

College Policy & Procedures Manual	
Category	7 - Research
Policy #	7.1.2

7.1.2 ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN SUBJECTS

PREAMBLE

The College of the Rockies carries a commitment to ensure that high ethical standards in research involving humans are upheld. College recognizes the importance of protecting potential participants and communities in which research may take place. The TCPS 2- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans three core principles (2014): 1) respect for persons, 2) concern for welfare and 3) justice guide the ethical review process at College and are supported in this policy

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

1. PURPOSE

The purpose of this policy is to:

- Create a research environment in which human research participants and communities are protected
- Establish an independent research ethics review process
- Outline the procedural guidelines and the College REB's responsibilities to assist researchers in determining whether research requires ethical review.
- Ensure the safety, welfare and rights of research participants (including cultural groups) through the application of core ethical principles of respect for persons, concern for welfare and justice
- Take steps to ensure confidentiality and protection of privacy
- Ensure there is no undue influence, coercion, constraint or undue inducement to participate

2. SCOPE

- A. This policy applies to researchers engaged in any research activities that include human subjects and involve the College through:

- the inclusion of College employees and/or students, either as researchers or subjects; including course based research
 - an affiliation between the College and other institutions and/or members of the public (including, but not limited to, partnerships and/or sponsorships); and/or
 - non-college individuals or organizations using the College name or its resources and/or conducting research on College students and/or employees.
- B. This policy does not apply to ongoing information gathering activities that are related directly to the normal administering, evaluating, or improving of an operation, program, service or activity within the college.

3. DEFINITIONS

Deception: A situation in which information is withheld from research a participant 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.

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*).

Ethics Review means the processes and guidelines by which research proposals are evaluated to determine if they meet the quality and ethical principles and standards for research involving human subjects.

Minimal Risk means risk that is considered to be within the range normally encountered by, and acceptable to, the human subject in his/her everyday life.

Principal Researcher(s) means the person(s) primarily responsible for conducting a particular research activity.

Research Involving Human Subjects is defined as an undertaking intended to extend knowledge through a discipline inquiry or systematic investigation, which involves living individuals, human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals (TCPS 2).

Risk means the likelihood that something harmful might occur and the magnitude of the harm

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

4. AUTHORITY

4.1 Related Acts and Regulations

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is a joint policy of Canada's three federal research agencies- The Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council (SSHRC).

http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

The purpose of the *BC Freedom of Information and Protection of Privacy Act* is to make public bodies more accountable to the public and to protect personal privacy by: a) giving the public a right of access to records, b) giving individuals a right of access to, and a right to request correction of, personal information about themselves, c) specifying limited expectations to the rights of access, d) preventing the unauthorized collection, use or disclosure of personal information by public bodies and e) providing for an independent review of decisions made under the act.

http://www.bclaws.ca/Recon/document/ID/freeside/96165_00

4.2 Related College Policies

7.1.2 Research at College of the Rockies

3.5.2.2 Guidelines: Free and Informed Consent

3.5.2.3 Guidelines: Privacy and Confidentiality

3.5.2.6 Guidelines: Conflicts of Interest in Research

3.5.3 Integrity in Research and Scholarship

5. RELATIONSHIPS WITH COLLECTIVE AGREEMENTS

[College of the Rockies Faculty Association Collective Agreement](#)

6. GUIDELINES

6.1 Research Ethics Board Responsibilities

- A. The College will regulate the conduct of all research involving human subjects in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*. Any new versions of the TCPS will be adhered to by the COLLEGE REB.
- B. The College is committed to safeguarding the rights and well-being of human subjects of research activities in which the College is involved by adhering to ethical standards for research involving human subjects stipulated in this and other College of the Rockies policies and guidelines.
- C. The College will establish a Research Ethics Board (REB) with the primary responsibility to evaluate and monitor the ethical standards of College research activities that involve human subjects. This body will have the authority to cease research activity that has not been approved through the Proportionate Ethics Review process described below.
- D. Researchers, the College, and the College's Research Ethics Board (REB) are jointly responsible for safeguarding the rights and well-being of human subjects of research activities in which the College is involved. Regardless, the primary responsibility for adhering to the principles and guidelines stated in this policy and for ensuring high standards of conduct in research involving human subjects rests with the principal researcher(s).
- E. No research involving human subjects is to commence, nor may funds for such

purposes be released, until an ethics review, based on a Proportionate Ethics Review process, has been completed. In extenuating circumstances, funds may be released in the development stage of research by the College Research Compliance Officer provided the study is in the process of ethics review.

- F. The College REB chair is responsible for ensuring that continuing review of ongoing research takes place to its satisfaction. Review of approved research will take place at a minimum of once a year. Yearly updates and a final report will be part of the College REB process.
- G. The College is responsible for the ethical conduct of research undertaken by its employees or students regardless of the location where the research is conducted. Thus, review of research by the College's REB is required in addition to review by any agency having jurisdiction over the site of the research.
- H. A Research Appeal Process Agreement will be forged with another college REB in cases in which a researcher(s) appeal a decision made by the College REB.

6.2 Proportionate Ethics Review

All research proposals and activities that involve human subjects will be reviewed through a Proportionate Ethics Review process which is based on the ethical principle that, while all research involving human subjects must be reviewed adequately to ensure protection for the subjects, the greater the potential for risk or harm to the subjects, the greater the scrutiny required in reviewing the research. In accordance with this principle, research proposals will be reviewed through one of the following three levels as determined by the College REB Chair:

- A. **Full REB review** of student and faculty research that involves human subjects.
- B. **Delegated review** of research that is expected to involve minimal risk may be approved by the REB chair (or chair's designate).
- C. **Course-Based Research** Involving Human Participants expected to involve minimal risk reviewed by the COLLEGE REB chair (or chair's designate) and the Dean.

It is the responsibility of faculty to identify to the Dean all student research and projects involving human subjects.

6.3 Research and Activities Not Requiring REB Review

The TCPS 2 differentiates research requiring REB review from non-research activities that have been traditionally employed methods and techniques similar to those employed in research.

The following activities are not considered research and do not require review by the College REB. It must be noted that in these situations professional or disciplinary associations or best practice guidelines will guide ethical decision making:

- A. Research that relies exclusively on publically available information when the information is: 1) legally accessible to the public and appropriately protected by law or 2) the information is publically accessible and there is no reasonable expectation of privacy (TCPS 2, Art. 2.2)
- B. REB review is not required for research involving the observation of people in public places where: 1) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups, 2) individuals or groups targeted for observation have no reasonable expectation of privacy, and 3) Any dissemination of research results does not allow identification of specific individuals (TCPS 2, Art. 2.3)
- C. Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational environments when used exclusively for assessment, management or improvement purposes, do not constitute research for purposes of this Policy and do not fall within the scope of College REB review (TCPS 2, Art. 2.5)
- D. Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review (TCPS, Art. 2.6)

6.4 Protocol for review

An application for College REB approval for research involving humans shall be submitted to the College REB which shall review the form and proposal and make of the following decisions:

- a. **Approval:** A certificate of approval is issued and the research may begin (The College REB may include minor requests for information or suggestions with this approval), or
- b. **Provisos-** some concerns need to be addressed before approval can be given. The College REB may authorize its chair to issue a certificate of approval once the concerns have been satisfactorily addressed, or
- c. **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 College REB has formally approved a final research proposal.

- d. **Deferral**- based on documentation provided by 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 a later full board review at such time as the investigators submit the supplementary information or documentation as specified by the College REB.
- e. **Rejection.**

The Chair of the College REB will transmit, as quickly in 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.

6.5 Delegated Review

Delegated review and approval can be provided by the College REB Chair or by another College REB member delegated by the chair or by a College REB subcommittee. Such review will be well-documented and reported to the full College REB and Vice President of Education and Applied Research. Full board review is the default requirement for research involving humans, however, an applicant may request from the College REB Chair a delegated review for minimal risk research, and the Chair will consider the request based on the following aspects of the proposal:

6.5.1 Rationale

6.5.2 Protection of participant confidentiality

6.5.3 Vulnerable populations

6.5.4 Whether research meets the criteria of minimal risk

6.5.5 Proposal includes minimal risk changes to approved research, annual renewal or 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.

Research involving waivers or alteration to elements of informed consent, including deception, shall not be eligible for delegated review. Delegated reviewers retain the prerogative to refer any research proposal or matter related to their review to the full COLLEGE REB for review or consideration.

6.6 Guidelines for Course-Based Research Ethics Review Panels

Course-based research projects are small research projects where students pose research questions, gather data from human participants and analyse the data for presentation. Forms of data may include conducting interviews, designing and implementing questionnaires or surveys, or other any activities that would be considered research within the disciplinary tradition in which the course is being taught. Please refer to Appendix A: Ethical Review of Course-Based Research Involving Human Participants Procedures to compliment the following information.

Course-based research projects at the College must comply with the following criteria:

- 1) Research projects must be no more than minimal risk as defined by the TCPS2. Examples of minimal risk include:
 - Participants are competent adults, youth or children
 - Participants live freely in the community (not in prison or hospital)
 - The topics are non-controversial and carry little or no risk to the participants
 - Methods are non-invasive, such as the use of questionnaires or interviews
- 2) The research participants must be drawn from the general population, capable of giving free and informed consent, and may not include vulnerable subjects such as persons who are not legally competent to consent, mentally incompetent persons, legal wards or therapeutically dependant
- 3) The student projects must not involve any personal, sensitive or incriminating topics or questions that could place participants at risk
- 4) The student projects must not manipulate behaviour of participants beyond the range of “normal” classroom activity or daily life
- 5) The student projects must not involve physically invasive contact with the research participants
- 6) The student projects must not involve deception

Course-Based Projects Not Requiring REB Approval

- Projects where students are conducting research on themselves during class time
- Projects involving the use of records or information that is in the public domain; including the use of anonymous secondary data and surveys or questionnaires that have already been published.
- Projects involving the use of naturalistic observation where the participants are seeking public visibility and participant confidentiality and anonymity are ensured
- Practicum or job training projects where students are fully integrated into the organization’s operational practices and are not conducting research

- Projects where the intent is to use the information to provide advice, diagnosis, identification of appropriate interventions or general advice for a client
- Projects where the intent is to develop skills which are standard practice within a profession (i.e. observation, assessment, intervention, evaluation, auditing)
- Projects where the information gathering processes are part of the normal relationship between the student and the participants.

6.6.1 The College REB Chair 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. The College REB Chair will work in consort with the appropriate Dean in this process. The Dean will keep a record of current course-based projects on file for information purposes. This will include the project description and course outline. The College REB documentation including the original application, course outline, project description and approval letters will be kept by the College REB Chair on a secure server or in a locked filing cabinet in the REB office.

6.6.2 The College REB Chair will provide review as quickly as possible and in writing, a decision of an instructor's application. Where approval is not given, the Review panel shall provide written reasons to the instructor.

6.6.3 All forms and related documents for course-based review will be stored by the Office of the President and be retained for a minimum of five years after an application has been rejected or accepted.

6.6.4 Course-based applications will be given three (3) year approval periods- if the assignment changes in its focus, population or structure the REB chair must be notified and the proposal re-reviewed.

6.7 Storage of REB Records

All forms once completed and either approved or rejected will be submitted to and stored by the Office of the President. Researchers shall maintain comprehensive records of their research including documentation of all submissions to the COLLEGE REB, for a minimum of five years following completion of the research or termination of the research by the COLLEGE REB, or as required by law (whichever is greater).

7.0 Rights to Review and Appeal

In the case that an applicant requests a reconsideration of a decision made by the COLLEGE REB the TCPS 2 will be followed in that:

- 7.1. The COLLEGE REB will reconsider any decision negatively impacting a research project upon the researcher's request (TCPS Sec. 1, D5, Art. 1.10)
- 7.2. The COLLEGE REB will provide an explanation of the reasons for opinions or decisions and written grounds for the decision
- 7.3. Researchers are provided the right to request reconsideration, "to be heard" by the REB and to rebut the stated grounds and opinions for decisions

In the case that consensus cannot be reached the researcher will be notified of the appeals process. This process includes re-review and submission to a partner institution in which a memorandum of understanding has been created for this purpose. Notwithstanding, the College has the right to refuse certain research to be conducted under the College's name, even though the REB has found it ethically acceptable.

8.0 Research Involving Indigenous Peoples

This policy acknowledges that Western knowledge has often advanced into Indigenous Peoples' communities with little regard for the notions of Indigenous worldviews and self-determination in human development (Ermine et al., 2004, p.9). The COLLEGE REB aligns with the recommendations of the Indigenous Peoples' Health Research Centre (2004) document: The Ethics of Research Involving Indigenous People- Report of the Indigenous Peoples' Health Research Centre to the Interagency Advisory Panel on Research Ethics(http://ahrnets.ca/files/2010/05/ethics_review_iphrc.pdf) and the Tri-council Policy Statement: Research Involving the First Nations, Inuit and Métis People of Canada.

8.1 Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by institutional REBs and will not exempt researchers affiliated with an institution from seeking REB approval at their institutions.

8.2 Researchers and REBs should recognize that research ethics review by community bodies will often pursue purposes and apply criteria that differ from the provisions of the TCPS 2. The express purpose of most Indigenous community codes of research practice is to ensure the relevance of research undertakings to community needs and priorities and respect for First Nations, Inuit and Métis identities, cultures and knowledge systems (TCPS 2, 2010, p.120).

8.3 When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise the College REB in how they have engaged or intend to engage, the relevant community.

8.4 Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and community should be set out in a research agreement before participants are recruited. This should be part of the College REB application package for review.

8.5 The researcher(s) will require additional approval from Indigenous Research Ethics boards before receiving permission to engage in the proposed research.

This document was developed using:

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010.

Ermine, W., Sinclair, R., Jeffery, B (2004). The ethics of research involving Indigenous peoples: Report of the Indigenous peoples' health research centre to the interagency advisory panel of research ethics. Regina: Indigenous Peoples' Health Research Centre. Retrieved from http://ahrnets.ca/files/2010/05/ethics_review_iphrc.pdf

Langara College Ethical Conduct for Research Involving Humans B5007 Document (November, 2014). Retrieved from <http://langara.bc.ca/about-langara/policies/pdf/Policy-B5007-EthicalConductForResearchInvolvingHumans-approvedCouncil2014-11-04.web%20versionpdf.pdf>