

Title **Policies and Ethical Guidelines for Research Involving Humans**

Effective Date  
**June, 2012**

Replaces  
**Policies and Ethical Guidelines for Research Involving Human - June 14, 2007**

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## **A. Cambrian College Policies and Mandate**

### **1. Overview**

Cambrian College will promote and facilitate the use of research in the College community in order to contribute to the development and application of knowledge, to critically examine practices and keep current with merging knowledge relevant to education, and to promote professional practice. The College is committed to ensuring that all research meets the highest scientific and ethical standards.

This policy applies to funded and non-funded research investigations involving human participants carried out on or off campus by Cambrian College faculty, staff, students, and to anyone conducting research at or under the auspices of the College. All College employees involved in research involving humans are expected to be aware of, and responsive to, the preceding principles and to ensure that they are reflected in the research design and execution. Failure to comply with Cambrian College research policies constitutes misconduct.

Policies regarding ethical conduct in research are reviewed every two years by the Executive Committee based on the recommendations put forth by the College’s review committees and the Director of Planning and Research.

#### **1.1 Tri-Council Policy**

The College’s policies on ethical conduct in research comply with the standards and procedures required by the Tri-Council.

The Tri-Council Working Group has established current guidelines to ensure that researchers are meeting the minimum and necessary standards of ethical conduct. The group consists of representative from three of the major Federal research granting councils of Canada (Natural Science and Engineering Research Council, Social Sciences and Humanities Research Council and Canadian Institutes of Health Research). For the purposes of human research, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human (TCPS 2) outlines established procedures and standards for ethics review of research involving humans.

Tri-Council Policy statements and guidelines can be found on the website of any member agencies or in the Planning and Research Department.

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Note: Cambrian College follows the policies outlined by the tri-council Ethical Conduct for Research Involving Humans. Where in question research will follow their guidelines, policies and procedures, which can be found at: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>, and is also found on the college website.

## **1.2 Education and Dissemination of College Research Policies**

The College’s research policies are meant to protect both the individual researcher/employee and the institution. To this end, it is important that individuals involved in research be knowledgeable about the College's policies. Via the Planning and Research Department, individuals conducting research will be provided with a copy of the College's Research Policies as part of the research application package. Planning and Research Department staff is available to clarify any questions regarding ethical guidelines and procedures. The research office will develop and deliver workshops about the research application review process and issues involving research integrity and conflicts.

## **2. Core Principles**

Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due (*TCPS 2, Section B*). In this policy, respect for human dignity is expressed through three core principles – Respect for Persons, Concern for Welfare, and Justice (*TCPS 2, Article 1.1*).

- **Respect for Persons:** This principle recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research and those who are participants because their data or human biological materials are used in research. Incorporates the dual moral obligation to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- **Concern for Welfare:** Researchers should aim to protect the welfare of participants, and in some circumstances, promote that welfare in view of any foreseeable risks associated with research. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as physical, economical and social circumstances.

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- **Justice:** Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. In consideration of justice there must be no imbalance of power in the relationship between the researcher and participant.

The Research Ethics Committee recommends the practices outlined above to ensure that individuals who volunteer to participate in research projects conducted by the College be engaged in studies that adhere to rigid ethical guidelines. The principles have been widely adopted by diverse research groups. As such, they express common standards, values and aspirations of the research community. In addition to ensuring that a proposed investigation meets scholarly standards, review of research protocols by the REC will involve consideration of the adequacy of the study in meeting these standards.

### **3. The Principal Investigator**

As the individual primarily responsible for the implementation of research, the principal investigator bears the responsibility of ensuring the ethical treatment of every research participant. The Principal Investigator must ensure that all members of the research team comply with the requirements of the Research Ethics Committee, and that consent of participants is informed and freely given.

It is incumbent upon all Principal Investigators conducting research involving humans to read, and comply with, the Tri-Council Policy Statement (TCPS 2). An online tutorial is available (<http://www.pre.ethics.gc.ca/english/tutorial/index.cfm>) to assist researchers in the use, interpretation and implementation of the TCPS 2.

## **B. Research Committees**

### **1. Applied Research Planning Committee (APRC) - Terms of Reference**

The Applied Research Planning Committee (ARPC) advises the College on applied research activities and reviews applied research projects. Specifically, the ARPC is responsible for:

- Developing and revising research policies and procedures as required.
- Reviewing applications for applied research projects and recommend to the Director of Planning and Research for approval.

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- Referring applicants to the Research Ethics Committee, as needed.
- Reviewing and evaluating the scope and quality of research undertaken each year in light of the College’s research mission and strategic priorities.
- Preparing an annual report for presentation to the College’s Executive Committee and College Council outlining research initiatives undertaken the previous year.

All research associated with Cambrian College must receive the approval of ARPC before research begins. These projects would include those where:

- The College name or affiliation is used in a proposal or contract bid to an outside research supporting agency or in a proposed partnership or alliance, or in a research activity, or
- The College participates as a sponsor financially or through provision of release time, study leave, use of facilities, use of College personnel, administration of a grant from an outside agency, or other College resources, or
- College employees or students are participants for whom the College has responsibilities to regulate legal or ethical aspects of the research or where databases will be used which contain information about the aforementioned groups, including requests received from Cambrian employees who wish to do research (e.g., as part of their academic studies) and requests to do research within the Cambrian community received from persons or organizations external to College, or
- Research proposals name Cambrian employees who conduct research external to Cambrian and who use their status at the College to gain entry to the research site and/or participants.

Research conducted by the College where such research is conducted to meet external reporting requirements such as KPIs, or to facilitate the normal operation or management of the institution (e.g., First Year Student Survey, Student Feedback Survey, and Exit Survey) does not require approval of the ARPC.

## **1.1 Membership**

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Members of the ARPC are appointed by the President and are expected to be knowledgeable about issues related to research ethics and integrity. The ARPC is composed of:

- Vice President, Academic (ex officio, non-voting)
- Coordinator, Staff Relations and Staff Development (ex-officio, non-voting).
- Representative from Academic Advisory Council.
- Representative from College Services.
- Representative from Finance and Administration.
- Two Faculty representatives.

As appropriate, the ARPC will provide information/obtain feedback from College Council (whose membership includes academic, support staff and student representation) and/or the Academic Advisory Council.

The term of appointment for members will normally be 3 years, renewable with staggered appointments in order to ensure continuity within the Committee.

The ARPC shall elect annually a Chair and Vice chair. The Chair is responsible for convening meetings, developing agendas, representing and speaking on behalf of the Committee, acting as liaison between the Committee and the Planning and Research Department. The Chair also will assist the Director of Planning and Research in preparing the annual report. The Vice Chair is responsible for assuming the duties of the Chair should he/she not be available. Normally, the Vice Chair is expected to assume the role of Chair the following year.

## **1.2 Meetings**

The ARPC shall meet at least twice a year on an ad hoc basis to review research applications. Meetings will be called by the Chair upon receipt of an application from the principal investigator. Documents of the meeting and research application, including decisions and follow up measures, will be maintained in the ARPC files, housed in the Planning and Research Department.

Quorum will be 50% plus one of the voting members. Decisions will be reached by consensus. In the event that efforts to reach consensus have failed, decisions will be made on the basis of a simple majority vote of those members present. Minutes will be taken of every meeting including attendance, decisions and a summary of the discussion of pertinent issues.



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## 2. Research Ethics Committee (REC) - Terms of Reference

Cambrian College's Research Ethics Committee is formally constituted to review and monitor all research involving human participants conducted under the auspices of the College. The REC is an autonomous entity whose primary responsibility is ensuring the safety and well-being of all human participants involved in research programs carried out on or by the College. As part of this mandate, REC has the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of, Cambrian College, using the considerations set forth in this Policy as the minimum standard. In conjunction with the Planning and Research Department, the REC is responsible for setting and educating the College community about policies concerning research involving human participants.

Specifically, the REC is responsible for:

- Developing policies regarding ethical issues related to the use of human participants in research.
- Reviewing all proposals requiring ethical approval and annual progress reports.
- Reviewing annually all policies regarding ethical issues to ensure that the policies remain current.
- Preparing an annual report for submission to the College's Executive Committee.

### 2.1 Membership

The membership of the REC is designed to ensure competent independent research ethics review. Members are to be appointed in accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans ([www.nserc.ca](http://www.nserc.ca)).

The REC shall consist of at least five members, including both men and women of whom:

- at least two members who have expertise in the area of research covered by the committee;
- at least one member who is knowledgeable in the area of ethics;
- at least one member who has no affiliation with Cambrian College;
- At least one member who is knowledgeable in the relevant law (mandatory for biomedical research).

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The REC Chair may appoint ad hoc members or call on specialists to provide advice when reviewing projects requiring specific expertise (e.g., methodology, technology, health, community representation). Such advisors will not have voting rights unless it can be demonstrated that the ad hoc member has the knowledge and expertise to review applications.

The term of appointment for members will normally be 3 years, renewable, with staggered appointments.

The Committee will elect a Chair and Vice-chair annually. The Chair is responsible for convening meetings, developing agendas, representing and speaking on behalf of the Committee, acting as liaison between the Committee and the Planning and Research Department. In conjunction with the Director of Planning and Research, the Chair will assist in writing the annual report. The Vice-chair is responsible for assuming the duties of the Chair should he/she not be available. It is normally expected that the Vice-chair will assume the role of the chair the following year.

## **2.2 Meetings**

The REC members shall meet at least three times per year and as required to review research applications. The committee will have the authority to delegate to academic departments the ability to carry out and approve ethical review of student projects that are conducted under faculty supervision as part of approved college courses.

Meetings will be called by the Chair, who receives the application from the principal investigator on the specific research initiative. Documents of the meeting and research application, including decisions and follow up measures, will be maintained in the REC files, housed in the Planning and Research Department.

Quorum will be 50% plus one of the voting members. Decisions will be reached by consensus. In the event that efforts to reach consensus have failed, decisions will be made on the basis of a simple majority vote of those members present.

Minutes will be taken of every meeting including attendance, decisions and a summary of the discussion of pertinent issues.

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The REC will submit an annual report to the College’s Executive Committee. The report will summarize the activities of the REC including the number of proposals reviewed (expedited and full review), an overview of ethics issues and concerns that were addressed in the past year, and, if necessary, recommendations concerning changes to policy or procedures for conducting ethics review.

### **2.3 The College Administration**

The College administration, under the direction of the Director of Planning and Research, is ultimately responsible for ensuring that all research involving humans conducted by the College is responsible and ethical. The Administration is responsible for ensuring that sufficient resources are allocated to the Research Ethics Committee to allow it to perform its duties as outlined in the REC Terms of Reference.

Academic administrators such as Deans and Directors have a responsibility for the conduct of research carried out within their jurisdictions. They have a responsibility to be aware of ongoing research and a duty to create an environment that promotes responsible, ethical research.

The College, via the Planning and Research Department, is responsible for informing College employees involved in research about policy, standards and procedures.

### **2.4 Research Requiring Ethics Review**

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. Most research involving human participants conducted at, or under the auspices of Cambrian College, must be reviewed and approved by the Research Ethics Committee (REC) before the research begins. Research involving human biological materials, as well as fetuses, fetal tissue, reproductive materials and stem cells must be reviewed by the REC (*TCPS 2, Article 2.1*).

Research involving human participants that **does not** require ethics review includes:

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- Research or other study about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews. Such research only requires ethics review if the participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to policies outlined in the TCPS 2.
- Quality assurance studies, performance reviews, questionnaires concerning employee performance or course content distributed to a class by instructors or others within normal educational requirements.
- Research conducted by the college where such research is conducted to meet external reporting requirements or to facilitate the normal operation or management of the institution (e.g., First Year Student Survey, Withdrawal Report, KPIs).

**C. Review Procedures**

Anyone conducting research at Cambrian College must submit an application for review to the ARPC before beginning implementation of a project or acquiring resources for it. This applies to all projects whether or not financial support is involved and whether or not ethical review is required by another agency.

The ARPC will notify researchers as to whether a more detailed review of the project will be required. Anyone conducting human research will be required to submit an application for ethical review to the REC, unless excluded as outlined previously.

All forms that researchers must file for project approval are available on Staffnet and the Cambrian College Research website. The application form can also be obtained from the Planning and Research Department (Room 3166). The Planning and 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.

Students conducting research projects under faculty supervision must submit an application for ethical review to the academic manager of their program or course or an appointed

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designate who will forward to the Departmental Ethics Committee. It is the responsibility of the Departmental Ethics Committee to ensure that the project receives the necessary approval from the ARPC and, where applicable, the REC.

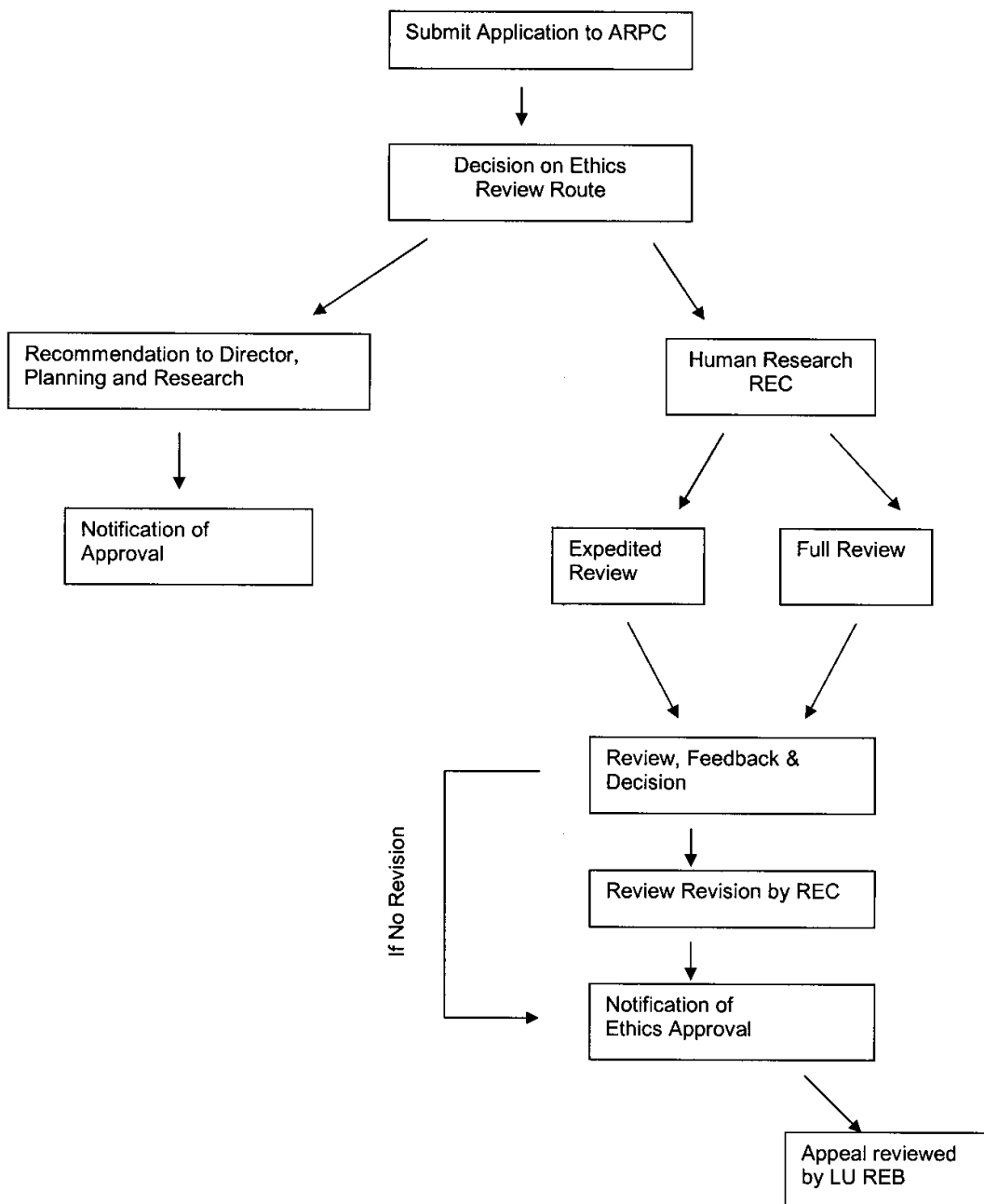
A flowchart of the review process is presented in Figure 1.

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**Figure 1: Review Process for Research Involving Human Subjects**



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## **1. Principle of Proportionate Review**

The REC will use a proportionate approach based on the general principle that the more invasive the research, the more diligent the assessment of the perceived risks inherent in the study procedures must be in assessing the research. Based upon this principle, REC review applications in terms expedited review or full review.

### **1.1 Full Committee Review**

Research that requires full review shall include the following:

- The research involves more than minimal risk.
- Children or other vulnerable populations (e.g., institutionalized individuals, incompetent populations, aboriginal peoples).
- Deception.
- Physically or psychologically invasive procedures.
- Collection of sensitive information (e.g., information which, if known outside the research, could reasonably place the participant at risk of civil or criminal liability or damage to the participant’s social standing, financial standing, or employability).

A full review requires face-to-face review of the research protocol before the full REC. In such cases, investigators are encouraged to participate in discussions about their proposals, but the investigators may not be present when the REC is making its decisions.

### **1.2 Delegated Review**

A proposal may proceed via delegated review if it meets one of the following criteria:

- The research involves no more than minimal risk. The investigator is responsible for an acknowledgement of minimal risk to the REC.
- The research has already received approval by the REC, has complied fully with any requirements, has an up to date file, and the applicant is simply renewing the ethical approval certificate without significant changes to the ongoing research process.

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- The research involves review of patient records by hospital personnel.
- Affirmation that conditions laid down by the REC as a condition of approval have been met.

The researcher must **choose** to apply for delegated review. The REC Chair may reject the application for expedited review and refer it to the Committee for full review.

Research proposals are reviewed by the Chair (or delegates) 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.

### **1.3 School/Departmental Review**

If a study is a teaching exercise (i.e., part of a diploma or undergraduate degree level course), and entailing no more than minimal risk, it must be reviewed by a school/departmental level committee on behalf of the REC and in compliance with the TCPS. The School/Departmental Ethics Committee must report results of such reviews to the REC at the end of the academic year.

## **2. Decisions by the Research Ethics Committee**

Decisions resulting from the ethics review of research protocols will be provided in writing to the principal investigator within two weeks of the meeting. 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.

If the application is not approved as presented, written documentation will be provided to the principal investigator with a rationale for the decision and recommendations for changes. Re-submission of the research application for ethics review may be made following recommended amendments at any time.



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## **2.1 Modifications to Proposed Research**

Any request for modification of proposed research by REC shall include an explanation of why the modification is required, with specific reference to relevant sections of the Tri-Council Policy.

Applications which have been modified to comply with REC requests shall be reviewed by the REC Chair. If the modified protocol meets the REC requirements approval shall be granted. If not, the Chair may meet with the applicant to attempt to resolve the matter. Should the meeting be unsuccessful, the applicant may elect to appeal the decision.

## **2.2 Reconsideration of Decisions**

An applicant has the right to have a negative REC decision reconsidered. Reconsideration shall be done promptly by the REC responsible for the original decision. The applicant shall be invited to be present to discuss the application with the REC prior to decision making. If the decision of the REC, on reconsideration, remains negative, the applicant may file and appeal with the Appeal Committee.

## **2.3 Appeals Process**

When the applicant does not agree with the REC, he/she may appeal the decision to the Appeal Committee. An agreement has been reached with the Research Ethics Board at Laurentian University to provide this arms length service.

The Laurentian 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, documents and records, including REC minutes pertaining to the submission.

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.

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The Appeal Committee will communicate its decision in writing, with reasons, to the researcher and to Cambrian's REC. The Appeal Panel 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.

### **3. Review of Ongoing Research**

All research projects, a year or more in duration, are required to submit an annual status report to the REC summarizing the progress of the research investigation to date. 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. At the conclusion of a project, the researcher is required to submit a brief final report.

### **4. Adverse Events**

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

### **5. Review of Multi-Centre Research**

Research protocols that have been reviewed and approved by research ethics boards, other than Cambrian College, may be considered for Expedited review provided the researcher provides 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.

### **6. Research Conducted In Another Jurisdiction or Country**

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.

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## **7. Publication of Research**

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 allow a sponsor to file for patent protection or to satisfy agreements with funding agencies.

In addition, where a source provides “Confidential Data”, the research will be published without identifiable reference to confidential data.

## **D. Free and Informed Consent**

All research involving human participants, as outlined in the Tri-Council Policy, must take into account the requirements of free and informed consent.

### **1. Requirement for Free and Informed Consent**

Free and informed consent represents the foundation from which all ethical research involving human participants is conducted. As discussed in the Tri-council Policy (TCPS 2 *Article 3.1*), the process of informed consent refers to the dialogue, information sharing and general process through which prospective participants choose to participate in research involving themselves. Obtaining informed consent involves meeting with a potential participant, determining whether he or she is capable of giving consent and discussing the purpose, risks, and benefits of participation.

#### **1.1 Exceptions to Requirements of Free and Informed Consent**

In some fields of research, in particular in social/behavioral research, studies cannot be conducted without deception, concealment or covert observation. The REC may approve a consent procedure which does not include, or which alters some or all elements of the normal requirements for informed consent, or waive the requirement to obtain informed consent, provided the REC documents that:

- the research involves no more than minimal risk to the participants;
- the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the waiver or alteration;

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- whenever possible and appropriate, the participants will be provided with additional pertinent information after the participation; and
- the waived or altered consent does not involve a therapeutic intervention. [TCPS 2, Article 3.7]

Consent is not required from organizations such as corporations or governments for research about their institution. However, individuals who are approached to participate in a research project about their organization have the right to give free and informed consent. In particular, they should be fully informed about the views of the organization’s authorities, if these are known, and of possible consequences of participation.

**2. Informed Consent: Instructions for Preparation of an Information Letter**

**Should include:**

- A statement that indicates that the participant understands the conditions of his/her involvement. This information should be stated in a cover letter or introductory statement to the participant. It should include such things as:
  - Title of study
  - Purpose of study, in lay terms
  - Brief description of participant involvement (including dates, compensation, etc.)
  - Name of principal investigator and how can be reached
  - Benefits/risk for participation
  - Confidentiality
- A statement that reconfirms the voluntary nature of the participation and the ability to withdraw at any time, without penalty, regardless of the reason.
- Name and signature of the participant, dated. If the research is deemed to be invasive, the consent form should include a place for a witness to sign and date as well as the name, signature, and date for the person who explained the study to the participant.

A sample research consent form is provided below.

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**Sample Research Consent Form for Human Participants  
Cambrian College of Applied Arts and Technology**

You are being invited to participate in a study entitled (**TITLE**) that is being conducted by (**INVESTIGATOR(S) NAME(S)**). (**INVESTIGATOR’S NAME**) is a (**faculty member, student, etc.**) in the (**DEPARTMENT NAME**) at Cambrian College and you may contact him/her/them if you have further questions by calling (**PHONE NUMBER**) or e-mailing (**E-MAIL ADDRESS**).

The purpose of this research project is (**INCLUDE A DESCRIPTION OF THE STUDY IN LAY TERMS**).

You are being asked to participate in the study because (**INCLUDE INFORMATION ABOUT WHY/HOW SUBJECTS ARE CHOSEN**)

If you agree to participate in this research, your participation will include (**INCLUDE INFORMATION RELATING TO THE TIMELINES, DATES, INVOLVEMENT OF SUBJECT, AMOUNT OF TIME COMMITMENT INVOLVED, ETC. If applicable, describe any compensation for subjects.**)

**(You must include one of the following):**

- There are no known or anticipated risks to you by participating in this research

**OR**

- There are some potential risks to you by participating in this research and they include (**INCLUDE THE IDENTIFIED RISKS; IF APPLICABLE, DESCRIBE BENEFITS**).

Your anonymity will be protected by (**INCLUDE THE APPROPRIATE INFORMATION**) regarding how data will be kept secure and when destroyed.

Your participation in this research is completely voluntary. If you decide to participate, you may withdraw at any time without penalty and you will not be required to provide an explanation. If you do withdraw, your data will (**INCLUDE INFORMATION ABOUT HOW DATA WILL BE HANDLED**).

It is anticipated that the results of this study will be shared with others in the following ways (**INCLUDE HOW RESULTS OF THE STUDY WILL BE DISSEMINATED**).

If you wish to verify the ethical approval of this study, or raise any questions or concerns, you are encouraged to contact the Director, Research and Development at Cambrian College (705-566-8101, ext. 7888) who will direct your concerns to the Research Ethics Committee.

Your signature below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered.

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Date

\*Copy to be given to participant.

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### 3. **Voluntariness**

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion (see TCPS 2, *Article 3.2*). Undue influence may include physical duress; fraudulent misrepresentation; abuse of power relationships; economic incentives; or emphasis of benefits over risk. Particular attention must be taken in cases where the prospective participants are students, employees, and patients dependent upon family or other caregivers, or residents in long-term care facilities or psychiatric institutions.

Payments or incentives must be reasonable and must not place undue pressure on a participant to either join or remain in the project. Generally, participants may be reimbursed for transportation costs, lost wages and inconvenience.

### 4. **Naturalistic Observation**

Ethics 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 REC review since it can be expected that the participants are seeking public visibility. Naturalistic observation that does not allow for the identification of the participants, and that is not staged, should normally be regarded as minimal risk and is eligible for delegated review.

In considering research involving naturalistic observation, researchers (and REC) should consider the ethical implications of such factors as: the nature of the activities being observed; the environment in which factors are to be observed (in particular, whether it is staged for the purposes of research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the participants).

### 5. **Informing Potential Participants**

Researchers are required to provide prospective participants or authorized third parties with all relevant information necessary to provide free and informed consent. Throughout the consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation.

The researcher must provide information concerning:

- the voluntary nature of their participation;
- the purpose, duration and nature of the research;

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- potential harms and benefits;
- assurances regarding freedom to withdraw at anytime;
- the possible commercialization of research findings;
- the presence of any apparent, actual or potential conflict of interest on the part of the researcher, their institution or sponsor(s).

Additional information that researchers may be required to provide in some areas of research for the purpose of obtaining free and informed consent is presented in Table 1.

## **6. Disclosure of Information**

Information must be presented verbally and, in most cases, 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 consent must be documented. In most cases, a written statement of the information conveyed in the consent process, signed or not, should be left with the subject.

## **7. Debriefing**

Generally, participants in human research should be provided with feedback at the end of their participation in the research. Participants involved in human research, where it was necessary to deceive research participants, must be debriefed at the conclusion of their participation in the study.

Often debriefing can be quite simple and straightforward. In sensitive cases, researchers should provide, in addition to candid disclosure, a full explanation as to why participants were temporarily led to believe that the research or some aspect of it had a different purpose, or received less than full disclosure. They should give details about the importance of the research, the necessity of having to resort to partial disclosure, and their concern about the welfare of the participant.

Immediate, full debriefing of all persons who have contributed data may not be feasible in all cases. In studies with data collection over a longer term, debriefing may have to be deferred until the end of the project. In some cases it may be more appropriate to debrief parents, guardians, or authorized third parties, entire families or community.

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## **8. Competence**

Competence means that a person is capable of making a morally and legally valid choice to participate in research. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision and to provide free and informed consent. To be considered competent to make a valid choice, prospective research participants should be able to understand and appreciate the following:

- the nature and purpose of the research in question;
- what participation in the research means;
- the potential benefits of participation;
- any negative consequences that may arise as a result of participation;
- that they will be free to withdraw from participation at any time during the course of the study;
- that there will be no negative consequences to themselves or their care should they choose not to participate or withdraw;
- the confidentiality of the information they provide;
- who can answer questions about the research and/or their rights as research participants.

### **8.1 Minimal Conditions**

Individuals who are not legally competent to consent to research shall only be asked to become research participants if:

- the research question can only be addressed using individuals within the identified group(s); and
- if the research does not expose them to more than minimal risks without the potential for direct benefits for them; and
- if the researcher demonstrates free and informed consent will be sought from an authorized representative(s) as well as how the participant's best interests are protected. The authorized third party cannot be the researcher or any other member of the research team; and
- if a participant who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.



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If a legally incompetent individual is capable of understanding the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential participant’s dissent will preclude his or her participation.

**9. Research in Emergency Situations**

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with the criteria established in advance during ethics review.

Seeking free and informed consent in advance may not be possible due to the unforeseeable nature of the causes of the medical emergency. Research may be carried out without consent provided all of the following apply:

- A serious threat to the prospective participant requires immediate intervention; and
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
- Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and
- The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- 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, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

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**Table 1. Additional information that may be required for some projects**

1. An assurance that new information will be provided to the participants in a timely manner whenever such information is relevant to a participant’s decision to continue or withdraw from participation;
2. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;
3. Information on the appropriate resources outside the research team to contact regarding ethical issues in the research;
4. An indication as to who will have access to information collected on the identity of the participants, description of how confidentiality will be protected, and anticipated uses of data;
5. An explanation of the responsibilities of the participants;
6. Information on the circumstances under which the researcher may terminate the participant’s participation in the research;
7. Information on any costs, payments, reimbursement for expenses or compensation for injury;
8. In the case of randomized trials, the probability of assignment to each option;
9. For research on biomedical procedures, including health care interventions; information about (a) foregoing alternative procedures that might be advantageous to the participant, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and (c) particularly in trials of therapeutic interventions, the care provided if the potential participant decided not to consent to participate in the study
10. The ways in which the research results will be published, and how the participants will be informed of the results of the research.

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### **E. Privacy and Confidentiality**

Confidentiality refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another. The recipient has an obligation not to use that information for any purpose other than that for which it was given.

Privacy is the right to decide the extent to which personal data, not already in the public domain, may be disseminated.

Wherever there is an expectation of privacy, investigators are expected to protect the anonymity of participants and to ensure confidentiality of all personal information or sensitive data. Measures by which anonymity and confidentiality are to be achieved must be explained as part of the research proposal. If confidential information is stored for future use, details must be provided which outline how and where material will be sorted and explain measures taken to ensure confidentiality.

REC approval must be obtained for all research which involves the collection of potentially identifiable personal. Investigators must comply with the Freedom of Information and Protection Privacy act ([www.ipc.on.ca](http://www.ipc.on.ca)).

In cases where participants have given written consent for disclosure of information, such information may only be disclosed within the limits of the terms of consent.

Individuals requesting access to secondary data (such as school records) must submit their research proposal to the REC if the possibility exists that individuals may be identified as a result of the research.

### **F. Conflict of Interest**

Researchers, Applied Research Planning Committee members and Research Ethics Committee members must disclose actual, perceived or potential conflicts of interest.

The following is an overview of conflict of interest concerns as it relates to the College, REC and the researcher. The College's Policy on Conflict of Interest details the College's position with respect to identifying and addressing Conflict.

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## **1. Institutional Conflict of Interest**

The REC is an autonomous committee, with a mandate to ensure that all research investigations are in compliance with the standards outlined by the Tri-Council Policy. Situations may arise where the College has a strong interest in seeing a project approved before all ethical questions are resolved. The public trust and integrity of the research process require that the REC maintains an arms-length relationship with the College and manage actual or apparent conflicts of interest.

### **1.1 Conflicts of Interest ARPC and REC Members**

If the ARPC or REC is reviewing research in which a member of the board has a personal interest (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the Committee is discussing or making its decision.

No member of an ethics committee should adjudicate on research in which he/she has any conflict interest, including personal involvement or participation in the research, financial interest in the outcome, involvement in competing research, or an interest as an academic supervisor of a student researcher.

### **1.2 Conflicts of Interest Involving Researchers**

In order to assess the likelihood of an actual or apparent conflict of interest, researchers should consider the following:

- Whether an outsider would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests.
- Whether the public would believe that the trust relationship between the relevant parties could reasonably be maintained if they had accurate information on the potential sources of conflict of interest.

When conflict of interest exists, but is manageable, the researcher may proceed with the study provided he/she discloses the conflict to prospective subjects during the free and informed consent process.

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## **G. Inclusion in Research**

Where research is designed to survey individuals because of their involvement in generic activities (e.g., child poverty, access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so. That is not to say, that a researcher is precluded from focusing on a single individual (such as a biography) or on a group of individuals who share a particular characteristic (e.g., painters who happen to be all one sex, race or religion).

### **1. Researching Involving Women**

Woman shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.

### **2. Research Involving Persons Who Are Mentally Incompetent**

Researchers should consider that those who are not competent to consent for themselves should not be automatically excluded from research which could potentially benefit them as individuals or the group that they represent.

An incompetent participant's withdrawal of consent must be respected, whether or not the participant was competent at the time of withdrawal.

### **3. Research Involving Aboriginals**

Researchers interested in conducting research involving aboriginal peoples should consider the following "good practices" outlined in TCPS 2:

- To respect culture, traditions and knowledge of the aboriginal groups;
- To conceptualize and conduct research with aboriginal group as a partnership
- To consult members of the group who have relevant expertise;
- To involve the group in the design of the project;

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- To examine how the research may be shaped to address the needs and concerns of the group;
- To make best efforts to ensure that the emphasis of the research, and the ways chosen to conduct it, respect the many viewpoints of different segments of the group in question;
- To provide the group with information respecting the following:
  - protection of the aboriginal group’s cultural estate and other property
  - the availability of a preliminary report for comment
  - the potential employment by researchers of members of the community appropriate and without prejudice
  - researchers’ willingness to cooperate with community institutions
  - researcher’s willingness to deposit data, working papers and related materials in an agreed-upon repository
- To acknowledge in the publication of the research results the various viewpoints of the community on the topics researched; and
- To afford the community the opportunity to react and respond to the research findings before the completion of the final report.

A number of relevant documents relating to special considerations of research involving aboriginals are available. These documents include but are not limited to the following:

1. *Ethical Principles for the Conduct of Research in the North*, Association of Canadian Universities for Northern Studies, Ottawa, ACUNS, 1982; 1988
2. *Ethical Guidelines for Research*, Royal Commission on Aboriginal Peoples Appendix B; RCAP, 1993