

Note – While this policy does not subscribe to approved College policy format, its content was approved by Langara Council on November 4, 2014.

A re-formatted version will be posted in early 2015.

Title: **Ethical Conduct for Research Involving Humans**

Policy No.: **B5007**

Applicability: All Employees, Students and other Individuals, either paid or volunteer, involved in Research or Scholarly Activity at or through Langara College.

Effective Date: November 4, 2014

Source(s): Langara Council

Approval: _____
President

PREAMBLE

Langara College is committed to ensuring the highest level of ethical standards in research involving humans and to seeing that their safety, health, welfare, dignity, and rights are adequately protected. Langara College recognizes that the ethical treatment of humans in research shall be guided by three core principles: respect for persons, concern for welfare, and justice.

Langara College shall regulate and monitor all research involving humans conducted at Langara College. It will do so through the Langara College Research Ethics Board (hereafter: LREB).

1. PURPOSE

- 1.1 Langara College recognizes the importance of research to educational progress, and affirms that the welfare of the individual or collective must prevail over the researcher's involvement of human participants for that purpose. The College has a responsibility to ensure that the activities it supports respect the rights of the public it serves.
- 1.2 This policy delineates Langara College's position on the involvement of human participants in research. The procedural guidelines and the LREB's responsibilities outlined below are offered to assist the researcher in:

- 1.2.1 Determining whether contemplated research requires ethical review;
 - 1.2.2 Determining who will be responsible for ethical review, the LREB or Course-Based Research Ethics Review Panel.
 - 1.2.3 Ensuring that the highest ethical standards are upheld for research involving humans.
- 1.3 It is the intention of Langara College, where research activities involving humans are carried out under its purview, to ensure that:
- 1.3.1 The safety, welfare and rights of research participants (including cultural groups) are adequately protected through due application of the core ethical principles of respect for persons, concern for welfare, and justice;
 - 1.3.2 Information communicated to participants is appropriate to ensure an informed consent is obtained from participants;
 - 1.3.3 Participants are made aware that their participation is voluntary and that they have the right to withdraw from the research or study at any time;
 - 1.3.4 Steps are taken to ensure confidentiality and protection of privacy; and
 - 1.3.5 There is no undue influence, coercion, constraint or undue inducement to participate.

2. DEFINITIONS

“Deception”: Deception is a situation in which information is withheld from research participants that is material to their decision to participate, or to continue participating, in a study, and/or they are intentionally misled about any matter related to the research, including procedures and purposes.

“Human Participant” and “Human Subject”: The terms “participant” and “subject” refer to those individuals whose data, or responses to interventions, stimuli or answers to questions by the researcher, are relevant to answering the research question. In this policy, we shall use the term “participant” to refer to individuals who are involved in research as just described. Researchers may use either “subject” or “participant.” Human participants refer to living individuals and also to groups of individuals (for example, social, ethnic, religious, or economic groups). Also included are human biological materials (tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids) as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

“Informed Consent”: An informed consent to participate in research is made:

- by a competent individual;
- on the basis of adequate information regarding the nature and foreseeable consequences of the research (as these are known at the time the request is made) and all available alternatives; and
- without undue or controlling influences such as 'force, fraud, deceit, duress, over-reaching, or other ulterior forms of constraint or coercion' (adapted from the *National Council of Bioethics in Human Research*).

“Minimal Risk Research”: 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.

“Research”: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

“Vulnerable Populations”: Individuals or groups where a power differential could operate to their disadvantage as participants (for example, students, minors, prisoners, employees, military personnel, disadvantaged minority groups, incapacitated people, individuals with cognitive impairments or intellectual disabilities, and the socially-deprived).

3. AUTHORITY

3.1 Related Acts and Regulations

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
B.C. Freedom of Information and Protection of Privacy Act

3.2 Related Policies

B3004 – Integrity in Scholarly Activity
B3005 – Conflict of Interest Related to Research
B3008 – Human Rights
B5001 – Access to Information

4. RELATIONSHIPS WITH COLLECTIVE AGREEMENTS

Langara Faculty Association Collective Agreement

5. GUIDELINES

5.1 Research subject to ethical review by the LREB:

5.1.1 Unless specifically excluded under Item 5.3 below, any research conducted within the jurisdiction or under the auspices of Langara College by faculty, staff, or students, regardless of where the research is conducted, that involves a) living human participants, or b) research on human biological materials and human embryos, fetuses, fetal tissue, reproductive materials and stem cells (this applies to materials derived from living and deceased individuals). Ethics review and approval is mandatory prior to the commencement of the research.

5.1.2 All student research that falls within 5.1.1 a) or b) that meets any of the following criteria:

- 5.1.2.1 Is not part of a course requirement;
- 5.1.2.2 Is part of a researcher's own research program, whether or not it is part of a course requirement.
- 5.1.2.3 Is part of a course requirement and is conducted solely for pedagogical purposes.
- 5.1.3 All research involving a) living human participants, or b) research on human biological materials and human embryos, fetuses, fetal tissue, reproductive materials and stem cells (this applies to materials derived from living and deceased individuals), or c) student research under 5.1.2 proposed by outside educational institutions/community agencies to be carried out at Langara College.
- 5.2 Student research that is conducted solely for pedagogical purposes under 5.1.2.3 shall be reviewed by the Chair of the LREB, or a member of the LREB delegated by the Chair, according to the procedures and requirements for Course Based Research Ethics Review under 6.7 and 8.6 below.
- 5.3 Research not subject to ethical review by the LREB. The following kinds of research are specifically exempted from the need for ethical review by the LREB.
 - 5.3.1 Research that relies exclusively on publicly available information when: (a) the information is legally accessible to the public and appropriately protected by law; or (b) the information is publicly accessible and there is no reasonable expectation of privacy.
 - 5.3.2 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.
 - 5.3.3 Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. ("Anonymous" means that the information or materials never had personal identifiers associated with them.)
 - 5.3.4 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements at Langara when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of LREB review. These include:
 - (a) Questionnaires concerning teaching performance or course content distributed to a class by instructors, Deans or others;
 - (b) Research conducted to meet external reporting requirements or to facilitate the management of the institution.

- 5.4 If data are collected for the purposes under 5.3.4 but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require LREB review in accordance with this policy. See *TCPS2* Section D of Chapter 5 for guidance concerning secondary use of identifiable information for research purposes.
- 5.5 Creative practice activities (i.e., processes through which an artist makes or interprets a work or works of art or studies the process of generating a work of art), in and of themselves, do not require LREB review. However, research that employs creative practice to obtain responses from individuals that will be analyzed to answer a research question is subject to LREB review.
- 5.6 If a researcher is uncertain whether contemplated research does or does not require approval under this policy, the researcher shall consult with the Chair of the LREB. See *TCPS2* Articles 2.22.6 and related discussion for clarification.

6 PROTOCOL FOR REVIEW

- 6.1 The LREB requires that an Application for Ethics Approval for Research Involving Humans as set out in Schedule “A” here be completed for all proposed research involving humans.
- 6.2 An Application for Ethics Approval for Research Involving Humans shall be submitted to the LREB which shall review the Form and proposal and make one of the following decisions:
- 6.2.1 **Approval** – A certificate of approval is issued and the research may begin (The LREB may include minor requests for information or suggestions with this approval), or
- 6.2.2 **Provisos** – Some concerns need to be addressed before approval can be given. The LREB may authorize its chair to issue a certificate of approval once the concerns have been satisfactorily addressed, or
- 6.2.3 **Preliminary Approval (to release funds to commence a project)** – Projects that require ethical review to obtain research funds with which to develop infrastructure for a research project involving humans or to develop a questionnaire or survey (etc.) may receive preliminary approval with the understanding that any part of the research dealing with humans cannot commence until the LREB has formally approved a final research proposal.
- 6.2.4 **Deferral** – Based on documentation provided the LREB is unable to make a final decision (this may involve concerns about fundamental ethical issues regarding the research, including basic concerns about methodology). The decision is deferred for later full board review at such time as the investigators submit the supplementary information or documentation as specified by the LREB, or
- 6.2.5 **Rejection.**

- 6.3. The Chair of the LREB will transmit, as quickly as possible, in writing to the researcher in charge a decision on the request for approval. Where approval is given, the statement is to identify the specific researcher and project approved and shall be in the form as set out in Schedule E attached hereto.
- 6.4. Delegated Review.
- 6.4.1 Full board review is the default requirement for research involving humans, however, an applicant may request from the Chair a delegated review for minimal risk research, and the Chair will consider the request based on the following aspects of the proposal:
- 6.4.1.1 Rationale
 - 6.4.1.2 Protection of participant confidentiality
 - 6.4.1.3 Vulnerable Populations
 - 6.4.1.4 Whether the research is minimal risk
- In the case of such delegated reviews, every effort will be made to transmit a decision within ten (10) working days.
- 6.4.2 Research involving waivers or alteration to elements of informed consent, including deception, shall not be eligible for delegated review.
- 6.4.3 Delegated review may also be permitted for minimal risk changes to approved research, annual renewal of approved minimal risk research, annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve recruitment of new participants, and the remaining activities are limited to data analysis.
- 6.4.4 Delegated review and approval can be provided by the Chair, or by another LREB member delegated by the chair or by an LREB subcommittee. Such review will be well-documented and reported to the full LREB.
- 6.4.5 Delegated reviewers retain the prerogative to refer any research proposal or matter related to their reviews to the full LREB for review or consideration.
- 6.5 All forms once completed and either approved or rejected will be submitted to and stored by the Office of the President. See 8.4.5 below.
- 6.6 Researchers shall maintain comprehensive records regarding their research, including documentation of all submissions to the LREB, for a minimum of five (5) years following completion of the research or termination of the research by the LREB, or as required by law, whichever is greater.
- 6.7 Guidelines for Course-Based Research Ethics Review Panels:
- 6.7.1 The Chair of the LREB or someone delegated by the Chair shall have the authority to conduct an ethical review of course-based research involving humans conducted solely for pedagogical purposes as per the procedures described in 8.6 below.

- 6.7.2 The Course-Based Research Ethics Review shall transmit, as quickly as possible and in writing, a decision on the status of an instructor's application for approval of students to conduct course-based research involving humans. Where approval is not given, the Review Panel shall provide written reasons to the instructor.
- 6.7.3 All forms and related documents for course-based research once submitted and either approved or rejected will be stored by the Office of the President.
- 6.7.4 The records related to Course-Based Research Ethics Review shall be stored by the Office of the President and be retained for a minimum of five (5) years after an application has been rejected or an instructor no longer teaches a course that is approved for course-based research involving humans, or as required by law, whichever is greater.

7 RIGHTS TO REVIEW AND APPEAL

- 7.1 Investigators submitting research proposals that are not approved have the right to request a review of a decision by the full membership of the LREB. Researchers may do so by submitting a letter in writing to the Chair of the LREB, providing a rationale for their request for review.
- 7.2 If a request for a review is unsuccessful in resolving the disagreement, the researcher has the right to a formal appeal of the LREB's decision. Upon application by a researcher for a formal appeal of an LREB decision, the President shall refer the matter to an appeal committee. The President may either refer the matter to an appeal committee at another institution or may establish a special Research Ethics Appeal Board to hear the appeal. In either case, no member of the LREB whose decision is being appealed may be a member of the Board that hears the appeal. If the matter is referred to another institution, that institution must have a Research Ethics Policy and Board whose operations are compliant with the Tri-Council Policy Statement and Langara must have a prior agreement in place with that institution to refer appeals under this policy. In either case, the decision of a properly constituted appeal Board shall be final.

8 RESEARCH ETHICS BOARD'S MANDATE AND RESPONSIBILITIES

- 8.1 The LREB has the responsibility to:
 - 8.1.1 Ensure that no research involving humans proceeds without prior ethical review and approval by the LREB, as described in 5.1 above.
 - 8.1.2 Consult with and provide feedback to the appropriate Dean regarding the on-going operation, of Course-Based Research Ethics Review as described in section 8.6.
 - 8.1.3 Review on an on-going basis for their ethical content all Langara College policies and procedures affecting research involving humans and report any issues requiring attention to the appropriate individual or body.
 - 8.1.4 Maintain a list of all active projects approved by the LREB.

- 8.1.5 Review, at its discretion, on-going projects according to the projects' schedules (through interviews, written updates from investigators, or other means) so that the LREB is assured that approved research is being conducted according to this policy. Ongoing research shall be subject to continuing review. The rigour of the review shall be in accordance with a proportionate approach to ethics assessment. As part of each research proposal submitted for LREB review, the researcher shall propose to the LREB the continuing review process deemed appropriate for that project. Normally, continuing review should consist of at least the submission of a succinct annual status report to the LREB. The LREB should be promptly notified when a project concludes.
 - 8.1.6 Maintain current copies of statutes, regulations, policies and guidelines pertaining to research involving human participants, and help relevant members of the College community to become familiar with them.
 - 8.1.7 Investigate reports of non-compliance with this policy and procedures or complaints of improper research involving human participants.
 - 8.1.8 Prepare, maintain and retain comprehensive records, including (but not limited to):
 - 8.1.8.1 Minutes of meetings, including a record of LREB members' attendance, deliberations and decisions,
 - 8.1.8.2 Copies of all applications for research approval and related documentation,
 - 8.1.8.3 Any notifications of changes to approved research,
 - 8.1.8.4 Written reasons regarding the acceptance or rejection of applications, and
 - 8.1.8.5 Records of investigation of complaints or reports of non-compliance with this policy and procedure.
 - 8.1.9 Promote awareness of the highest ethical standards in research involving humans throughout Langara College by meeting with Departments, instructors, staff, students and by promoting research ethics education at Langara College through offering workshops, symposia, public lectures, and other events.
- 8.2 LREB Membership
- 8.2.1 The LREB shall consist of at least five (5) members, including both men and women, who serve staggered two year renewable terms to maintain continuity and ensure diversity of background and expertise.
 - 8.2.2 All appointments are made by the President in consultation with the Chair of Education Council according to the following criteria:
 - 8.2.2.1 At least two (2) members who have broad expertise in the methods or areas of research covered by the LREB;
 - 8.2.2.2 At least one member who is knowledgeable in ethics
 - 8.2.2.3 For biomedical research, at least one member knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research;

8.2.2.4 At least one (1) community member who has no affiliation with Langara College drawn from the Langara College region.

8.2.3 The President in consultation with the Chair of the Education Council shall, on a bi-annual basis, appoint one (1) member of the LREB as Chair to serve a two year renewable term.

8.2.4 There shall be only one research ethics board established at Langara College.

8.3 Conflicts of Interest

8.3.1 The LREB shall adhere to the "conflict of interest" guidelines as outlined in Chapter 7 of *TCPS2* and as outlined in Langara College's Conflict of Interest Related to Research Policy.

8.3.2 Members of the LREB will disclose any actual, perceived or potential personal interest in research presented to the LREB and shall be absent during discussion or decision making when these proposals are reviewed.

8.3.3 The LREB will analyze disclosures of conflicts of interest and will ensure that researchers inform participants, including potential participants, during the free and informed consent process of any potential or real conflicts.

8.3.4 Conflicts of interest will be managed proportionately. Where conflicts are unavoidable the ethics review process will be more stringent.

8.3.5 Members of the LREB will not be present when their own research is reviewed. As well, they will disclose disputes, conflicts, or collaborations with researchers whose research is being reviewed, so that the LREB can make a determination as to whether they may participate in the review.

8.4 Authority, Independence, and Accountability

8.4.1 The LREB is established by, and is accountable, to the President of Langara College.

8.4.2 The LREB will provide to the President of Langara College, on an annual basis, a report which summarizes its activity for the year.

8.4.3 The LREB acts independently, and at arm's-length from the administration of Langara College, thereby maintaining its autonomy over ethical questions even when the institution has a strong interest in seeing a project approved.

8.4.4 The Office of the President, in consultation with the Chair of the LREB, shall appoint a "Research Ethics Administrator" who shall perform managerial and administrative support functions related to the operations of the LREB. The Research Ethics Administrator shall not be a voting member of the LREB but shall attend LREB meetings and act as its principal organizational resource person.

- 8.4.5 The records of the LREB shall be kept by the Office of the President which shall retain these records for a minimum of five (5) years or as required by law, whichever is greater. For records pertaining to specific research projects, these will be kept for a minimum of five (5) years following the following completion of the research or termination of the research by the LREB, or as required by law, whichever is greater.
 - 8.4.6 The Office of the President shall maintain records related to LREB membership, including qualifications of members and relevant research ethics training.
- 8.5 Meetings of the LREB, Quorum and Votes
- 8.5.1 The LREB shall establish and publish a schedule of meetings for each calendar year, including a schedule of deadlines for submissions to be considered at each meeting.
 - 8.5.2 The Chair of the LREB shall ensure that LREB members have at least two (2) day's notice of any meeting and that copies of all documents to be considered at the meeting are provided with the notice.
 - 8.5.3 A quorum of the LREB will be at least five (5) members. The quorum shall possess the range of expertise required by 8.2.2.
 - 8.5.4 The LREB's review of research proposals shall be based on detailed research proposals or, where applicable, progress reports.
 - 8.5.5 The LREB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions.
 - 8.5.6 Researchers have the right to request, and REBs have an obligation to provide prompt reconsideration of decisions affecting a research project. When the LREB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before reconsideration and making a final decision. (See TCPS2 Articles 6.19 – 6.20)
 - 8.5.7 Every effort will be made to reach a decision by consensus; only when necessary will decisions be made by a simple majority vote.
 - 8.5.8 All decisions will be recorded in the minutes.
 - 8.5.9 Every effort will be made to review proposals at face-to-face meetings. However, if necessary, the LREB may make decisions via a telephone or email vote organized by the Chair, provided that:
 - 8.5.9.1 The research to be reviewed is of minimal risk,
 - 8.5.9.2 Does not involve deception or vulnerable populations, or waiver or alteration to the elements of informed consent,
 - 8.5.9.3 The rule requiring two (2) day's notice is followed,
 - 8.5.9.4 All LREB members are sent copies of all the relevant documentation,
 - 8.5.9.5 All members vote, and
 - 8.5.9.6 There is no dissenting vote.

- 8.5.10 Decisions taken via a telephone or email should be noted on the agenda and included in the minutes of the next formal meeting.
 - 8.5.11 For purposes of clarification, the LREB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but shall not be present when the LREB is making its decision.
 - 8.5.12 Minutes of all LREB meetings shall be prepared and maintained by the Research Ethics Administrator or designate. The minutes shall clearly document the Committee's decisions and any dissents and the reasons for them. Minutes are accessible to authorized representatives of the institution.
 - 8.5.13 The LREB may consult ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. Such ad hoc advisors are not members of the LREB and are not entitled to vote on research proposals.
- 8.6 Procedures for Course-Based Research Ethics Review
- 8.6.1 An instructor wishing to offer a course that requires or permits students to participate in research involving humans solely for pedagogical purposes shall submit to the LREB Chair an application that includes the following information:
 - a) a description of the course;
 - b) the course syllabus;
 - c) a general description of the type(s) of research projects that are likely to be part of the course;
 - d) a description of the instructor's training and familiarity with research ethics;
 - e) the means by which the students in the course are made familiar with appropriate ethical standards, with copies of printed materials;
 - f) the means by which the students submit their research to the instructor;
 - g) the means by which students' research plans are assessed and approved by the instructor;
 - h) the means by which the conduct of the research is monitored by the instructor; and
 - i) any other relevant information.
 - 8.6.2 Where the Chair of the LREB or a member of the LREB delegated by the Chair is satisfied that a course involving research on human participants meets the standards established by this policy, he or she shall designate the instructor's course as a "Research Ethics-Approved Course." This designation shall be published on the LREB webpages and will remain in effect as long as the course description, general methods of teaching the course, and the instructor does not change. No re-application is necessary in these circumstances. The designation does not apply and re-application under the Course Based Research Ethics Review process is necessary where the general methods of teaching the course change, or types of research or research methodologies change that are taught within the course are different from those approved by the LREB Chair or delegate.

- 8.6.3 The LREB Chair or delegate shall only approve course-based research involving humans that involves minimal risk to participants.
- 8.6.4 Approval of course-based research involving humans is only given for student research that is conducted solely for pedagogical purposes. Any student research involving humans that is not conducted solely for pedagogical purposes, including research that contributes to an instructor's or any other researcher's research, must follow the protocol for LREB review set out in 6.1-6.6 above.
- 8.6.5 The LREB Chair or delegate and instructors responsible of overseeing course-based research involving humans shall carefully consider the safety of student researchers in addition to reviewing the ethical treatment of human participants within such research
- 8.6.6 The LREB Chair or delegate may consult with or refer any matter to the LREB to seek its advice.

8.7 Scholarly Review as Part of Ethics Review

- 8.7.1 The LREB 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.
- 8.7.2 The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.
- 8.7.3 Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the LREB to be peer reviewed.
- 8.7.4 Research that may have a negative effect on public figures in politics, business, labour, the arts, or other walks of life, or on organizations should not be blocked solely by the use of harms-benefits analysis or because of the potentially negative nature of the findings. See also Article 3.6 and the related discussion of "critical inquiry" in Chapter 3 of *TCPS2*.

8.8 Review of Multicentred Research

Langara College LREB is responsible for ethical acceptability of research undertaken within its jurisdiction. In case of any ethical concerns, Langara College's LREB may communicate these concerns and coordinate with other institutional REBs that will consider the project.

8.9 Review of Research in Other Jurisdictions or Countries

Research under the auspices of the LREB that is to be performed outside the jurisdiction of Langara College or outside Canada shall undergo prospective ethics review by both the LREB and by the appropriate local REB where such exists. The LREB shall satisfy itself that the requirements of this policy and *TCPS2* are met.

9. REQUIREMENT FOR FREE AND INFORMED CONSENT

- 9.1 Subject to exceptions noted in this policy, research governed by this policy may begin only if:
- prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation; and
 - their free and informed consent has been given and is maintained throughout their participation in the research.
- 9.2 Evidence of free and informed consent by the participant 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. The LREB 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 LREB 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 welfare of the participants;
 - (c) It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
 - (d) Whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with *TCPS2* Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with *TCPS2* Article 3.1; and
 - (e) The research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.
- 9.3 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.
- 9.4 Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.
- 9.5 Naturalistic Observation. LREB 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 LREB review since it can be expected that the participants are seeking public visibility. See section 5.3.2 above.

9.6 Informing Potential Participants.

- 9.6.1 Researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information necessary for making a free and informed decision to participate in a research project.. 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 exceptions noted in this policy, 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 statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
 - (c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
 - (d) an assurance that prospective participants:
 - are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
 - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
 - will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
 - (e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
 - (f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
 - (g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
 - (h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
 - (i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see *TCPS2* Article 5.2), a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

- (j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- (k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
- (l) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

9.6.2 Following consent, participants must be presented with new information, including incidental findings from the research, that may affect their willingness to continue in the study.

9.7 Subject to applicable legal requirements, the LREB shall ensure that individuals who are not legally competent shall only be asked to become research participants when, as a minimum, the following conditions are met:

- (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 to 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.

9.8 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. Regardless of the individual's ability to understand the significance of the research, dissent must always be respected where participation in the research has no prospect of direct benefit to the participant.

9.9 The principles of informed consent can be found in *TCPS2, Chapter 3*. In general, research is viewed as a partnership between the researcher and the research participants.

10 SPECIAL CONSIDERATIONS

10.1 Research involving Individuals or Groups in Vulnerable Circumstances

- 10.1.1 Special measures may need to be adopted to ensure informed, voluntary consent of vulnerable individuals or groups participating in research. In particular, researchers must be alert to the potential for undue influence affecting their decisions to participate, or continue to participate, in research (e.g., false or unrealistic hopes of benefit from participating in research, coercive threats or undue inducements made by others to encourage participation in research, the influence of power relationships including relations between employers and employees, teachers and students, commanding officers and members of the military, or correctional officers and prisoners).
- 10.1.2 Individuals or groups whose circumstances make them vulnerable may require special measures to ensure their safety in the context of research.
- 10.1.3 Vulnerable individuals and groups shall not be inappropriately or automatically excluded from participation in research on the basis of their circumstances.
- 10.1.4 The assent/dissent of incompetent individuals in vulnerable circumstances must be carefully monitored. See section 9.8.

10.2 Research involving Children

- 10.2.1 Informed consent of the parent or guardians of the child must normally be obtained before using minors in research. In school, camps or other group settings, consent of the Principal, Director and/or other appropriate authority must also be obtained.
- 10.2.2 Children must be individually given the opportunity to refuse to participate or to withdraw. See section 9.8.

10.3 Research involving Indigenous People and other Cultures and Ethnic Groups

- 10.3.1 Research involving individuals and/or communities in culture(s) and ethnic group(s) require careful consideration. Researchers should explain that they have come to learn about their way of life, languages, customs and beliefs, and must be respectful of differences at all times. Permission/approval by a community(ies)/group(s) may be necessary. See *TCPS2*, Chapter 9, "Research Involving the First Nations, Inuit, and Metis Peoples of Canada" and in particular the discussion in Section C of the "Requirement of Community Engagement in Aboriginal Research." Other research policies may also be helpful. See, for example, *Ownership, Control, Access and Possession* (National Aboriginal Health Organization, 2007).
- 10.3.2. When researchers outside their own culture are operating from a position of advantage, they have particular responsibility to research participants. There is a responsibility that research participants shall not be exposed to legal sanctions, ridicule or danger. Also, there is a responsibility to portray customs sensitively.

- 10.3.3 A communication gap may make informed consent impossible, as the people under study may be unable to estimate the risks to their reputations, or potential damage to their descendants. Absence of informed consent places additional responsibility and restrictions on researchers. Researchers must satisfy the review concerning these safeguards in the methodology.
- 10.4 Deception in Research
 - 10.4.1 Deception is not permitted when the risk of harm to the participant is greater than minimal risk or when it is not possible to advise participants subsequently as to the reasons why the deception was necessary.
 - 10.4.2 Deception should only be used when significant scientific advance could result and no other methodology would suffice.
 - 10.4.3 Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value and determine whether alternative procedures are available that do not use concealment or deception; and also ensure that the participants are provided with sufficient explanation as soon as possible.
 - 10.4.4 After the data are collected, the investigator shall provide the participant with information about the nature of the study, offer an opportunity to discuss the deception with the participant, and attempt to remove any misconceptions that may have arisen and to re-establish any trust that may have been lost. Participants must be informed that they may contact the LREB if they have any concerns about the use of deception. Where scientific or humane values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.
- 10.5 Critical Inquiry
 - 10.5.1 Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation. See *TCPS2* Article 3.6 and the related discussion of "critical inquiry."

11 RESEARCH IN EMERGENCY HEALTH SITUATIONS

Participant to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the LREB. The LREB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

- (a) a serious threat to the prospective participant requires immediate intervention;
- (b) either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
- (c) either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
- (d) the prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
- (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.

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

12 **REVIEW OF POLICY**

This policy shall be reviewed two years after the appointment of the initial members to the LREB and at least once every five (5) years thereafter.

APPENDIX A

**Application for Ethics Approval for Research Involving
Humans**

Instructions:

1. Download this application and complete it on your computer. Hand written applications will not be accepted.
2. Please refer to the appropriate college policies before completing this application.
3. Submit the original and one (1) copy of this completed, signed application with all attachments to: Chair, Langara College Research Ethics Board, c/o Office of the President.
4. If you require assistance, contact the LREB Chair.
5. Incomplete applications cannot be processed and will be returned to the applicant.

A. Principal Investigator

There can be only one local Principal Investigator. For co-investigator and other research team members, provide their name(s) and contact information below in Section B, Other Investigator(s) & Research Team.

Last Name: _____ First Name: _____

Department/Faculty: _____ Email: _____

Phone: _____ Fax: _____

Mailing Address: _____

Title/Position: _____

B. Project Information

Project Title: _____

Anticipated Start Date: _____ Anticipated End Date: _____

Geographic location(s) of study: _____

Keywords: 1. _____ 2. _____ 3. _____ 4. _____

For Research Ethics Board use	Application No.	
Research Ethics Board Chair Approval:	Date:	
Start Date:	Expiry date:	File closed:

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Other Investigator(s) and Research Team:

(Include co-investigators, students, employees, volunteers, community organizations).

Contact Name	Role in Research Project	Institutional Affiliation	Email or Phone

C. [Agreement and Signatures](#)

Principal Investigator affirms that:

- *I have read this application and it is complete and/ accurate.*
- *The research will be conducted in accordance with Langara College regulations, policies and procedures governing the ethical conduct of research involving humans.*
- *The conduct of the research will not commence until ethics approval has been granted.*
- *The researcher(s) will seek further LREB review for any changes to the approved research.*
- *Adequate supervision will be provided for students and/or staff.*

Principal Investigator

Signature

Print Name

Date

Dean

I affirm that adequate research infrastructure is available for the conduct and completion of this research and that the researchers are qualified to conduct the research.

Signature

Print Name

Date

D. [Project Funding](#)

Have you applied for funding for this project? Yes No

Has notice of award been received? Yes No

If yes to either, please complete the following:

Source(s) of Project Funding	Project Title used in Funding Application(s)

Will this project receive funding from US Funders (e.g. NIH)? Yes No

If yes, provide further information:

E. [Level of Risk](#)

For the purposes of this Policy, “minimal risk” research is defined 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. (TCPS2, p. 23)

Based on this definition, do you believe your research qualifies as “minimal risk” research?

Yes No

Explain your answer by referring to the level of risk stated in the TCPS2 definition above:

F. [Scholarly Review](#)

What type of scholarly review has this research project undergone?

- External Peer Review (*please attach a copy of external peer review*)
 - Supervisory Committee or Supervisor
 - None
 - Other, please explain:
-

G. Other Approvals

Do you need to seek approval from other agencies, community groups, local governments, Aboriginal communities etc.?

Yes No

(Please attach proof of having made a request for permission and any approval letter already received. Please forward further approvals upon receiving them.)

H. Description of Research Project

1. Purpose and Rationale of Research

Briefly describe in lay language suitable for review by non-scientific LREB members:

(Please use 150 words or less.)

1a. The research purpose and objective(s) *(please attach a copy protocol)*

1b. The importance and anticipated contributions of the research

I. Recruitment

1 Recruitment and Selection of Participants

1a. Inclusion Criteria: Briefly describe the target population(s) for recruitment. Ensure that all participant groups are identified *(e.g. group 1 - teachers, group 2 - administrators, group 3 – parents)*.

1b. Why is this population of interest?

1c. What is the expected number of participants? (For multi-site studies, include total number of participants and the number of participants that are expected to be recruited locally.)

1d: Exclusion criteria: Describe which participants will be excluded from participation, and explain the criteria for their exclusion.

1e. Provide a detailed description of your exact recruitment process. Explain:

i) Who will recruit/contact participants (*e.g. researcher, assistant, third party*)

ii) Describe any relationship between the investigator(s) and participants(s) (*e.g. instructor-student, manager-employee*). Complete item 3 if there is a [power over relationship](#).

iii) Describe how recruitment will be conducted (*e.g. in person, by telephone, letter, snowball sampling, word of mouth, advertisement*) and from what source(s) will the participants be recruited. If applicable, include how contact information for participants will be obtained. (Note that “cold-calling” is not normally permitted).

iv) Describe the steps in the recruitment process, including how participants will be consenting.

v)

Recruitment Materials Checklist:

As applicable, attach all documents referenced in this section (*check those that are appended*):

Script(s) – in-person, telephone, 3rd party, e-mail, etc.

Invitation to participate

Advertisement, Poster, Flyer

2 Power-Over

Are you or any of your co-researchers in any way in a position of authority or power over participants? Examples of a “power-over” situation include teachers-students, therapists-clients, supervisors-employees and possibly researcher-relative or researcher-close friend.

Yes No Varies

If *yes* or *varies*, describe below:

The nature of the relationship.

- i) Why it is necessary to conduct research with participants over whom you have power.
- ii) What safeguards (steps) will be taken to minimize undue influence ,coercion or potential harm.
- iii) How the dual-role relationship and the safeguards will be explained to potential participants.

J. Data Collection Methods

1. Data Collection

1a. Which of the following methods will be used to collect data? (*Check all that apply.*)

<input type="checkbox"/> Interviewing participants: <input type="checkbox"/> in-person <input type="checkbox"/> by telephone <input type="checkbox"/> using web-based technology (explain) <input type="checkbox"/> Conducting group interviews or discussions (including focus groups) <input type="checkbox"/> Other, describe Attach draft review questions.	
<input type="checkbox"/> Administering a questionnaire or survey: <input type="checkbox"/> In person <input type="checkbox"/> by telephone <input type="checkbox"/> mail back <input type="checkbox"/> email <input type="checkbox"/> web-based <input type="checkbox"/> Other, describe:	<input type="checkbox"/> Attach questionnaire or survey: <input type="checkbox"/> standardized (one with established reliability and validity) <input type="checkbox"/> non-standardized (one that is untested, adapted or open-ended)
<input type="checkbox"/> Administering a computerized task (<i>describe in 1b</i>)	
<input type="checkbox"/> Observing participants <i>{In 1b, describe who and what will be observed. Include where observations will take place.}</i>	
<input type="checkbox"/> Recording of participants using: <input type="checkbox"/> audio <input type="checkbox"/> video <input type="checkbox"/> photos or slides	Will images be used in disseminating results? <input type="checkbox"/> Yes (<i>If yes, please include release to use participant images in consent materials.</i>) <input type="checkbox"/> No
Analyzing secondary data or secondary use of data (Refers to information/data that was originally gathered for a purpose other than the proposed research and is now being considered for use in research., <i>e.g. patient or school records, personal writings, lesson plans</i>). <input type="checkbox"/> Secondary data involving anonymized information (Information/data is stripped of identifiers by another researcher or institution before being shared with the applicant; information/data is only anonymous if it cannot be re-linked to participants). <input type="checkbox"/> Secondary data with identifying information (Data contains names and other information that can be linked to individuals, <i>e.g., student report cards, employment records, meeting minutes, personal writings</i>). <i>In item 1b describe the source of the data, and explain whether and how consent was obtained from the individuals for use of their data.</i>	
<input type="checkbox"/> Using human samples (<i>e.g., saliva, urine, blood, hair</i>) <i>Ensure that you comply with Biosafety regulations regarding the storage and use of biological materials. Please consult the Conflict of Interest Policy B3005, Section 2.6.</i>	
<input type="checkbox"/> Other , specify:	

1b. Provide a sequential description of the procedures/methods to be used in your research study. List all of the research instruments and assessment tools, and in an appendix provide copies of all instruments. If not yet available, provide drafts or sample items/questions. For multi-method or other complex research, use the following sections in ways best suited to explain your project.

1c. Where will participation take place? (Provide specific location, *e.g.*, *Langara classroom, private residence, participant's workplace.*)

1d. How much time will be required of participants?

Data Collection Methods Checklist:

As applicable, attach all documents referenced in this section (*check those that are appended*):

- Standardized Instrument(s)
- Survey(s), Questionnaire(s)
- Interview and/or Focus Group Questions
- Observation Tools

K. Possible Inconveniences, Discomforts, Benefits, Risks and Harms to Participants

1. Benefits

Identify any potential or known benefits associated with participation and explain below. *Keep in mind that the anticipated benefits should outweigh any potential risks.*

- To the participant To society To state of knowledge

2. Inconveniences

Identify and describe any known or potential inconveniences to participants:
Consider all potential inconveniences, including time devoted to the research.

3. Estimate of Risks, including Discomforts, Physical, Psychological, Economic or Social Risks. (These risks can include such things as embarrassment, fatigue, stigmatization, and loss of status or privacy)

3a. What are the risks?

3b. What will you do to try to minimize or prevent the risks?

3c. How will you respond if the risk of harm occurs? (*e.g. what is your plan?*)

L. Compensation and Remuneration

1. Compensation

1a: Is there any compensation for participating in the research (*e.g. reimbursement for transportation, parking, childcare, etc.*)?

Yes No

1b: Is there any remuneration (i.e. payment for time and effort) for participating in the research (e.g. gifts, honoraria, bonus points)

Yes No

If yes, explain the nature of the remuneration and why you consider it to be necessary:

1b. Explain what will happen to compensation and/or remuneration if participants withdraw during or any time after data collection (*e.g. compensation and/or remuneration must be pro-rated, full compensation/remuneration will be given, etc.*).

M. Free and Informed Consent

The following questions address the competence of participants to give consent, the process used in your research to obtain consent, ongoing consent, and the participants' right to withdraw.

1. Participant's Capacity (Competence) to Provide Free and Informed Consent

Identify your prospective participants: (Check all that apply.)

Competent	Non-Competent
<input type="checkbox"/> Competent adults <input type="checkbox"/> A vulnerable population (e.g. Inmates, children)	<input type="checkbox"/> Non-competent adults: <input type="checkbox"/> Consent of legally authorized representative will be obtained <input type="checkbox"/> Assent of the participant will be obtained
<input type="checkbox"/> Competent youth <input type="checkbox"/> Youth 13 to 18 (incl.): consent of youth will be obtained, and parental agreement will be sought <input type="checkbox"/> Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will be sought <input type="checkbox"/> Youth 13 to 15 (incl.): consent of youth will be obtained, and parental agreement will NOT be sought <input type="checkbox"/> Youth 16 to 18 (incl.): consent of youth will be obtained, and parental agreement will NOT be sought	<input type="checkbox"/> Non-competent youth 13-18 (incl.): <input type="checkbox"/> Consent of parent/guardian will be obtained <input type="checkbox"/> Assent of the youth will be obtained
<input type="checkbox"/> Competent children <input type="checkbox"/> Children under 13: consent of child will be obtained, and parent/guardian agreement will be obtained <input type="checkbox"/> Other, explain:	<input type="checkbox"/> Non-competent children under 13: <input type="checkbox"/> Consent of parent/guardian <input type="checkbox"/> Assent of the child will be obtained

2. Informed Consent

2a If you are requesting a waiver or alteration (e.g. deception) to Informed Consent, describe how your research complies with TCPS2 Article 3.7 and 3.8.

2b Describe the exact steps you will follow in the process of explaining and obtaining informed consent.

3. Means of Obtaining Consent:

(Check all that apply, attach copies of all consent materials.)

- Signed** consent. *(Attach consent script(s) and consent form(s).)*
- Verbal** consent. *(Attach information letter(s). Explain below why written consent is not appropriate and how verbal consent will be documented.)*
- Implied** consent *(e.g. anonymous, mail back or web-based survey. Attach information letter.)*
- Other** means. Specify.

Consent **will not be obtained**.

4. Ongoing Consent

Ongoing consent is required for research that occurs over multiple occasions and/or multiple research activities and or extended periods of time (i.e., more than one point of contact, including second interviews, review of transcripts, etc.)

4a. Will your research occur over multiple occasions or an extended period of time?

- Yes No

4b. If yes, describe how you will obtain ongoing consent:

5. Participant's Right to Withdraw

Free and informed consent requires that participants have the right to withdraw at any time without consequence or explanation.

Describe what participants will be told about their right to withdraw from the research at any time.

6. What will happen to the person's data if s/he withdraws part way through the study?

Free and Informed Consent Checklist:

As applicable, attach all documents referenced in this section (*check those that are appended*):

- Consent Form(s) – Include forms for all participant groups and data gathering methods
- Letter(s) of Information for Implied Consent
- Verbal Consent Script

N. Anonymity and Confidentiality

1. Anonymity

Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual participants.

1a. Will the participants be anonymous in the data gathering phase of research?

- Yes No

1b. Will the participants be anonymous in the dissemination of results (*e.g. use of video, photos*)?

- Yes No

2. Confidentiality

*Confidentiality means the protection of the person's identity and the protection, access, control and security of his or her data and personal information during the recruitment, data collection, reporting of findings, dissemination of data (if relevant) and after the study is completed (*e.g., storage, destruction*).*

2a. Will the confidentiality of the participants and their data be protected?

- Yes, completely (no exceptions, legal or otherwise)
 Yes, with limits (*Check relevant boxes below.*)

- Limits due to the nature of group activities (*e.g. focus groups*) the researcher cannot guarantee confidentiality
- Limits due to context: The nature or size of the sample from which participants are drawn makes it possible to identify individual participants (*e.g. school principals in a small town*)
- Limits due to selection: The procedures for recruiting or selecting participants may compromise the confidentiality of participants (*e.g. participants are identified or referred to the study by a person outside the research team*)
- Limits due to legal requirements for reporting
- Other:

No - If confidentiality will not be protected, explain why. If you are asking the participants to waive their right to confidentiality (you plan to identify them with their data), explain what steps will be taken to respect their privacy, if any.

2b. If confidentiality will be protected, describe the procedures to be used to protect the identity of participants and for preserving the confidentiality of their data (*e.g. assignment of unique study numbers to participants, use of pseudonyms, changing identifying information and features, coding sheet, use of master lists linking participants to coded research data forms, etc*).

2c. If there are limits to confidentiality due to the methods (*e.g. group interview*), sample size or legal requirements (*e.g. reporting child abuse*) so that you cannot guarantee confidentiality, explain what the limits are and how you will disclose them to the participants:

O. Use and Disposal of Data

1. Use(s) of Data

1a. How will all the data be used to support the research objectives?

1b. Will your research data be analyzed, now or in future, by yourself for purposes other than this research project?

Yes No Possibly

1c. If yes or possibly, how will you obtain consent for future data analysis from the participants (*e.g. request future use in current consent form*)?

1d. Will your research data be analyzed, now or in future, by other persons for purposes other than explained in this application?

Yes No Possibly

1e. If yes or possibly, by whom and how will you obtain consent from the participants for future data analysis by other researchers (*e.g. request future use in current consent form*)?

2. Commercial Purposes

2a. Do you anticipate that this research will be used for a commercial purpose?

- Yes No

2b. If yes, explain how the data will be used for a commercial purpose:

3. Maintenance and Disposal of Data

Describe your plans for preserving, protecting and destroying all the types of data associated with the research (*e.g. paper records, audio or visual recordings, electronic recordings, coded data, master lists*) after the research is completed:

3a. means of storing data (*e.g., a locked filing cabinet, password protected computer files*):

3b. location of storing data:

3c. duration of data storage (if data will be kept indefinitely, explain):

3d. methods of destroying or archiving data:

4. Dissemination

How do you anticipate disseminating the research results? (*Check all that apply*)

- | | |
|--|---|
| <input type="checkbox"/> Directly to participants | <input type="checkbox"/> Thesis/Dissertation/Class presentation |
| <input type="checkbox"/> Presentations at scholarly meetings | <input type="checkbox"/> Published article, chapter or book |
| <input type="checkbox"/> Internet | <input type="checkbox"/> Media (<i>e.g. newspaper, radio, TV</i>) |
| <input type="checkbox"/> Other, explain: | |

P. Researchers

1. Conflict of Interest

1a. Are you or any of the research team members in a perceived, actual or potential conflict of interest in regard to this research project (*e.g. in relation to participants, partners in research, private interests in companies or other entities*)? (See Policy B3005: Conflict of Interest Related to Research.)

Yes No

1b. If yes, please provide details of the conflict and how you will manage it:

2. Researcher(s) Qualifications

In light of your research methods, the nature of the research and the characteristics of the participants, what training or qualifications do you and/or your research team have?

3. Risk to Researcher(s)

3a. Does this research study pose any risks to the researchers, assistants and data collectors?

3b. If there are any risks, explain the nature of the risks, how they will be minimized, and how they will be responded to if they occur.

Q. Further or Special Questions

1. Multiple Site Research

1a. Does this project involve collection of data at multiple sites within Canada requiring the approval of other sites, bodies or organizations (*e.g., other ethics board(s)*)?

Yes No

1b. If you responded Yes to 1a. above, list the sites, bodies or organizations:

2. International Research

2a. Will this study be conducted in a country other than Canada?

Yes No

2b. If yes, describe how the laws, customs and regulations of the host country will be addressed:

3. Other Information

If there is anything else you would like to inform the LREB about this study, provide the details below:

Attachments*

*Ensure that all applicable attachments are included with all copies of your application.

Incomplete applications will not be processed and will be returned to the applicant.

As applicable, label and attach the following documents (check those that are appended):

Section I - Recruitment Materials:

- Script(s) – in-person, telephone, 3rd party, e-mail, etc.
- Invitation to participate
- Advertisement, Poster, Flyer

Section J - Data Collection Methods:

- Standardized Instrument(s)
- Survey(s), Questionnaire(s)
- Interview and/or Focus Group Questions
- Observation Tools

Section M - Free and Informed Consent:

- Consent Form(s) – Include forms for all participant groups and data gathering methods
- Letter(s) of Information (including for Implied Consent)
- Verbal Consent Script

Other documents

- Approval from external organizations (or proof of having made a request for permission)
- Permission to gain access to confidential documents or materials
- Copies of external peer reviews
- Copies of protocol
- Human Tissues form
- Other, please describe: