

Ethical Conduct of Research Involving Humans

Policy Number: 3303

Key Process Area:

Research, Innovation & Experiential Education

Owner: Current Approved Date: VP AR June 18, 2018

POLICY STATEMENT

The Tri-Council, representing the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) stipulates its requirements for the ethical conduct for research involving humans in its Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014).

All research conducted by and at New Brunswick Community College (NBCC) that involves human participants shall comply with the standards established in the Tri-Council Policy Statement (TCPS2 2014). This includes: all research involving human participants conducted by staff and students of NBCC; research carried out on College premises or using College resources; research conducted elsewhere under the auspices of the College; as well as research conducted by external researchers at the College.

Guiding Principles

NBCC supports the ethics principles outlined in the TCPS2 (2014) - Tri Council Policy Statement: Ethical Conduct for Research Involving Humans. "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." In the TCSP2 (2014), respect for human dignity is expressed through three core principles:

Respect for Persons - recognizes the intrinsic value of human beings and the respect and consideration that they are due

Concern for Welfare – involves the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental, and spiritual health, as well as their physical, economic and social circumstances.

Justice - refers to the obligation to treat people fairly and equitably.

PURPOSE

The purpose of this policy is to ensure that the rights of humans participating in research are respected and that such research is conducted ethically. The scope is restricted to the review and assurance of the ethical conduct of research involving humans.

SCOPE AND LIMITATIONS

Ethics review is limited to research involving human participants. Research is defined by TCPS2 (2014) as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (Article 2.1). The TCPS2 (2014) further indicates: "It is important to note that choice of methodology and/or intent or ability to publish findings are not factors that determine whether or not an activity is research requiring ethics review" (Article 2.1). Also, according to TCPS2 (2014), "human participants (referred to as "participants") are those individuals whose data, or responses to interventions, stimuli, or questions by the researcher, are relevant to answering the research question" (Article 2.1).

Some research activities involving human participants are out of scope for ethical review. These are detailed in the REB Terms of Reference (in Related Documents). It is important to note here that most continuous improvement evaluations or assessments of the College's program and services are out of scope. "Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review" (TCPS2, 2014, Article 2.5).

1.0 DEFINITIONS

Not applicable.

2.0 ROLES AND RESPONSIBILITIES

2.1 Researcher

The researcher may be a student, staff, faculty, or someone external to NBCC. The researcher or principal investigator is responsible for the conduct of the research, and for the actions of any member of the research team. As such, they are responsible to:

- a) become familiar with applicable ethical guidelines and abiding by these guidelines and the policies of this College
- b) determine whether proposed research requires ethical review. If there is any uncertainly on this point, the researcher should consult with the Chair of the Research Ethics Board (REB)
- c) submit a fully completed application to the REB to request ethical approval
- d) ensure REB approval is received in writing prior to starting the research
- e) abide by all decisions and requests of the REB
- f) obtain free and informed consent from all participants as outlined in this procedure
- g) maintain confidentiality of data as required by the REB
- h) promptly report to the Chair of the REB any injuries to participants, any unanticipated problems which involve risks or unusual costs to the participant, or other adverse events resulting from the research
- i) promptly report to the Chair of the REB any proposed changes in the research or status of the project which would result in a significantly different involvement of participants and wait for REB approval before proceeding with the changes.

2.2 Research Supervisor

A research supervisor is someone supervising the work of a researcher. This may be a senior researcher, department head or instructor supervising students engaged in course-based applied research projects. The role of the supervisor is to ensure the researcher is aware of the policy and procedures to guide the ethical conduct of research involving human participants.

2.3 NBCC Research Ethics Board (REB)

NBCC's Research Ethics Board ensures that research involving human participants conducted by faculty, staff and students of the College, and otherwise conducted under the auspices of the College, respects the rights and assures the well-being of those persons agreeing to be research participants in accordance with the TCPS2 (2014) - Tri Council Policy Statement: Ethical Conduct

for Research involving Humans. NBCC shall establish its Research Ethics Board (REB) in accordance to the TCPS2 (2014). See REB Terms of Reference under Related Documents.

2.4 Application for REB Review of Proposed Research

Applications for REB review for proposed research involving human participants are to be submitted to the Applied Research and Innovation Office prior to any such research being conducted. The Ethics Review Application form can be found under Related Documents.

2.5 Review of Proposed Research

2.5.1 Principle of Proportional Review

The REB will use a proportional approach to the review process based upon the general principle that the more invasive the procedures involved in the research, the more diligent the assessment of the perceived risks inherent in the review. The REB Chair shall review applications to determine the level of review required.

2.5.2 Types of Review

The level of ethical review required for research depends upon the level of potential risk to participants.

- a) Departmental Review is allowed for some research conducted by students as per TCPS2 (2014) Clause 5.3.4.
- b) Delegated REB Review is permitted when there is no more than minimal risk.
- c) Full REB review is required when an ethical review of research is either required due to funding grant requirements or the risk to individuals involved in research is considered to exceed minimal risk.

2.5.3 Departmental Review of Student Research

In accordance with the principle of proportional review, delegates from the student's academic department or faculty may conduct ethics review of minimal risk student course-based research. In cases where student research is viewed as more than minimal ethical risk, application to the REB by the student researcher is required. All departments shall have review procedures in place for research projects involving human subjects.

2.5.4 Delegated REB Review

Applications for research involving no more than minimal risk shall be assigned to an REB member for review.

2.5.5 Full Review

Applications with more than minimal risk, deception, or partial disclosure, and which do not clearly satisfy the consent procedure outlined in the TCPS2 policy Clause 2.1(c) will require Full REB Review.

2.5.6 Reconsiderations of REB Decisions

An applicant has the right to have a negative REB decision reconsidered. Reconsideration shall be done promptly by the REB.

2.5.7 Research Ethics Appeal Committee (REAC)

UNB's REB will act as NBCC's Research Ethics Appeal Committee (REAC) in the event of an appeal.

2.6 Free and Informed Consent

Throughout the process of free and informed consent, the researcher shall ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation.

2.7 Third Party Consent

If potential participants are not legally competent to make an informed decision on consent, a third party, who possesses no conflict of interest with regards to the research and are not part of the research team, may be appointed to make an informed decision on behalf of the participant.

3.0 OTHER RELATED DOCUMENTS

Checklist for Research Involving Human Participants (3303.4896)

Completion Report for Research Involving Human Participants (3303.4761)

Consent to Participate in a Research Project (3303.4650)

Ethics Request for Amendment or Extension (3303.4725)

Ethics Review Application (3303.4652)

Requirements for Informed Consent Forms (3303.4651)

REB Member Manual

REB Process (3303.4838)

REB Reciprocal Agreement

REB Terms of Reference

Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2)