



Policy Supporting Document:	E-3.2.1
Policy Holder:	President

# GUIDELINES FOR THE RESEARCH ETHICS BOARD (REB)

## IN SUPPORT OF POLICY *E-3.2: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN SUBJECTS*

**Please Note:** This document forms part of the set of research related policies at Camosun College. Its function is to serve as explanation and elaboration only. Should there be a discrepancy between this guideline and any Camosun Policy, the Policy will supersede.

This guideline outlines the role of the Research Ethics Board (REB) and the standards and procedures to be used for ethics review.

### A. TERMS OF REFERENCE

#### 1. Terms of Appointment

The terms of REB appointments will be two years and will be renewable. Every attempt will be made to maintain continuity and ensure diversity of opinion and the opportunity to spread knowledge and experience gained from REB membership throughout the College and community.

#### 2. Mandate

The REB has a review as well as educational mandate:

- a) The general mandate of the REB is to
  - i. familiarize themselves with and adhere to the College's as well as national and international research guidelines;
  - ii. evaluate all research activities involving human subjects by conducting independent, multidisciplinary reviews and ensure that (1) quality and ethical standards and principles are applied, (2) appropriate scholarly reviews are undertaken, and (3) ongoing research activities are monitored through accountable reporting processes; and
  - iii. decide whether research activities will be permitted to start or to continue.
- b) The educational mandate of the REB is to serve the College research community as a consultative body and thus contribute to the community's education in research ethics.

#### 3. Membership

The Camosun Research Ethics Board (REB) will consist of at least five members, including both men and women, appointed by the Vice President Responsible for research. The College may exceed the stipulated minimum requirements whenever necessary to ensure competent ethics reviews.

- a) **At least two members will have broad expertise in the methods of, and/or in the areas of, research areas commonly covered by the REB.**

The basic REB membership is designed to ensure the multidisciplinary expertise and independence essential to competent review of ethical issues pertaining to research areas frequently covered by the REB. Independence implies that the responsibilities of the majority of REB members are in research and/or teaching in those research areas commonly covered by the REB.

- b) **At least one member will be knowledgeable in ethics.**

The majority of REB members will have expertise in ethical issues pertaining to research areas commonly covered by the REB in order to alert the REB to potential ethics issues and options for resolution.

Members will also have general knowledge of ethics in research involving human subjects in order to make sound judgements.

Because the College's REB operates within the context of the ethical values of larger society, its membership ideally should be broad enough to reflect a spectrum of societal values.

- c) **At least one member will have no affiliation with the College but will be recruited from the College's local community.**

The community member requirement is essential to help broaden the perspective and value base of the REB beyond the College, and thus advance dialogue with and accountability to local communities.

As the size of an REB increases beyond the minimum of five members, the number of community representatives should increase as appropriate in order to maintain effective community representation.

- d) **For biomedical research, at least one member will be knowledgeable in the relevant laws. Knowledge of relevant laws is advisable, but not mandatory, for other areas of research.**

The College's legal counsel will not be a member of the REB.

The role of the member knowledgeable in a particular law that is applicable to a research area is to alert the REB to legal issues and their implications, not to provide formal legal opinions, nor to serve as legal counsel for the REB.

An understanding of relevant legal issues and contexts is advisable for the REB, although for non-biomedical research, such insights may be sought from someone who sits on the REB only for specific research projects.

#### **4. Conflicts of Interest**

The researcher and the (REB) members hold trust relationships which can be compromised by real or perceived conflicts of Interest. Actions taken in the course of performing their functions related to research neither party may cause or suggest the reality or perception that there is private gain or interests.

The researcher and the (REB) must identify and address conflicts of interest—real or apparent—to maintain the public confidence and trust, discharge professional obligations, and ensure accountability.

Researchers and REB members must disclose real or perceived conflicts of interest to the Chair of the REB. In the cases where a member of the REB has a conflict with the research under review, that person should not be present when the REB is discussing or making decisions on that research. (See *E-3.2.6 Research Guidelines: Conflicts of Interest in Research.*)

## **5. Meetings**

- a) REB members will meet regularly, face to face, to discharge their responsibilities.
- b) A schedule of REB review meetings will be established and published to enable researchers to receive a timely review of their proposals.
- c) The REB will also hold non-review meetings for such purposes as orientation, education and development of the REB, and discussion of issues.
- d) To expedite and facilitate the review process, members of the REB and researchers may request informal meetings with each other prior to the formal review process. Such informal meetings cannot, however, substitute for the formal review process.

## **6. Attendance**

Regular attendance by REB members at meetings is important. Therefore, frequent unexplained absences will be construed as a notice of resignation.

## **7. Quorum**

When there is less than full attendance, decisions requiring full review will be adopted only if the members attending the meeting possess the range of background and expertise required to conduct the review.

## **8. Record Keeping**

The REB needs to act, and be seen to be acting, fairly and reasonably. To ensure accurate and fair administration and integrity of the research process, the maintenance of satisfactory records and documentation is essential. Failure to do so may expose researchers and the College to legal liability. Therefore,

- a) The REB is responsible for ensuring the minutes are correctly prepared and maintained.
- b) The minutes will clearly document the REB's decisions, any dissents, and the reasons for them.
- c) The minutes must be accessible to authorized persons—who may include but are not limited to representatives of the College, researchers and funding agencies—in order to assist in internal and external audits, research monitoring, and/or to facilitate reconsideration or appeals of REB decisions.

# **B. RESPONSIBILITIES**

## **1. Responsibilities of the REB**

The responsibility of the REB is to meet its mandate. (See Section A2.)

## **2. Responsibilities of the REB Chair**

The REB Chair, who is appointed by the Vice President responsible for research, is responsible for providing leadership to the REB and ensuring its functionality. The Chair will:

- a) Chair REB meetings.
- b) Review all applications for ethical review, determine whether expedited or full review is required, conduct expedited reviews, and report all expedited reviews to the REB.
- c) Be available to advise chairs who are responsible for the Department Level Review.
- d) Be available to the College community to advise on quality and ethical principles and standards and on applicable policies.
- e) Prepare an annual report for the Vice President responsible for research.
- f) Identify and notify the Vice President responsible for research of emergent issues.

## **3. Responsibilities of the Vice President Responsible for Research**

The Vice President responsible for research is responsible to:

- a) Establish the REB and enable its appropriate independence so that it can fulfill its mandate.
- b) Appoint the REB Chair.
- c) Appoint appropriate adhoc and substitute members to enable the Board to meet its mandate (see A2 and A3.)
- c) Notify REB members of the conclusion of their term.

## **4. Responsibilities of the College**

- a) Camosun is responsible for the research carried out in its own jurisdiction; therefore, it may refuse to allow certain research to occur that may damage the College's reputation, even though the REB has found it ethically acceptable.
- b) Camosun authorizes its REB to consider and accept reviews of other institution's REBs.
- c) The College may appeal a decision of the REB but may not override a negative decision reached on grounds of ethics.

## **C. PROPORTIONATE APPROACH TO ETHICS REVIEW**

A proportionate approach is based on the general principle that the more invasive the research, the greater should be the care in assessing the research. The concept of proportionate review gives practical expression to the general principle that, especially in the context of limited resources, the more potentially invasive or harmful is the proposed and/or ongoing research, the greater should be the care in its review. While all research must be reviewed adequately, proportionate review is intended to reserve most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of a harm and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant to substantial. A proportionate

approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential subjects, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimum risk provides a foundation for proportionate review.

In practice, proportionate review implies different levels of REB review for different research proposals. The REB Chair will vet all applications to determine whether full or expedited review is required. The three levels are full REB review; expedited REB review by the REB Chair; and departmental-level review of student projects within Camosun course requirements carried out by Departmental Chairs.

### **1. Full REB Review**

Full review by an REB is the default requirement for all research involving human subjects.

### **2. Expedited REB**

Research that is expected to involve minimal risk may be approved by the REB chair or chair's designate.

All expedited reviews approved by the REB chair must be reported back to the full REB, permitting the REB to maintain surveillance over the decisions made on its behalf. Regardless of the review strategy, the REB is responsible for the ethics of all research involving human subjects that is carried out within the College.

Some examples of categories for which an expedited REB review would be appropriate include the following: research protocols that involve no more than minimal risk; and annual renewals of approved projects in which there has been little or no change in the ongoing research.

### **3. Department-level Review**

The REB delegates Department Chairs to conduct ethics reviews of research that is carried out by Camosun students as part of their course requirements. The REB Chair will be available to advise department chairs responsible for department-level review.

## **D. ETHICS REVIEW DECISION-MAKING**

### **1. Principles of Natural Justice**

The REB will be guided by the principles of natural justice which provide for (1) a reasonable opportunity to be heard; (2) an explanation of the reasons for opinions or decisions; (3) the opportunity for rebuttal; (4) fair and impartial judgement; and (5) reasoned and written grounds for the decisions.

- a) The REB decisions must be impartial. Decisions will be based on whether or not the proposed research meets the ethical standards, as noted in these guidelines. The REB should not reject research proposals (1) because of members' personal biases or preferences and/or (2) because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.
- b) Reasons for REB decisions must be well-documented and based on (1) fully detailed research proposals; (2) scholarly review as appropriate (see D4); and (3) where applicable, progress reports for ongoing research which has been previously reviewed and approved by the REB.

## **2. Involvement of Researchers in the Decision-making Process**

Whenever possible, the formal REB decision on whether to allow the research will be preceded by discussion with researchers. Such discussions are often very helpful to both the REB and the researcher and, moreover, are integral to fulfilling the REB's educational mandate. Especially in complex research proposals, the REB should accommodate reasonable requests from researchers to participate in extensive discussions about their proposals.

- a) Discussions involving the researcher may result in a deferral of the REB's decision until the researcher has considered the discussions and possibly modified the proposal.
- b) When an REB is considering a negative decision, it will provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.
- c) Researchers may not be present when the REB is making its formal decision.

## **3. Disagreement**

- a) In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort will be made to reach consensus. Consultation with the researcher, external advice, and/or further reflection by the REB will be sought as appropriate.
- b) If disagreement persists among the REB, a decision of the majority rules. The Chair will monitor the REB's decisions for consistency, ensure that these decisions are recorded properly, and ensure that researchers are given written communication of the REB's decisions (with reasons for negative decisions) as soon as possible.
- c) The Chair will inform the Vice President responsible for research of dissenting votes and the reasons for them.

## **4. Scholarly (Peer) Review**

The purpose of scholarly (peer) review is to elucidate whether the research project (1) adheres to established, high scholarly standards stipulated by the relevant discipline; (2) is capable of addressing the questions being asked in the research; and (3) will further the understanding of the phenomenon or issue in question.

- a) It is the REB's responsibility to ensure that an appropriate form of scholarly review has been completed for each research project that requires full review.
- b) It is the researcher's responsibility to make arrangements for the undertaking of the review.
- c) If requested by the researcher, the REB may assume responsibility for assessing the scholarly merit of the research if the REB deems that it has the necessary scholarly expertise in the relevant discipline, and if it so desires.

## **5. Guidelines for Review of Balance and Distribution of Harms and Benefits**

### **a) Research in the Public Arena**

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.

**b) Risk of Undue or Excessive Offers of Benefit**

There is a threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation.

**c) Children as Research Subjects**

The notion of harm applied to children should be understood differently from harm in adults. Harm induced in children may have longer-term consequences to their growth and development. Furthermore, harms and benefits for children with chronic disabilities and terminal illnesses require special consideration. Every researcher working with child subjects must consider the possibility of the children suffering pain, anxiety or injury, and must develop and implement suitable precautions and ameliorating measures. Cumulative physical, moral, psychological and social consequences (relevant to pain, anxiety and injury) should be reviewed by the REB when assessing the probability, magnitude and character of any harmful impact the research may have on the child.

**d) Clinical Research**

The College does not presently engage in clinical research, but if it does so in the future, it will follow TCPS (Tri-council Policy Statement) guidelines.

**e) Human Remains**

The College does not presently engage in research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses, but if it does so in the future, it will follow the TCPS (Tri-council Policy Statement) guidelines.

**E. RECONSIDERATION & APPEALS OF REB REVIEW DECISIONS**

Requests for reconsideration of REB Review decisions should be made prior to requests for appeals.

**1. Reconsideration**

As stated in section D1, the principles of natural justice provide for (1) a reasonable opportunity to be heard; (2) an explanation of the reasons for opinions or decisions; (3) the opportunity for rebuttal; (4) fair and impartial judgement; and (5) reasoned and written grounds for the decisions. Accordingly, researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

**2. Appeals**

In cases when researchers and REBs cannot reach agreement, the researchers may appeal the REB decision. The University of Victoria's REB will act as Camosun's appeal board.

## **F. CONTINUING REVIEW OF ONGOING RESEARCH**

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

The REB is responsible to ensure that continuing review of ongoing research takes place to its satisfaction. Review will take place at a minimum of once a year. The REB must ensure it has received notification of conclusion of research.

The REB will work with the researcher to develop an appropriate plan for continuing review and the reporting structure for the termination of the project. Some examples of continuing review plans include:

1. formal review of the process of free and informed consent;
2. establishment of a safety monitoring committee;
3. periodic review by a third party of the documents generated by the study; review of reports of adverse events; review of patients' charts; or
4. a random audit of the process of free and informed consent.

## **G. REVIEW OF MULTI-CENTRED RESEARCH**

The REB will endeavour to work cooperatively with other REBs.

## **H. REVIEW OF RESEARCH IN OTHER JURISDICTIONS OR COUNTRIES**

### **Ethics Review**

Research to be performed outside the jurisdiction of the College that employs the researcher, or else performed in another country, will undergo prospective ethics review both (a) by the College's REB and (b) by the REB, where such exists, in order to meet the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

The College is responsible for the ethical conduct of research undertaken by its employees or students regardless of the location where the research is conducted. Thus, review of research by the College's REB is required in addition to review by any agency having jurisdiction over the site of the research.

### **Review Considerations**

Rules pertaining to research abroad should be created and interpreted in the spirit of the Helsinki Accords and subsequent documents that encourage the free movement of researchers across national boundaries. REBs should, therefore, not veto research about authoritarian or dictatorial countries on the grounds that the regime or its agents have not given approval for the research project or have expressed a dislike of the researchers. The REB should, however, legitimately concern themselves about the safety of research subjects and the security of research materials.

College research should be open. It is thus unethical for researchers to engage in covert activities for intelligence, police or military purposes under the guise of College research. The REB must disallow any such research.

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## Endnotes

<sup>1</sup> "At the start of the trial, there must be a state of clinical equipoise regarding the merits of the regimens to be tested, and the trial must be designed in such a way as to make it reasonable to expect that, if it is successfully conducted, clinical equipoise will be distributed." Freedman, B., "Equipoise and the Ethics of Clinical Research." *New England Journal of Medicine*. 1987, 317.3: 141–145.