**GUIDELINES FOR APPLICANTS**

**Purpose of Guidelines**

This document provides guidance for individuals preparing applications for review by the Lethbridge College (LC) Research Ethics Board (REB) for ethical review of research studies involving humans.

**Role of the REB Committee**

The REB reviews ethics applications to ensure that research studies meet the highest ethical standards of research involving humans, in accordance with Lethbridge College’s Research Involving Humans Policy and the Tri-Council Policy Statement (TCPS2 2014)

[http://www.lethbridgecollege.ca/sites/defLClt/files/imce/policies\_procedures/Research\_%26\_Copyright/research-involving-human-participants-policy.pdf](http://www.lethbridgecollege.ca/sites/default/files/imce/policies_procedures/Research_%26_Copyright/research-involving-human-participants-policy.pdf)

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

**Provincial/Federal Acts**

Research may be affected by provincial/federal Acts respecting freedom of information and protection of privacy and electronic communications. Researchers should familiarize themselves with the following legislation:

1Alberta *Freedom of Information and Protection of Privacy Act (FOIPP)*, available at: <http://www.qp.alberta.ca/1266.cfm?page=F25.cfm&leg_type=Acts&isbncln=9780779743568&display=htm>

2) Canada’s *Anti-Spam Legislation (CASL)*, available at:

<http://laws-lois.justice.gc.ca/eng/acts/E-1.6/index.html>

3) Alberta *Health Information Act (HIA)*, available at:

<http://www.qp.alberta.ca/570.cfm?frm_isbn=9780779777365&search_by=link>

For new Investigators, research assistants and student research assistants: please complete the *Tri-Council Policy Statement (TCPS2) Tutorial* and include the certificate with your submission. Follow this link to begin. <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

Send your submissions for REB review to the Operations Coordinator: appliedresearch@lethbridgecollege.ca or Christine.picken@lethbridgecollege.ca

**Levels of Review**

There are three levels of review:

|  |  |  |
| --- | --- | --- |
| Level 1: | Full REB Review  | • External advice and expertise may be solicited |
| Level 2:  | Delegated Review  • Chair Review | • Supplementary information to proposals that have been identified as requiring revision following full REB review is considered by the Chair. • Reviews of Modification Requests • Requests for Ethics Approval Renewal • Emergency review of minimal risk studies • Applications for Ethics Exemption  |
| Level 3:  | Delegated Review • Chair Review  | • Expedited review of minimal risk student-researcher studies  |

**Research Studies that Require REB Review**

All research studies involving humans, with the exception of the exclusions listed below, conducted by members of the college community or by external researchers who use LC resources or recruit participants from LC, must receive prior written approval from the LC Research Ethics Board (REB).

The ‘college community’ comprises all LC faculty, staff, research assistants, students and visiting researchers. Approval is required irrespective of the source of financial support (if any), and irrespective of the location of the research study (in the latter case, as long as the investigator represents the work as LC research).

Review is available normally only to members of the LC research community, researchers in formal collaboration with LC members, or for research conducted at or under the auspices of LC by external researchers.

**Exclusions (subject to FOIPP)**:

The following types of research do not require REB review; however they are subject to Alberta legislation (FOIPP) as noted earlier.

1) Research about living individuals in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials of third-party interviews. Such research requires review by the REB only if the subject is approached directly for interviews or for access to private papers;

2) Course evaluations; and

3) Quality assurance studies, performance reviews or testing within normal educational requirements. However, performance reviews or studies that contain an element of research in addition to assessment may need ethics review.

**Exclusions (excluded under FOIPP)**:

The following type of research does not require REB review and is excluded under the FOIPP Act:

1) Research undertaken by members of the college community under their own auspices, or under the auspices of another institution, and not under the auspices of LC.

2) REB review is normally required for research involving naturalistic observation. However, observation of individuals in public places where there is no reasonable expectation of privacy (e.g. at a political rally, public meeting, demonstration) should not require REB review, since it can be expected that the participants are seeking public visibility.

**Student Research:**

*Research Studies*

A student must, at the planning stage, discuss his or her research study with the supervisor. As the supervisor oversees the research study, he/she is responsible for reviewing the student’s application and indicating their support/approval before the student submits the application for ethics review. The supervisor is copied on all correspondence relating to their students’ applications.

*Course Assignments*

The instructor, in the case of course-based research, holds primary responsibility for the ethics review application and for student adherence to ethical treatment of human participants; the student holds secondary responsibility.

**Please submit an electronic copy of the following documents (if applicable), two weeks prior to the REB meeting:**

* *General Protocol Review Form (1 signed original)* – including any study materials given or seen by subjects (e.g. information letters, surveys, advertisements, consent form)
* *Consent Form* **-** should be in its final form, including LC letterhead
* *Study Protocol* (including data collection forms)

**APPLICATIONS will be reviewed on the basis of a minimum of the following criteria**

Personnel Information

The Principal Investigator (PI) is the responsible leader of the research team and must be clearly designated. Usually there is one PI per protocol. Please list Other Investigators participating in the research.

Funding

If no funding is involved for this study, describe how the research will be supported.

If the study is SSHRC funded, indicate how you will meet the SSHRC Archiving Policy requirements

Project Details

*Research Summary:*Please ensure that the abstract, rationale and hypothesis/research question are written in lay language; the submission should be understandable to those outside your area of expertise.

*Purpose & Objectives*

The purpose of the study, research question(s) to be answered, etc.

*Research Design / Research Method*

Example: exploratory, descriptive, experimental, quasi-experimental, survey, grounded theory, phenomenology, focus group, ethnography, case study, etc.

Describe the basic study design and method. If this is a randomized trial, explain how subjects will be assigned to each group. If this is a pilot study, indicate briefly how the data will be used to develop a full follow up study.

*Source of research participants*

Selection of subjects must be equitable. Please include the rationale for the choice of control group if applicable. If a population experiencing vulnerable circumstances is used (e.g., children, incompetent adults), please include justification for this choice (e.g., has the research question been previously addressed in a less vulnerable population?). Justification is not required at institutions where these vulnerable populations are the primary population (e.g., geriatric centres). If a group (e.g, women of childbearing potential, the elderly) is excluded from a study involving a general patient population, this should be justified.

*Sample Size Justification*

For quantitative studies, include sample size calculations and source for standard deviation. For qualitative studies indicate approximate sample size and rationale. You may refer to the protocol for this information.

Health Records include but are not limited to: slides (e.g. pathology), radiology films/reports, surgical lists and databases.

The REB must review all study-related materials that will be given to subjects, including advertisements or letters regarding recruitment. Please note that no specific dollar amount of payments to subjects should be listed in the advertisement.

*Data Collection Techniques*

Example, questionnaire, interview, performance videotape, field notes, pictures; structured, semi-structured, open-ended, etc. Research instruments (questionnaires, interview guides, rating scales, etc.) must be uploaded with the application.

*Method of Analysis*

Example: content, statistical, textual, grounded theory, etc.

Explain what methods will be used to analyse the study data. You may refer to the protocol.

*Primary outcome measures*

Please list the primary endpoints, or key data items that are required to answer the study question.

Recruitment and Informed Consent

The REB recognizes that the procedures for obtaining informed consent may differ from research study to research study. Participants must be given enough time to think about the information before consent is collected. The information may be included in a recruitment instrument, a script, or an informed consent letter.

A copy of each recruitment aid, information letter, script, informed consent letter, etc. must be uploaded to the application.

Indicate who will make the initial contact and who will conduct the informed consent discussion. Issues to consider include whether the contact person is known to the subject/authorized third party, has access to subject information as part of their normal professional duties, or is able to assess capacity to consent. Consideration will be given as to whether the person approaching the prospective subjects has any relationship with them that might make them feel pressured or coerced into participating (e.g. is this person their physician or employer or teacher?).

Under normal circumstances, participants must sign a letter or form to indicate their consent to participate based upon their consideration of the information the researcher has told them about the research study. A statement may be included, such as *“I have read and understood the information contained in this letter, and I agree to participate in the study, on the understanding that I may refuse to answer certain questions, and I may withdraw at any time during the data collection period.”*

*Parental/Guardian Consent*

May be gathered for legally incompetent participants or those under 18 years of age; however, the assent of the individual participant must also always be sought and maintained. Individual information and consent documents or scripts should be worded at the appropriate comprehension levels for the parent/guardian and the research participant.

*Non-written Consent*

When situations warrant, consent may be gathered in other ways than writing. In these cases, provide the script and description of other method that will be used for gathering and recording non-written consent.

*Deemed Consent*

Deemed Consent is often employed for online surveys or other types of anonymous questionnaires. To maintain anonymity, it is not appropriate to request someone to sign a consent form. Therefore, a statement such as *“You are giving your consent to participate in this study when you [press submit] or [return the questionnaire/survey]”* should be included somewhere in the instructions at the front and back of the instrument.

If enrollment of persons who may have problems with the standard process of informed consent is expected, please indicate what special procedures will be followed to protect subject interests and promote subject autonomy. For subjects whose capacity may change during the research period, please describe what plans are in place to regularly assess capacity. Please also refer to the separate informed consent instructions for more detail regarding informed consent requirements.

*Anonymity for participants*

Please specify how potential subjects will be identified and by whom. Respect for subject privacy requires that subject records be reviewed by persons who have access to subject information as part of their normal professional duties, or their delegates (e.g. study coordinator working on behalf of investigator who has access).

Storage, Retention, and Disposition of Data

Details on how and where data in various formats will be stored, who will have access to the data, when the data will be destroyed (month/year) and how the data will be destroyed.

Study data and samples must be kept secure from theft, interception, unauthorized reading and copying. Investigators must state their means of protecting study data or samples from such violation, for instance by coding systems and/or security systems.

Access to existing records for research purposes may involve a variety of data stewards or custodians. These different custodians may have different policies regarding access to records. Indicate the source of any records that will be used, and the requirements for access.

Provide detailed information about where and how data will be stored, whether it is computerized or hard copy, and who will have access to the data. Information about web-based applications must be provided. Indicate provisions made to protect confidentiality during long-term storage (e.g. after study completion).

If any secondary use of the data or future necessity to contact participants is anticipated (e.g. for any purposes outside completion of the present research study) it is advisable to word the consent documents in such a way as to facilitate such future actions. Secondary use will require further REB approval, if a later study is designed

Identify any agencies or individuals who will have access to data from this research study, or the report, now or in the future (e.g. employer, service provider, etc.). Indicate how the raw, confidential data from this study will be guarded against any misuse by any third party (e.g. employer).

If there is an absence of retention guidelines within the professional research practice of the applicant’s discipline, the REB suggests a minimum of five years. Be specific by considering encryption mechanisms, locked filing cabinets, password protections on computer equipment, etc.

Concealment of hypothesis

The Tri-Council Policy Statement (TCPS) permits the REB to approve a consent procedure which does not include, or which alters some information about the study only when the deception or lack of disclosure poses no more than minimal risk, the research could not practicably be carried out in another way, the subjects are provided with full disclosure at a later date (where possible) and the deception or lack of disclosure does not involve a therapeutic intervention. Deception or lack of disclosure is used most often in social science or psychology research, where full disclosure would likely affect the responses of the subjects and thus invalidate the research. A debriefing should include:

* clear statement of the research question
* disclosure of any deception involved in the study and the rationale for its use
* explanation of how the participants' data will be used to seek an answer to the question
* opportunity for participants to ask questions and/or seek clarification
* contact information for the researcher and the REB that approved the study

Risk/Benefit Estimates

It is the expectation of the Tri-Council Policy Statement that proposed research will be designed to benefit participants where possible. Studies that involve significant risk without a balance of significant benefit may be inappropriate.

*Potential Harms*

Please describe all risks associated with the study interventions and the likelihood of these events occurring. If there are no known risks, please indicate this.

*Criteria for Early Withdrawal*

Please indicate what endpoints or stopping rules will serve as triggers/thresholds for early withdrawal for subject safety (e.g. regarding treatment failure/adverse events).

Publication/Dissemination of Results

Since the contribution to knowledge is one of the primary purposes of research, researchers are encouraged to publish the results of their research. Furthermore, where possible, researchers are strongly encouraged to share the study results of the research with the subjects who made the research possible, and/or with the relevant subject communities.

Describe how and where results of the research study will be disseminated and whether or how they will be made available to interested participants.

If there is a likelihood that reportable information may arise during the research study, the following sentence must be included in all information letters where mandatory reporting would be applicable (e.g. protected populations, revelation of illegal or heinous act): *“All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported.”*

Conflicts of Interest

The term "conflict of interest" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a researcher’s professional judgments. The bias such conflicts could conceivably impart may inappropriately affect the goals of research.

“Apparent” or “perceived” conflicts of interest refer to situations which appear to present a conflict to an outside observer, although they may not give rise to an actual conflict. The mere appearance of a conflict may be as serious and potentially damaging as an actual conflict.

“Immediate family” includes an investigator’s spouse and dependent children (including stepchildren).

Consult the following documents for information on conflicts of interest: Tri-Council Policy Statement (TCPS2 2014) – Chapter 7

Subjects should not be expected to incur expenses as a direct result of participation in a research study; reimbursement for out-of-pocket expenses (e.g. travel) is encouraged. Payment should not be used in such a way that it could be construed as an undue inducement to participate (e.g. unreasonable amount, payment tied to completion of study). Reimbursement should be for expenses, time or inconvenience, but should not be used to encourage subjects to accept increased risk. If reimbursement for time is proposed, please explain. It is expected that any payments will be pro-rated.

**Reb Review - Results**

Written responses from the REB committee will be sent as soon as possible following the REB monthly meeting/delegate review. Responses are issued through by the Coordinator of Operations via email.

Approved Research can begin immediately upon receipt of letter indicating Ethics Certification.

Revisions Required Research cannot be initiated. The researcher is required to submit additional information or revisions outline in the letter.

Unable to Approve *Research CANNOT be initiated*. Resubmission in accordance with the normal deadlines for submission of a **complete, revised proposal is required for reconsideration by** way of full REB review.

**Appeal Process**

A researcher may appeal the REB decision. Please refer to the [Research Involving Human Participants procures (Appendix A).](http://www.lethbridgecollege.ca/sites/default/files/imce/policies_procedures/Research_%26_Copyright/research-involving-human-participants-app-a.pdf)