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5.1.2 PROCEDURES FOR RESEARCH INVOLVING HUMANS

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. At the University, the purpose of ethics review of research involving human participants is guided by three principles: the protection of research participants; the protection of the University community; and the education of those involved in research.

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 Associate Vice President (VP), Research as the administrator responsible. The administrator responsible shall establish and maintain the Emily Carr University of Art + Design Research Ethics Board (ECU-REB) to help ensure that ethical principles are applied to research involving human participants.

A. GUIDING PRINCIPLES

1. In carrying out its responsibility, the ECU-REB will act at all times guided by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition, 2010, TCPS2 (reference: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) or future standards, as may come to stand in its place. In particular, the ECU-REB will adopt, as the University ethical principles, the core principles contained and defined and most recently amended within the Tri-Council Policy statement:

   (a) Respect for Persons;
   (b) Concern for Welfare; and
   (c) Justice

2. In addition, the ECU-REB honours the respectful relationships and collaboration and engagement of research involving First Nations, Inuit and Metis Peoples of Canada.

B. DEFINITIONS

The "Core Ethical Principles" that form the basis for these procedures for research involving humans are understood as follows. Further information can be found in the TCPS2, 2010.

Respect for Persons: This principle requires the recognition of the intrinsic value of human beings and the respect and consideration that they are due. Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

Concern for Welfare: The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Concern for welfare means that researchers should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research. They are to provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation in the research.

Justice: Refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research of denied the benefits of the knowledge generated from it.

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 participants. 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 participants, embryos or fetuses.

Minimal Risk: The Tri-Council Policy Statement 2 (TCPS2) defines minimal risk research as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Human Participant: A human participant is any person who provides data in response to methods such as but not limited to: interviews, questionnaires, ethnography and participant observation, or digital documentation, and is also exclusively a source of primary data in regard to the project's research question

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 ECU-REB

1. The ECU-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 ECU-REB is doing so as the designated agent of the President and the University.

2. The principal decision-making responsibilities of the ECU-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 ECU-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 ECU-REB review by both the ECU-REB, and the Research Ethics Board 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 ECU-REB in their submission of the other REBs that will be reviewing the proposal. The ECU-REB will communicate with the other REBs to discuss any concerns that it may have, and to discuss potential remedies.

6. Decisions of the ECU-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 + Industry Liaison, together with a copy of the research proposal, any conditions imposed by the ECU-REB, and the Chair's notice to the researcher.

7. In collaboration with the Associate VP, Research, the ECU-REB shall recommend, develop and implement research ethics educational opportunities for researchers and participants. All researchers shall successfully complete the pre-ethics tutorial course on research ethics (TCPS2. Core). Researchers are expected to repeat the tutorial every five years, or whenever the tutorial is revised. Undergraduates who complete the tutorial as part of an introduction to research ethics in a lecture setting in second year, should be instructed to complete a refresher before embarking on a participant research graduation or thesis project.

8. Minutes of meetings of the ECU-REB must be filed with the Office of Research + Industry Liaison. An annual report summarizing the activities of the ECU-REB must also be sent from the ECU-REB to the Associate VP, Research and to the President.

9. It is not the responsibility of the ECU-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 ECU-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 Associate VP, Research and not the ECU-REB.

D. MEMBERSHIP

1. The ECU-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 ECU-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 ECU-REB shall meet regularly, according to a schedule appropriate to the number of proposals being considered.

3. The determinations of the ECU-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 ECU-REB reviews of proposals above minimum risk, a quorum shall consist of five voting members (four internal and one external), and this quorum must be representative of the normal representation of the ECU-REB. The Chair is a voting member. The Chair's vote becomes the deciding vote in the event of a tie.

5. The Associate VP, Research or delegate shall provide institutional support to the ECU-REB.

6. Members of the ECU-REB will normally serve for three-year terms. Members can be reappointed.

7. The Associate VP, Research will consult with the ECU-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 ECU-REB to the President for review and approval.

8. All members of the ECU-REB shall attend a workshop or orientation to reinforce the principles and practices of ethical review. ECU-REB members may complete the on-line tutorial, accessed through the Tri-Councils website, or a similar tutorial approved by the ECU-REB to meet this requirement.

9. The Associate 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.

10. In the event that the ECU-REB lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently, the ECU-REB will seek the counsel of ad hoc advisors.

11. To conduct the business of the ECU-REB in an orderly manner, the ECU-REB will adopt a succession plan to ensure that the composition as described in Article D of this policy and Article 6.4 in TCPS2, is maintained as members rotate on and off the Board.

12. ECU-REB members who rotate off the Board will need to recommend replacements to the ECU-REB Chair and Associate VP Research. Such recommendations need to be reviewed by the ECU President who makes the final decision on accepting or rejecting the recommendations.13. To conduct the business of the ECU-REB, the Board will designate a Chair and a Vice-Chair

(a) Chair shall:

i) preside over all meetings of the ECU-REB;

ii) call meetings of the ECU-REB as provided for in these procedures and in the *TCPS2* iii) determine and announce the business and the order in which it is acted upon;

iv) execute documents as authorized by the ECU-REB;

v) maintain a liaison with the Senate and Board;

vi) be the spokesperson and representative of the ECU-REB; and, perform such other duties as determined by the ECU-REB.

(b) Vice Chair shall:

i) fulfill the duties of the Chair in his/her absence; and,

ii) assist the Chair in the performance of his/her duties.

E. INDEPENDENCE OF THE ECU-REB

1. Consistent with the current Tri Council guidelines "Institutions shall respect the authority delegated to the ECU-REB". The institution may not override negative ECU-REB decisions reached on grounds of ethics except in the following extraordinary circumstances:

   (a) Where there is evidence that the decision of the ECU-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 participants; 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 ECU-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 ECU-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 ECU-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 ECU-REB decision, the process described in Section H of these Procedures, "Appeal and Reconsideration Process", shall be followed.

3. A positive decision of the ECU-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 ECU-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 ECU-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 ECU-REB for review, in care of the Office of Research + Industry Liaison and the Research Ethics Assistant. It is the responsibility of the principal investigator(s) to carry out research professionally and ethically, including the need to consider the core principles of Respect for Persons, Concern for Welfare and Justice. This also entails following the approved protocol and abiding by the decision of the ECU-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 ECU-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 ECU-REB is required.

(c) In addition to ECU-REB review, researchers who work with First Nations, Inuit and Metis peoples of Canada need to consult the Tri-Council Policy Statement 2 ,(TCPS2) Chapter 9 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 ECU-REB. A copy will also be sent to the Associate VP, Research.

(b) In the case of rejection or when more information is required before the submission can be considered, the Chair of the ECU-REB will communicate directly with the principal investigator. Before a negative decision is taken, the Chair of the ECU-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. Delegated Review

The ECU-REB will implement a delegated review process to be applied to research projects that are deemed by a team of three internal reviewers (two members plus the Chair) to be of minimal risk. Their decision as to the suitability of individual proposals for expedited review will be communicated promptly to the Associate VP, Research and will be reported to the next ECU-REB meeting. Decisions made under the delegated review process must be reported to the next ECU-REB meeting.

4. Ethical Review of Course-Based Research

(a) Faculty offering courses that involve students in human participant research must submit a course-based application to the ECU-REB for approval, and including:

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 and the students in the course have completed the on- line tutorial at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/, 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 ECU-REB is reviewing an application in which a member of the ECU-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 ECU-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 ECU-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 ECU-REB. The Chair of the ECU-REB or Vice Chair 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 ECU-REB for possible reevaluation. The results of the ECU-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 ECU-REB.

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

      i) the application as submitted to the University ECU-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 + Industry Liaison

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

2. If a change in the research procedures is contemplated, the principal investigator(s) will immediately submit an amended proposal to the ECU-REB for review.

3. An on-going status report on the research must be submitted to the ECU-REB by the principal investigator(s) annually, or as required by the ECU-REB.

4. A report must be submitted by the principal investigator(s) to the ECU-REB when a project is completed.

J. EXEMPTIONS FROM THE ETHICS REVIEW

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

   (e) Creative practice activities, in and of themselves do not require ethics review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

   Creative practice is a process through which an artist makes or interprets a work or works of art. It may also include a study of the process of how a work of art is generated. Creative practice activities do not require REB review, but they may be governed by ethical practices established within the cultural sector.

K. REQUIREMENT FOR FREE AND INFORMED CONSENT

1. Research governed by this Policy (see Article 3.1 in TCPS2) may begin only if (1) prospective participants, 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 3.1(to 3.12 in TCPS2).

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 ECU-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 ECU-REB finds and documents that:

   (a) The research involves no more than minimal risk to the participants;

(b) The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

(c) The research could not practicably be carried out without the waiver or alteration;

(d) Whenever possible and appropriate, the participants 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 participants nor those responsible for their care know which treatment the participants are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if participants 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

ECU-REB review is normally required for research involving naturalistic observation. However, REB review is not required for research involving the observation of people in public places where:

(a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups

(b) individuals or groups targeted for observation have no reasonable expectation of privacy; and

(c) any dissemination of research results does not allow identification of specific individuals. (TCPS2, 2010, p. 18).

N. INFORMING POTENTIAL PARTICIPANTS

Researchers shall provide, to prospective participants 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 participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.3 at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective participants 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 participants 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. CAPACITY

1. Subject to applicable legal requirements, individuals who lack the capacity, temporarily or permanently and are therefore not legally competent shall only be asked to become research participants 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 individuals who lack the capacity, either permanently or temporarily to decide for themselves whether to participate, the ECU-REB shall ensure that, as a minimum, the following conditions are met as outlined in Article 3.9 in TCPS2:

   (a) The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

   (b) The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;

   (c) The authorized third party is not the researcher or any other member of the research team;

   (d) The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit for the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and

   (e) When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation

3. Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their 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 ECU-REB. The ECU-REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant of their 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 participant; and

(d) The prospective participant 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 participant 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: ECU-REB application forms and templates for informed consent documents can be found online at http://www.ecuad.ca/research/reb