Student and Faculty Research That Involves Human Subjects

 Full review by an REB is the default requirement for all research involving human subjects.
- 2. Expedited REB Review of Student and Faculty Research That Involves Human Subjects

Research that is expected to involve minimal risk may be approved by the REB chair (or chair's designate) who will conduct an expedited review. All expedited reviews approved by the REB chair must be reported back to the full REB which may require full review.

3. Department Level Review of Student Research and Projects That Involve Human Subjects

The REB will delegate to each Department Chair authority for reviewing student research and student projects within the Department that involve human subjects and that are conducted under faculty supervision as part of Camosun course requirements.

Consulting with the Chair (or Designate) of the REB whenever questions about quality and ethical principles and standards arise, the Department Chair will approve those projects that do not exceed minimal risk and will submit for REB Review those that may possibly exceed the minimal risk threshold.

It is the responsibility of faculty to identify to the Department Chair all student research and projects involving human subjects.

C. RESEARCH ETHICS BOARD (REB) TERMS OF REFERENCE

1. REB Responsibilities

The REB will meet regularly in order to fulfill its roles as follows:

- a) Review research applications through a Proportionate Ethics Review process and
 - i. determine whether College research activities involving human subjects comply with quality and ethical principles and standards and/or this and other Camosun College policies and guidelines;
 - ii. notify principal researchers of approval or rejection of the application;
 - iii. advise principal researchers of any adjustments needed to make the application acceptable;
 - iv. decide whether to accept the review of other REBs or perform its own review when Camosun researchers propose to conduct research outside the College while still using the College's name.
- Monitor ongoing research activities and propose modifications as necessary to ensure ongoing compliance with quality and ethical principles and standards and/or this and other College policies and guidelines;
- c) Ensure that notification of completion or termination of a project is reported to the REB.
- d) Terminate ongoing research when it comes to the attention of the REB
 - i. that research is being conducted without the appropriate ethical review and approval by the REB; or
 - ii. that ongoing research no longer complies with quality and ethical standards and principles and/or this and other College policies and guidelines;
- e) Serve as a consultative, educational resource to College researchers regarding research ethics; and
- f) Provide the Vice President responsible for research with an annual report which summarizes the REB's activities and identifies trends and concerns.

2. REB Independence

Camosun shall respect the independence and authority delegated to the REB and may not override negative REB decisions reached on grounds of ethics without a formal appeal process. Notwithstanding, the College has the right to refuse certain research to be conducted under the College's name, even though the REB has found it ethically acceptable.

3. REB Membership

- a) Membership to the REB is established through appointment by the Vice President responsible for research.
- b) The terms of appointment for all members will be two years. Re-appointments are permitted.
- c) Committee members will be expected to attend all meetings, including extraordinary meetings, and to actively participate.
- d) The REB will consist of at least five members, including both men and women, of whom
 - i. at least two members have broad expertise in the methods or in the areas of research that are covered by the REB;
 - ii. at least one member is knowledgeable in ethics;
 - iii. for biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and
 - iv. at least one member has no affiliation with the institution, but is recruited from the community served by the institution.
- e) The Chair will be appointed by the Vice President responsible for research. The appointed person will be internal to the College and will have proven expertise in human research ethics.

D. RESPONSIBILITIES OF THE ADMINISTRATION

The key responsibility of the administration is to implement the decisions of the REB and to confirm when research is not appropriate to be conducted under the College's name.

E. RESPONSIBILITIES OF RESEARCHERS OF HUMAN SUBJECTS

Researchers are responsible for the following:

- 1. Submitting an application to the REB for Proportionate Ethics Review whenever there is any possibility whatsoever that current research activities
 - a) may fall within the scope of this policy;
 - b) may involve more than minimal risk (see definition); or
 - c) result in any change in method or an unforeseen event that may create more than minimal risk;

- 2. Seeking appropriate levels of approval from the College for research activities and resource commitment prior to engaging in research activity; and
- 3. Protecting the reputation of the College when undertaking research activities.

F. LINKS TO RELATED POLICIES, WEBSITES AND DOCUMENTS

Supporting Guidelines for this Policy

E-3.2.1 Guidelines: Research Ethics Board

E-3.2.2 Guidelines: Free and Informed Consent

E-3.2.3 Guidelines: Privacy and Confidentiality

E-3.2.4 Guidelines: Inclusion in Research

E-3.2.5 Guidelines: Research Involving Aboriginals

E-3.2.6 Guidelines: Conflicts of Interest in Research

Supporting Research Policies

E-3.1 Research at Camosun

E-3.3 Integrity in Research and Scholarship

Oriented Research Office

Research and Innovation at Camosun

National Document

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)