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| RESEARCH INVOLVING HUMAN PARTICIPANTS | | |

1. PURPOSE AND CONTEXT

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 -2010, referenced herein as the “Tri-Council Policy Statement” or “TCPS 2”)¹.

2. SCOPE AND LIMITS

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.

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. 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).

Any persons undertaking research involving human participants at Confederation College or its affiliated sites are required to indicate that they have read, and agree to comply with, the Tri-Council Policy.

3. ETHICAL REVIEW

Research Proposals Shall Be Subject To Ethical Review

- 1 Unless specifically excluded (see Section below), the requirement for ethical review applies to research proposals involving human participants whether or not financial support is involved and whether or not an ethical review is required by another agency.
 - 1.1 Human Subjects refers to living individuals and to groups of living individuals, such as publically identifiable social, ethnic, religious, or economic groups.

¹ At the time of drafting this Policy, the second edition of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* is the national standard and adherence to it by Confederation College is required by the tri-council funding agencies. It may be found at:
http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

- 1.2 Research means any gathering of information from or about human subjects. This includes 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.
 - 1.3 If there is any doubt about whether an ethical review is required, the researcher should check with the Chair of the Research Ethics Board
- 2 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.

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 then the research can be regarded as within the range of minimal risk". Research that poses "greater than minimal risk" to participants must be reviewed by the full REB.

- 3 The Research Ethics Board (or Dean in the case of supervised student research) 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.

A rejected application may be resubmitted to address shortcomings.

A resubmitted application that was rejected a second time may be appealed through the Reconsider and Appeal Process (identified below) within ten (10) working days of receipt of the decision. In the case of student research, appeals may be made to the Research Ethics Board within ten (10) working days of receipt of the decision.

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). 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.

Research not Subject To Ethical Review

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

- 1 Research or other study of the published writing or other public utterances of human subjects.
- 2 Quality assurance studies, performance reviews, questionnaires concerning employee or course content distributed to a class by instructors or others within normal educational requirements.
- 3 Research conducted by the College where such research is conducted to meet external reporting requirements or to facilitate the management of the institution.

The REB will assist through a systematic approach to the determination of whether or not a research proposal could be excluded.

Anyone Conducting Research Must:

- 1 Submit an Application for Ethical Review to the Research Ethics Board, unless excluded in Section above, 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.

1.1. Students conducting research projects under faculty supervision will follow the Student Course-Based

Ethics Review process.

- 1.2. Everyone else must submit an application for ethical review to the Chair of the Research Ethics Board.
2. Advise the Research Ethics Board of any change to the research procedures for a project as soon as a change is made, and submit a new Application for Ethical Review if the Board decides the change of a series or changes is substantial enough to warrant a new approval process.
3. Be familiar with and guided by applicable legislation and current professional standards and ethical guidelines (e.g., The Tri-Council Policies Dealing with Integrity in Research).
4. Follow all procedures established by legislation, this policy, and the Research Ethics Board.
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.

4. RESEARCH ETHIC 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. In particular the REB will adopt, as Confederation's ethical principles, the guiding principles contained and defined within the TCPS 2. The guidelines in this Policy are based on the following three core principles:

- Respect for Persons
- Concern for Welfare
- Justice

The importance of research and the need to ensure the ethical conduct of research requires both researchers and REB members to navigate a course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research. The application of the three core principles helps ensure that a balance between these two goals is maintained.

4.1 PURPOSE

The purpose of the REB is:

- 1) To fulfill the ethical responsibilities concerning research involving human participants in accordance with the standards developed by the Tri-Council (CIHR, NSERC and SSHRC) and contained in the TCPS 2. The Tri-Councils only provide funding to individuals and their institutions who are compliant with this Policy. Failure to remain compliant may result in loss of eligibility for the college.
- 2) To review the ethical acceptability of all research involving humans conducted within Confederation College's jurisdiction or auspices, that is by faculty members, staff or students, regardless of where the research is conducted in accordance with the TCPS 2. This includes approving, rejecting and proposing modifications to protocols, or terminating any proposed or ongoing research involving humans that is deemed to be non-compliant with the TCPS 2.
- 3) To establish and communicate ethics policies, procedures and standard operating procedures that are consistent with the TCPS 2 and to ensure that they remain current.
- 4) To serve the research community as a consultative body and to contribute to education in research ethics.

A) Authority of the REB

The President of Confederation College establishes the REB to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with the TCPS 2.

Although established by the President, the REB is independent in their decision-making. Confederation College shall respect the authority delegated to the REB and may not override an REB decision to reject a research proposal. Information regarding the appeal process is found in Section E of this document.

An REB approval applies to the ethical acceptability of the research, and does not, in itself, constitute authorization for the research to proceed (such reasons may be administrative or resource-based in nature).

B) Reporting Relationship

The REB shall work under the auspices of the President. When immediate reporting is required, the REB Chair will report directly to the President. In addition, correspondence pertaining to investigations, reports, appeals and final reviews of allegations of research protocol violations will be copied to the President.

The REB Chair shall prepare an annual report for the Senior Team to be presented by the Chair. The report shall include the number of proposals reviewed/rejected and the submitting faculties, a generic description of ethics issues/concerns that have been addressed in the past year, and if necessary, recommendations concerning changes to the REB Terms of Reference.

C) Reconsideration and Appeal Process

Confederation College's Research Ethics Appeal Board shall be Lakehead University's Research Ethics Board. The specific terms and procedures for filing an appeal shall be outlined in an inter-institutional agreement between the College and the University and be in accordance with the TCPS 2.

D) Meetings and Membership

Meeting Schedule and Notice

The REB will schedule meetings monthly from September through May. Additional meetings will be held whenever necessary. Seven (7) days notice shall be given for all meetings except that a meeting may be held at any time without due notice if quorum is met.

Meeting Decisions

Business involving decisions related to research protocols shall be by consensus as declared by the Chair. In accordance with the TCPS 2, in the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, peer review or further reflection by the REB may be helpful.

Quorum

In accordance with the TCPS 2, Article 6.9, when there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

Decisions without a quorum are not valid or binding.

Composition and Appointment of Members

The membership of the REB is designed to ensure competent independent research ethics review.

Annually, the REB determines the need for expertise in relevant research disciplines in order to ensure competent independent research ethics review (*TCPS 2 Article 6.4*). Members shall be appointed by the President on the recommendation of the Chair of the Research Ethics Board. The REB may consult with Deans, Directors and the Office of Sr. Vice President Academic in maintaining appropriate REB membership. Appointments are for three-year terms, renewable once.

The complement of the REB will be determined by the ongoing needs of the College, but should include:

1. Minimum of three full time faculty members who have expertise in relevant research disciplines, fields and methodologies covered by the REB.
2. One community member who has no affiliation with the institution but are recruited from the communities served by Confederation College.
3. One member with expertise in the area of ethics. This can be someone who has a teaching or research specialization in ethics, or someone who has had extensive experience in the area of research ethics.
4. One member whose research involves Aboriginal people.
5. One member knowledgeable in the relevant law (but the member should not be Confederation College's legal counsel or risk manager).
6. Research Analyst (Secretary to the REB and non-voting).

Each member shall be appointed to fulfill the requirements of the above categories.

Senior administrators (President, Vice-President, Executive Director, Dean) or members of the Board of Governors shall not serve on the REB, or directly or indirectly influence the REB decision-making process (*TCPS 2 Article 7.3*).

Ad hoc advisors may be consulted in the event that the REB lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

Chair Selection

The Chair shall be appointed by the President based on the recommendation of the REB normally from among the appointed members and shall serve, normally, for a term of three years, once renewable.

Meeting Attendance

Where a member is frequently absent (greater than 50% of face-to-face meetings), the Chair of the REB shall review whether that member should continue to serve on the REB.

Unexpected circumstances such as emergencies may prevent individual member(s) from attending the REB meeting. In these exceptional cases, input from member(s) by the use of technology (e.g., phone or video link) is acceptable.

Observers

At the Chair's discretion, observers may be admitted to REB meetings provided that they sign a confidentiality agreement and they do not have a conflict of interest with the specific meeting agenda. Observers may participate in discussions but will not be permitted to vote.

Conflicts of Interest

Those submitting applications to the REB must disclose any real or potential conflicts of interest regarding their proposal.

Any REB member who has a personal/professional interest or a real or perceived conflict of interest with a research proposal under review (as Principal Investigator, Co-Investigator, Supervisor, student, funder) shall not be present when the REB is making its decision.

E) Administrative Support

Secretary: Academic Research Analyst

Administrative Office: Office of the Senior Vice-President Academic

The REB will be provided human resources, meeting space and support services from the Office of the Senior Vice President Academic in order to fulfill the REB duties.

F) Student Course-Based Ethics Review

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.

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.

It is recommended that faculty members complete the TCPS 2 Course on Research Ethics (CORE) online training module prior to assigning primary research within their course.

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.

G) Partnerships

The REB will work closely with the Senior Team, SSALT, Academic Council and SUCCI to ensure that all research done on our campus or by our faculty, staff and students follow the TCPS 2 guidelines.