

## Purpose

To guide ethical Research practices at Cambrian College ('the College') involving Human Participants.

## Definitions

**Conflict of Interest:** A situation in which a person can derive personal benefit from actions, decisions or Research in their official capacity. Any real, potential or perceived conflict of interest, as well as institutional or community conflicts of interest shall be disclosed.

**Core Principles:** As defined by the TCPS 2 and includes Respect for Persons, Concern for Welfare, and Justice.

**Expedited Review:** Consists of a review of research involving Human Participants by the Research Ethics Committee Chair or by two experienced reviewers designated by the Chair from among members of the Committee. Their feedback is required to be provided to the Committee within 10 working days.

**Human Participant:** Those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the Researcher, are relevant to answering the Research question(s).

**Informed Consent:** Any prospective participants must be provided with a full disclosure of all information necessary for making an informed decision to participate in a Research project.

**Minimal Risk:** Research in which the probability and magnitude of possible harms implied by participation in the Research are no greater than those encountered by participants in those aspects of their everyday life that relate to the Research.

**Principal Researcher:** The individual undertaking a Research project who is responsible for ensuring compliance with the requirements the Research Ethics Committee and the TCPS 2 and, also, the ethical treatment of Research participants throughout the life of the project.

**Research:** An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

**Research Ethics Board (REB):** A synonymous term for Research Ethics Committee, typically used at universities, hospitals and health organizations.

**Research Ethics Committee (REC):** An autonomous entity, accountable to the Board of Governors, formally constituted to review and monitor all Research involving human participants through the application of the core principles of Research ethics, as defined in the TCPS 2.

## Scope

All Research involving human participants.

## Methodology

Research involving human participants encompasses a wide array of Research activities and can include surveys and questionnaires, individual interviews or focus groups, physiological, psychological or educational testing, tissue collection as well as therapeutic interventions.

All forms required for approval to conduct Research are available on the College's official intranet and Research Ethics web page (<https://cambriancollege.ca/about/planning-and-research/cambrian-research-ethics/>).

The Planning and Institutional Research office can assist Researchers with the completion of the application form and with any questions which they may have relating to the review process.

## Operating Procedure

### 1. Institutional Approval

- a. Anyone seeking to conduct Research involving Human Participants ('Research'), under the auspices of the College, must first obtain institutional approval prior to initiating any Research-related activities. Institutional approval to conduct Research is granted by the Office of the Vice President, Academic.
- b. To complete this process, Researchers must:
  - i. Complete the "*Research – Institutional Approval Form*".
  - ii. Submit the completed form to their administrator and then, the Office of Vice President Academic for approval.
  - iii. Submit the completed and approved form to [Research@cambriancollege.ca](mailto:Research@cambriancollege.ca).
- c. Students wishing to conduct course-related Research, under faculty supervision, must follow the same process as outlined above *except* they must submit the Institutional Approval Form to their Program Coordinator, who will process the request accordingly, per the outlined procedures.

### 2. Research Ethics Application Process

- a. Once Researchers have received institutional approval to conduct Research, they can proceed with submitting their ethics application to the Research Ethics Committee (REC) for ethical review and approval.
- b. To complete this process, Researchers must:
  - i. Complete Cambrian's "Ethics Review Approval Form" and prepare all required documents relating to the Research project.
  - ii. Submit the completed form, along with all supporting documents involved in the Research (e.g. consent forms, survey or questionnaire questions, recruitment script, etc.), to the Office of Planning and Institutional Research (PIR) at [Research@cambriancollege.ca](mailto:Research@cambriancollege.ca).
- c. PIR ensures that the application and required documents are complete and forwards these to the REC for its review.

### 3. Exemptions from Ethical Review

- d. Research ethics review and approval will not typically be required for:
  - i. Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes.

- If data is collected for the purposes of such activities but later proposed for Research purposes, a REC review may be required in accordance with this Policy.
- ii. Research that relies exclusively on information about individuals available in the public domain where there is no direct interaction or reasonable expectation of privacy. This includes publicly available information, documents, records, archival materials, or published third-party interviews.
- iii. Research involving the observation of people in public places where: it does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups; individuals or groups targeted for observation have no reasonable expectation of privacy; and, any dissemination of Research results does not allow identification of specific individuals.
- iv. Class Research projects which involve human participants, and which are conducted by students on other members of the class as exercises to learn how to conduct Research.
- v. 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. Secondary use refers to the use of information collected for a purpose but later proposed for Research purposes.

#### **4. Ethical Review Process**

- a. The REC uses a proportionate approach based on the general principle that the more invasive the Research, the more diligent the ethical review must be in the assessment of the perceived risks. Based on this principle, the REC makes determinations on the level of review required. All projects are reviewed on a case-by-case basis based on level of risk.
- b. Research proposals are reviewed by the Chair (or delegate) of the REC. The review is usually completed within two weeks of submission of a completed application form. The Chair is responsible for reporting all recommendations arising from delegated reviews to the full REC at the next available meeting.

##### **4.1 Full Board Review**

- a. Research that requires full review shall include the following:
  - The Research involves more than minimal risk (more than one might experience in their day to day life).
  - Children or other vulnerable populations (e.g., institutionalized individuals, people living with disabilities, elderly, people incapable to consent).
  - Deception.
  - Physically or psychologically distressing procedures or questions.
  - Questions involving sensitive questions, themes or topics.
  - Conflict of interest (real, potential or perceived)
- b. A full review requires face-to-face review of the Research protocol before the full REC. In such cases, Researchers are encouraged to participate in discussions about their proposals, but they may not be present when the REC is making its decisions.

##### **4.2 Delegated Review**

- a. A proposal may proceed via delegated review if it meets one of the following criteria:
  - The Research involves no more than minimal risk.
  - The review of secondary data using anonymized or unidentifiable data.
- b. The determination on the level of review for Research projects is made by the Chair of the REC; all decisions are final.

## 5. Review of Multi-Site Research

- a. Research protocols that have been reviewed and approved by Research ethics boards, other than that of Cambrian College, may be considered for Expedited Review provided the Researcher offers information regarding the particulars of approval by the other institution, including:
  - the application for ethics approval;
  - the consent form and letter of information (if applicable);
  - the advertising/recruitment material;
  - the debriefing information sheet;
  - tools and pictures of equipment being used in the project.

## 6. Research Conducted in Another Jurisdiction or Country

- a. All Research projects conducted in another jurisdiction or country, are required to undergo ethics review both (a) by Cambrian College's REC; and (b) by the appropriate REB, where such exists, which has authority in the country or jurisdiction where the Research is to take place.

## 7. Indigenous Research

- a. Indigenous Research will respect the distinct world views of the First Nations, Inuit, and Metis peoples and ensure that they are represented in planning and decision-making from the earliest stages of the project design through to analysis and dissemination of results.

## 8. Decisions by the REC

- a. Decisions resulting from the ethics review of Research protocols will be provided in writing to the principal investigator within two weeks of the meeting. The REC meets monthly as required.
- b. A decision on a submission can fall into one of the following categories:
  - Approval without questions or modifications.
  - Approval subject to clarifications and/or modifications.
  - Deferred, pending receipt of additional information or major revisions.
  - Not approved.
- c. If the application is not approved as presented, written documentation will be provided to the Researcher with a rationale for the decision and recommendations for changes.
- d. Re-submission of the Research application for ethics review may be made following recommended amendments at any time.

## 9. Reconsideration of Decisions

- a. An applicant has the right to have a negative REC decision reconsidered.
- b. Reconsideration shall be done promptly by the REC responsible for the original decision.

- c. The applicant shall be invited to be present to discuss the application with the REC prior to decision making.
- d. If the decision of the REC, on reconsideration, remains negative, the applicant may file and appeal.

### 10. Appeals Process

- a. When the applicant does not agree with the decision of the REC, they may appeal the decision to the Appeal Committee. As per the College's agreement with Laurentian University (LU), the Research Ethics Board (REB) at LU provides this arm's length service.
- b. The LU REB will conduct a full review of the application and associated documentation, which may include the original ethics application, the original REC decision, all subsequent written communications, and documents and records, including REC minutes pertaining to the submission.
- c. The Appeal Committee will render a final and binding decision by majority vote. The Appeal Committee may:
  - uphold the original decision,
  - modify the original decision, or
  - impose specific conditions for approval of the project.
- d. The Appeal Committee will communicate its decision in writing, with reasons, to the Researcher and to Cambrian's REC. The Appeal Committee will provide advice to the REC in the event of the modification of the original decision of the REC, or in the event of the imposition of specific conditions for approval of the project.

### 11. Modifications to Proposed Research

- a. Researchers are responsible for informing the REC if a change is required to an approved application.
- b. Any request for modification of approved Research by REC shall include an explanation of why the modification is required, with specific reference to relevant sections of the Tri-Council Policy.
- c. To request a change, Researchers must complete and submit a "*Change Request Form*".

### 12. Safeguards

- a. Appropriate safeguards regarding Research information will be in place that respect the privacy of participants and support researchers in fulfilling their confidentiality obligations.

### 13. Adverse Events

- a. Principal Investigators and supervisors must immediately report any adverse effects (undesirable and unintended, although not necessarily unexpected events) arising out of the Research.
- b. Reports are to be directed to the Chair of the REC and dealt with within 3 days of their occurrence.

### 14. Review of Ongoing Research

- a. All Research projects, a year or more in duration, are required to submit an annual status report ("*Status Report Form*") to the REC summarizing the progress of the Research investigation to date.
- b. Researchers, whose projects are deemed to exceed minimal risk, have the responsibility of submitting updates at least annually or more frequently as requested by the REC.
- c. At the conclusion of a project, the Researcher is required to submit a brief final report.

### 15. Research Renewal

- a. Researchers are responsible for ensuring that their ethics approval time frame does not lapse.
- b. To request an extension, Researchers must complete and submit the "Renewal/Completed Status Report Form" to [Research@cambriancollege.ca](mailto:Research@cambriancollege.ca).

### 16. Publication of Research

- a. Cambrian College has no institutional constraints on the publication of Research results. However, the College may agree to delay publication for no more than 12 months from the date of completion of a project to satisfy any pre-existing and related agreements with funding agencies.
- b. In addition, where a source provides "Confidential Data", the Research is to be published without any identifiable reference to confidential data.

## Quality Assurance Compliancy

The Vice President, Academic has the accountability for the overall integrity of Research as defined in this procedure and related processes.

Planning & Institutional Research has the accountability of managing the quality assurance of the Research Ethics Review Operating Procedure in consultation with the College's Research Ethics Committee.

## Related Documents /Policies

Ethics Review Approval Form

Change Request Form

Status Report Form

Renewal/Completed Status Report Form

Code of Conduct Policy

Conflict of Interest Policy

Intellectual Property Policy

Research – Institutional Approval Form

Reasonable Conduct of Research Policy

Tri-Council Policy Statement: Ethical Conduct for Research involving Humans – TCPS 2 (2018)