

Policy Number	5.1.2
Approval Body	PEC
Policy Officer	VP Research
Approval Date	November 2008

5.1.2 RESEARCH INVOLVING HUMANS PROCEDURES

Please note: This document forms part of a set of research related procedures that guide research activity at Emily Carr University of Art + Design (University).

ENABLING POLICY

5.1 Ethics in Research

PROCEDURE INTENT

These procedures are intended to promote and advance a high standard of ethics and integrity in research and scholarship affiliated with the University involving research with human participants. As well, these procedures will identify responsibilities for maintaining these standards.

SCOPE

These procedures apply to all University researchers engaged in research activities which involve human participants, including any University employee, any student enrolled in the University and/or partaking in research or anyone else engaged in research at the University in any capacity, whatsoever.

The President has designated the Vice President (VP), Research as the administrator responsible.

The administrator responsible shall establish and maintain a Research Ethics Board (REB) to help ensure that ethical principles are applied to research involving human participants.

The Templates attached to these procedures are intended to simplify and standardize applications to the Research Ethics Board.

A. GUIDING PRINCIPLES

1. In carrying out its responsibility, the REB will act at all times guided by the Tri-Council Policy Statement, reference:
<http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
 or future standards, as may come to stand in its place. In particular the REB will adopt, as the University ethical principles, the guiding principles contained and defined and most recently amended within the Tri-Council Policy statement:
 - (i) Respect for human dignity

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- (ii) Respect for free and informed consent
 - (iii) Respect for vulnerable persons
 - (iv) Respect for privacy and confidentiality
 - (v) Respect for justice and inclusiveness
 - (vi) Respect for harms and benefits
 - (vii) Minimizing harm
 - (viii) Maximizing benefit

2. The REB will also consider the specific ethical considerations inherent in research involving aboriginal people.

B. DEFINITIONS

University

For the purposes of these procedures, University means the Emily Carr University of Art + Design.

Research Involving Humans

For purposes of these procedures, research involving humans is defined as all research that involves human subjects. This includes most naturalistic observation, physical, sociological or psychological tests and measurements, survey research, non-intrusive systematic observation, and the study of recorded data from previous studies, databases and archives, in which it is possible to identify living individuals. This also includes human remains, cadavers, human organs, tissues and biological fluids from individually identified subjects, embryos or fetuses.

Minimal Risk

The current Tri-Council Policy Statement defines minimal risk as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk.

Human Participant

A human participant is any person who is exclusively a source of primary data in regards to the project.

Principal Investigator

The principal investigator is the researcher who has primary responsibility for a given research project. Primary responsibility for student research rests with the faculty advisor or instructor.

C. ROLE AND RESPONSIBILITY OF THE REB

1. The REB is charged by the President with the responsibility of ensuring that the University's ethical principles are followed when research involves human participants. When it performs this function, the REB is doing so as the designated agent of the President and the University.

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2. The principal decision-making responsibilities of the REB are:
 - (a) Approving a research proposal that complies with the above ethical principles, rejecting a research proposal that does not comply, proposing modifications to a research proposal in order to bring it into compliance, or rescinding approval of ongoing research that ceases to be in compliance.
 - (b) Consulting with experts it deems necessary who are not members of the committee in order to make an informed judgment on the ethical principles as they may apply to any individual research proposal.
 3. Consistent with current national guidelines, the REB shall satisfy 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.
 4. Research to be performed in other jurisdictions shall undergo a prospective REB review by both the University REB, and the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the jurisdiction where the research is to be done.
 5. Research to be performed in multiple centres, for example with other collaborating Universities or Colleges, the same research proposal may undergo REB review at several institutions at the same time. Researchers proposing such research shall notify the REB in their submission of the other REBs which will be reviewing the proposal. The REB will communicate with other REBs which will be reviewing the proposed research to discuss any concerns which it may have, and to discuss potential remedies.
 6. Decisions of the REB to approve, modify, or reject a research proposal or to rescind approval for ongoing research are to be filed with the Office of Research, together with a copy of the research proposal, any conditions imposed by the REB, and the Chair's notice to the researcher.
 7. In collaboration with the VP, Research, the REB shall recommend, develop and implement research ethics educational opportunities for researchers and participants. All researchers shall successfully complete the Tri-Council Tutorial.
 8. Minutes of meetings of the REB must be filed with the Office of Research. An annual report summarizing the activities of the REB must also be sent from the REB to the VP, Research and to the President.
 9. It is not the responsibility of the REB to determine whether or not research activities described in a research proposal:
 - (a) Conflict with the law of British Columbia or Canada or another jurisdiction where the research is proposed to be conducted except to the extent that it may be necessary for the REB to determine whether or not the proposed research methodology satisfies the University's ethical principles and policies in relation to such matters as privacy and human rights; or

(b) Subject the University to an unacceptable risk of legal liability for a claim for compensation for harm, loss or damage caused by the research activities.

Conflict with the law and legal risk will be assessed by the VP, Research and not the REB.

D. MEMBERSHIP

1. The REB shall consist of at least five members, including both men and women, of whom:
 - (a) At least two members have broad expertise in the methods, or in the areas of research that are covered by the REB;
 - (b) At least one member is knowledgeable in ethics; and
 - (c) At least one member has no affiliation with the University, but is recruited from the community served by the University.
2. The REB shall meet regularly, according to a schedule appropriate to the number of proposals being considered.
3. The determinations of the REB will preferably be made by consensus. If a consensus decision is not possible, the determination will be made by a majority vote.
4. For REB reviews of proposals above minimum risk, a quorum shall consist of four voting members, and this quorum must be representative of the normal representation of the REB. The Chair is a voting member. The Chair's vote becomes the deciding vote in the event of a tie.
5. The VP, Research or delegate shall provide institutional support to the REB.
6. Members of the REB will normally serve for two-year terms.
7. The VP, Research will consult with the REB annually to identify the expertise it requires to fulfill its mandate and to ensure that its membership complies with the relevant requirements. Based on this consultation, the VP, Research will recommend any changes to the REB to the President for review and approval.
8. All members of the REB shall attend a workshop or orientation to reinforce the principles and practices of ethical review. REB members may complete the on-line tutorial, accessed through the Tri-Councils website, or a similar tutorial approved by the REB to meet this requirement.
9. The VP, Research may appoint additional members in order to replace regular members who are absent or who resign during their term. Members appointed in this way will serve only for the remainder of the academic year of their appointment.

E. INDEPENDENCE OF THE REB

1. Consistent with the current Tri Council guidelines "Institutions must respect the authority delegated to the REB". The institution may not override negative REB decisions reached on grounds of ethics except in the following extraordinary circumstances:
 - (a) Where there is evidence that the decision of the REB was based on a description of a research proposal which either:
 - i. did not fully describe the research methodology or its application to human subjects; or
 - ii. did not fully disclose all the relevant information regarding the proposed research activity; or
 - (b) Where a palpable and overriding error made in arriving at its decision to approve a research proposal amounts to a failure of the REB to discharge its responsibilities including:
 - i. a failure to apply the Tri-Council ethical principles;
 - ii. a conflict of interest regarding the research proposal on the part of one or more members of the REB, who did not excuse himself or herself from consideration of the research proposal;
 - iii. actual bias or a reasonable apprehension of bias on the part of one or more members of REB who favoured the approval of a research proposal; or
 - iv. a mistaken assessment of the facts.
2. If an applicant wishes to appeal a negative REB decision, the process described in Section H of these Procedures, "Appeal and Reconsideration Process", shall be followed.
3. A positive decision of the REB that a research proposal satisfies the University's ethical principles does not necessarily mean that a research project may proceed or continue. Consistent with the current Tri-Council guidelines, senior administration may refuse to allow certain research within its jurisdiction, even though the REB has found it ethically acceptable. Senior administration will review applications for reasons including the determination of risk of legal liability for a claim for compensation for harm, loss or damage caused by the research activities, and may determine that the research will not proceed or continue.

F. REVIEW PROCESS

The REB will use the "proportionate approach" to Ethics Assessment. Those applications deemed to involve more than a minimal risk will be subject to a more complete review.

1. Application for Ethics Review
 - (a) The principal investigator(s) are responsible for submitting research proposals to the REB for review, in care of the Office of Research. It is the responsibility of the principal investigator(s) to carry out research professionally and ethically, including the need to consider the principles of free and informed consent, privacy and confidentiality, conflict of interest, and the needs of specific populations of research participants as outlined in the Tri-Council Policy statement. This also entails following the approved protocol and abiding by the decision of the REB if the project is not approved.

(b) A faculty member enrolled in a graduate program in another institution or otherwise conducting research approved by an REB at another institution shall submit a copy of the approval from that institution prior to engaging in the project or upon becoming affiliated with the University. Approval by the University's REB is required.

(c) In addition to REB review, researchers who work with Aboriginal peoples need to consult the Tri-Council Policy Statement for guidance on such research.

2. Notification

(a) In the case of acceptance, the notice of ethics approval will be sent to the principal investigator by the chair of the REB. A copy will also be sent to the VP, Research.

(b) In the case of rejection or when more information is required before the submission can be considered, the Chair of the REB will communicate directly with the principal investigator. Before a negative decision is taken, the Chair of the REB will communicate in writing with the researcher, shall provide the researcher with all the reasons for the possible negative decision, and shall allow the researcher an opportunity to reply before making a negative decision.

3. Expedited Review

The REB will implement an expedited review process to be applied to research projects that are deemed by the Chair to be of minimal risk. His/her decision as to the suitability of individual proposals for expedited review will be communicated promptly to the VP, Research and will be reported to the next REB meeting. Decisions made under the delegated review process must be reported to the next REB meeting.

4. Ethical Review of Course-Based Research

(a) Faculty offering courses that involve student research must submit to the REB for approval:

- i. the official course outline,
- ii. the types of student research that will be permitted,
- iii. methods by which the ethical standards are taught to students,
- iv. templates on which students propose their research, including the informed consent,
- v. methods by which these are assessed by instructors, and
- vi. evidence that the instructor has completed the on-line tutorial accessed at <http://www.pre.ethics.gc.ca/english/tutorial>, or a similar tutorial.

(b) Faculty must re-submit whenever there are material changes in any of the elements listed above. Re-submission will be required when the official course outline is reviewed according to the normal review schedule.

G. CONFLICTS OF INTEREST

If the REB is reviewing an application in which a member of the REB has a personal interest in the research under review, for example as a researcher or an entrepreneur, the member must not be present when the REB is discussing or making its decision. In such an event, the member with such a potential conflict of interest shall make this potential conflict known to the Chair of the REB before discussion of the application begins. The Chair shall determine whether the potential conflict is of such a nature that the member should not participate in the discussion of the application and the decision regarding the application.

H. APPEAL AND RECONSIDERATION PROCESS

1. Consultative Dialogue (initial appeal)

(a) Before initiating a formal appeal, the applicant should submit a written request for consultation with the Chair of the REB. The Chair of the REB or designate shall meet with the applicant within ten working days to consider this initial appeal.

(b) The Chair shall bring the results of this discussion to the next scheduled meeting of the REB for possible reevaluation. The results of the REB decision will be conveyed to the applicant in written form.

2. Formal Appeal

The University has entered into an agreement with the University of British Columbia under which the UBC REB will act as an appeal board to hear appeals. Appeals may only be made on the basis of alleged procedural error, which include real or apprehended bias, including bias based on validity, method, theory of the method, theoretical grounds of the work or scope, or undeclared conflict-of-interest on the part of one or more members of the University REB.

(a) An applicant wishing to appeal a decision of the University REB shall provide the VP, Research with the following:

- i. the application as submitted to the University REB,
- ii. a statement of alleged procedural grounds for appeal, and
- iii. the grounds for rejection issued in respect of the application.
- iv. a waiver in favour of each of the Institutions, available from Office of Research.

(b) The VP, Research is required to submit the materials to the Appeal Board within ten working days.

(c) All appeal decisions of the Appeal Board shall be final and binding upon the University and the applicant.

I. POST-APPROVAL MONITORING

1. The REB will maintain a continuing interest in the research after the project has undergone ethical approval. The REB will be available for additional advice, if requested.

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2. If a change in the research procedures is contemplated, the principal investigator(s) will immediately submit an amended proposal to the REB for review.
 3. An on-going status report on the research must be submitted to the REB by the principal investigator(s) annually, or as required by the REB.
 4. A report must be submitted by the principal investigator(s) to the REB when a project is completed.

J. EXEMPTIONS FROM THE ETHICS REVIEW

1. The following categories of research do not require approval by the REB, but researchers must consult, prior to initiating the project, with the chair of the REB if there is uncertainty as to whether a project constitutes research or requires approval from the REB.

(a) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third party interview is exempt. Such research only requires ethics review if the participant 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 provided that there is no private communication (e.g. personal, phone, mail, e-mail) with the participants of research;

(b) Quality assurance studies, performance reviews or testing within normal educational requirements are exempt, as are studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training. For example, students under the supervision of a faculty member or professional, performing activities governed under the code of ethics of that profession, would not be required to submit an application for ethics review;

(c) Research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility;

(d) Research conducted by University employees or students, outside their roles at the University and in compliance with the Conflict of Interest Policy. Such research must not involve the use of their University titles, the University name, or any form of communication that might be construed as support for, or involvement in, the research by the University.

K. REQUIREMENT FOR FREE AND INFORMED CONSENT

1. 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).

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2. Evidence of free and informed consent by the subject or authorized third party should 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 shall be documented.
 3. The REB 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 requirements to obtain informed consent, provided that the REB finds and documents that:
 - (a) The research involves no more than minimal risk to the subjects;
 - (b) The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
 - (c) The research could not practicably be carried out without the waiver or alteration;
 - (d) Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
 - (e) The waived or altered consent does not involve a therapeutic intervention.
 4. 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.

L. VOLUNTARINESS

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

M. NATURALISTIC OBSERVATION

REB 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 REB review since it can be expected that the participants are seeking public visibility.

N. INFORMING POTENTIAL SUBJECTS

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 process of free and informed consent, 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 process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

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- (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.

O. COMPETENCE

1. Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:
 - (a) The research question can only be addressed using individuals within the identified group(s); and
 - (b) Free and informed consent will be sought from their authorized representative(s); and
 - (c) The research does not expose them to more than minimal risk without the potential for direct benefits for them.
2. For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:
 - (a) The researcher shall show 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 may not be the researcher or any other member of the research team.
 - (c) The continued free and informed consent of an appropriately authorized third party will be 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 shall be sought as a condition

of continuing participation.

3. Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

P. RESEARCH IN EMERGENCY HEALTH SITUATIONS

1. Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:

(a) A serious threat to the prospective subject requires immediate intervention; and

(b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and

(c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and

(d) The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

(e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

(f) No relevant prior directive by the subject is known to exist.

2. When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

NOTE: Templates for Applications for REB Approval can be found online at:
<http://www.ecuad.ca/research/reb>