

Ch12-s1-04**Research Involving Human Participants**

Responsible Authority:	Research Ethics Board
Approval Authority:	Senior Team
Date First Approved:	2009-04-22
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PURPOSE

The purpose of this Policy is to promote ethical research practices, protect the interests of human participants, and describe institutional standards and procedures governing research involving human participants in compliance with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (second edition -2018 referenced herein as the “Tri-Council Policy Statement” or “TCPS-2(2018)”). The TCPS 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 of Canada (SSHRC).

SCOPE

This Policy applies to all research involving human participants conducted under the auspices of Confederation College. Research conducted under the auspices of Confederation College includes, but is not limited to, research where funds are provided through or administered by Confederation College; research where the researcher’s affiliation with Confederation College is explicit in contracts, reports or publications; research which utilizes Confederation College resources (including accountable and professional development time); and research conducted by Confederation students as a component of their course or program requirements.

Unless expressly exempted, all research involving human participants requires prior approval by the Research Ethics Board, either by full or delegated review, as outlined in subsequent sections of this Policy.

Any persons undertaking research involving human participants at Confederation College are required to indicate that they agree to comply with the Tri-Council Policy Statement.

Concerns or questions related to compliance of this policy shall be referred to the Research Ethics Board (REB) for consideration. The REB may refer to policy interpretations issued by the Councils, or consult with the Interagency Advisory Panel of Research Ethics (PRE) and/or the Research Ethics Officers of the Agencies as needed.

NOTE: Confederation College will not participate as a lead institution for research involving human biological materials relating to human reproduction, clinical trials, or collection and/or banking of genetic materials (as defined in TCPS-2(2018)). Confederation College employees and/or students may participate as part of a research team led by an institution with appropriate capacity and expertise. The

project must obtain formal external REB approval from the lead institution. Subsequent internal review and approval by the REB at Confederation College is required for Confederation College employees and/or students to participate.

DEFINITIONS

Word/Term	Definition
Research Ethics Board (REB)	The Confederation College Research Ethics Board (REB), as established by the President of Confederation College, is responsible for overseeing all matters related to research involving human participants undertaken by the members of the College community for teaching and/or research purposes. In carrying out its responsibilities, the REB will act at all times guided by the Tri-Council Policy Statement, or future standards as may come to stand in its place.
Research	Research means an undertaking intended to extend knowledge through a disciplined inquiry and/or systemic investigation (TCPS-2(2018)). It is any gathering of information from or about human subjects. This includes (but is not limited to): physical, sociological, or psychological tests and measurements, survey research, non-intrusive systematic observation, and the study of recorded data from previous studies, databases, and archives, in which it is possible to identify living individuals.
Human Subjects	Human Subjects refers to living individuals and to groups of living individuals, such as publically identifiable social, ethnic, religious, or economic groups.
Minimal Risk	According to the TCPS 2 (Chapter 2, Section B) minimal risk is defined as "the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research". Research that poses "greater than minimal risk" to participants must be reviewed by the full REB.

POLICY

Unless specifically excluded (see Section below), the requirement for ethical review applies to all research proposals involving human participants whether or not financial support is involved and whether or not an ethical review is required by another agency.

Students conducting research projects under faculty supervision will follow the Student Course-Based Ethics Review Process. A Student Course-Based Ethics Review approval process cannot be used when a student's project is part of a faculty member's own research program. Such research must receive ethics approval from the Confederation College Research Ethics Board.

Research not Subject To Ethical Review

The following kinds of research proposals are specifically exempt from the need for ethical review:

1. Research or other study of the published writing or other public utterances of human subjects. (2.2)
2. Research involving the observation of people in public places, where the researcher is not interacting or intervening with the observed individuals, observed individuals have no reasonable expectation of privacy, and research results do not identify specific individuals. (2.3)
3. Research that relies exclusively on secondary use of anonymous information so long as the research does not generate identifiable information (2.4)
4. Quality assurance studies, performance reviews, questionnaires concerning employee or course content distributed to a class by instructors or others within normal educational requirements. (2.5)
5. Research on creative works, or research in which the researcher creates or interprets works of art (2.6)
6. Research conducted by the College where such research is conducted to meet external reporting requirements or to facilitate the management of the institution.

If there is any doubt about whether an ethical review is required, the researcher should check with the Chair of the Research Ethics Board. The REB will assist through a systematic approach to the determination of whether or not a research proposal could be excluded.

PROCEDURE

<u>Action</u>	<u>Responsibility</u>
1. Anyone Conducting Research Must;	
1.1 Submit an Application for Ethical Review to the Chair of the Research Ethics Board, unless an eligible exemption applies, before beginning implementation of a project or acquiring resources for it. This applies to all projects whether or not special financial support is involved and whether or not an ethical review is required by another agency.	Researcher
1.2 Advise the Research Ethics Board of any change to the research procedures for an accepted project before the change is implemented.	Researcher
1.3 Be familiar with and guided by applicable legislation and current professional standards and ethical guidelines (e.g., The Tri-Agency Framework: Responsible Conduct of Research (2016)).	Researcher
1.4 Follow all procedures established by legislation, this policy, and the Research Ethics Board.	Researcher

1.5 Maintain appropriate stewardship of research data during the agreed upon time period (approved by the Research Ethics Board) and destroy all data using appropriate methods when that time period ends.

Researcher

2. Ethics Review process

2.1 The Research Ethics Board shall use a proportionate approach to research review based on the general principle that the more invasive the research, the greater the care in assessing the research. Review of proposals involving “Minimal risk” may be approved through an expedited review process.

REB

2.2 The Research Ethics Board shall assign each application to one of the following categories: accepted; conditionally accepted subject to revisions; or rejected. Applicants will be provided a written record of the decision, including reasons for the classification.

REB

2.3 A rejected application may be resubmitted to address shortcomings.

Researcher

2.4 If the Board decides the changes to an amended research project is substantial enough to warrant a new approval process, a new Application for Ethical Review must be submitted.

Researcher

2.5 A resubmitted application that is rejected a second time may be appealed within ten (10) working days of receipt of the decision. The appeal will be reviewed through an inter-institutional agreement by another REB.

Researcher

3. Student Course-Based Ethics Review

3.1 The REB delegates the ethical review of course-based research projects to the Academic Schools which are responsible for reviewing any student course-based research projects and honours theses that involve research on human subjects, and/or are a component of the pedagogical process.

3.2 The Dean/Associate Dean shall assign each application to one of the following categories: accepted; conditionally accepted subject to revisions; or rejected. Applicants will be provided a written record of the decision, including reasons for the classification.

Dean/Associate Dean

3.3 Deans/Associate Deans are responsible for referring to the REB any matter of ethical concern that they feel is greater than minimal risk as defined by the TCPS 2.

Dean/Associate Dean

3.4 Appeals may be made to the Research Ethics Board within ten (10) working days of receipt of the decision.

SUPPORTING DOCUMENTATION

All forms can be found on the REB website at www.confederationcollege.ca/research-ethics-board

RELATED MATERIALS

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 – TCPS 2 (2018) . http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html