

Nipissing University Terms of Reference For Research Ethics Board

Office of Accountability:	Board of Governors
Office of Administrative Responsibility:	Provost and Vice-President, Academic and Research
Approver:	Board of Governors
Scope:	Ensures compliance with Tri-Council Policy Statement 2 and extends to all members of the University community, as well as external researchers, who conduct research using human participants
Approval Date:	June 2012
Revision Date:	May 2015
Renewal Date:	June 2020
Last Reviewed:	June 2012
Policy Number:	NU-RES-2011.08

PRINCIPLE

The Nipissing University Research Ethics Board (NUREB) operates under the nominal oversight of the Provost and Vice-President, Academic and Research through the Associate Vice-President Academic (PVPAR) and is sanctioned by the Nipissing University Board of Governors.

Evaluation of the ethical aspects of research involving human participants follows the guidelines of the national granting councils - 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) - as set out in the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2)(2014)* <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

Core Principles

The guiding core principles of the TCPS2, which guides NUREB, are respect for persons, concern for welfare, and justice

NUREB balances respect for research and academic freedom with the necessity of protecting the participants.

MANDATE

The mandate of the NUREB is to assess and monitor the **ethical aspects** of all research involving human participants on behalf of Nipissing University, conducted under its jurisdiction by faculty, staff, administration and students, prior to its inception and during its execution. Guided by the TCPS2, NUREB can approve, reject, propose modifications or terminate any proposal for research involving human participants.

NUREB reviews all requests from external researchers seeking institutional approval.

PURPOSE

The purpose of NUREB is:

- I. To fulfill the legal and ethical responsibilities concerning research involving human participants in accordance with the norms and standards developed and refined by the Tri-Councils (CIHR, NSERC and SSHRC) and contained in the TCPS2. The Councils only provide funding to individuals and institutions which certify compliance with this policy.
- II. To review for ethical approval all research projects, funded by granting agencies, external sponsors or by the University, unfunded faculty research, graduate and undergraduate research, and administrative research, in order to ensure that appropriate ethical guidelines are met and regular procedures followed.
- III. To serve the Nipissing University research community as a consultative body and provide public education in research ethics.
- IV. To prepare by October 1, an annual report for submission to the Board of Governors.

AUTHORITY

NUREB is empowered by the Board of Governors to ensure that all research involving human participants is carried out according to the ethical principles set out in the TCPS2.

Nipissing University must ensure that NUREB has the appropriate financial and administrative independence to fulfill its primary duties. The Board of Governors shall approve an annual budget to support the administrative processes and educational activities required by the NUREB including:

- administrative support to maintain all documentation related to NUREB;
- operational costs of the NUREB;
- support attendance to CAREB annual meetings/conferences for the Chair (and/or any other member) of the NUREB.

NUREB has jurisdiction over all research involving human participants undertaken by faculty (including visiting and part-time) researchers, administration, undergraduate and graduate students, as well as all course-based research assignments that require students to collect data from human participants. NUREB approval is required for all such research, regardless of where the research is conducted.

All research involving human participants, including pilot studies, must be formally approved by the NUREB prior to undertaking the research, which means before recruiting participants or accessing the data.

NUREB can reject, propose modifications to, or terminate any proposed or on-going research that does not meet the required standards of ethics in accordance with Nipissing University policy and/or the TCPS2.

TCPS Tutorial Requirement

Any research protocol submitted to NUREB must include proof that the researcher and in the case of students, the faculty supervisor has completed the *Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)* located at <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/> NUREB will only consider protocols that include this proof.

All NUREB members are also required to complete this tutorial.

APPOINTMENTS AND TERMS OF SERVICE

The Nipissing University Board of Governors appoints NUREB members, including the Chair through a fair and impartial process. Recommendations are provided by the NUREB to the PVPAR for appointment by the Board of Governors, taking into account the needed qualifications and expertise. NUREB members shall serve for a three-year term that may be renewed once. When appointing members, the NUREB shall establish their terms to allow for continuity of the research ethics review process.

Membership

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

- a. at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- b. at least one member is knowledgeable in ethics;
- c. at least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
- d. at least one community member who has no affiliation with the institution.

Other NUREB members may consist of:

- one member represents OAI (Office of Aboriginal Initiatives)
- one member who is the Ethics Administrator (non-voting)

Any NUREB member who has a personal interest in a research proposal under review (as principal investigator, co-applicant, advisor or entrepreneur) shall not be present when the NUREB is discussing the application or making its decision, and shall not have a vote on any matter regarding that proposal.

If a NUREB member is found to meet any of the following criteria, s/he *may* be dismissed from NUREB duties and responsibilities upon a recommendation to the Provost and Vice-President, Academic and Research:

- Unexplained absences to meetings;
- Protocol reviews not completed in a timely manner;
- Failure to disclose conflict of interest;
- Systematic and/or repetitive obstruction of NUREB review processes.

MEETINGS AND ADMINISTRATIVE SUPPORT

NUREB shall meet monthly to discharge its responsibilities. These meetings will normally be face-to-face, but participation via videoconference or teleconference or other technologies is permitted, only in limited circumstances (including emergencies and other exceptions cases).

Regular attendance by NUREB members at meetings is important, and frequent unexplained absences should be construed as a notice of resignation.

Quorum will consist of 60% of the members and should meet the minimum requirements of membership representation outlined in the TCPS2, Article 6.4. When there is less than full attendance, decisions requiring full review will be adopted only when the members in attendance have the expertise and knowledge necessary to provide adequate review of the proposals under review.

The Ethics Administrator shall: provide adequate administrative support to enable the Chair to fulfill his/her duties; and maintain all documentation related to the applications submitted, collection of applications and distribution of applications to NUREB members, record attendance, and maintain accurate minutes. The NUREB minutes shall clearly document all decisions, any dissents and the reasons for them.

Application submission dates as well as the schedule of the NUREB meetings will be posted on the ethics website.

RESPONSIBILITIES

NUREB assesses the **ethical acceptability** of a research project through consideration of the foreseeable risks, the potential benefits and the ethical implications of the project.

NUREB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions.

NUREB communicates all decisions on **ethical acceptability**, requests for revision or modification, and/or refusal to researchers through the Romeo system.

Levels of Research Ethics Review

In keeping with a proportionate approach to research ethics review, the selection of the level of NUREB review shall be determined by the level of foreseeable risks to participants: the lower the risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). Minimal risk is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research)

1. Delegated Review:

Where the risk level of the research is minimal (i.e., there is little risk of psychological, physical or social harm), NUREB delegates ethics reviews to two NUREB members. Delegated reviewers may call upon other reviewers within the NUREB or refer projects back to the full

NUREB if they determine that full board review is required or that a protocol is deemed more than minimum risk. Approvals made by delegated reviews are well documented and reported in an appropriate and timely manner to the full NUREB.

- Where reviewers have questions or suggestions with respect to the protocol, *but these do not have an impact on the **ethical viability** of the project*, the reviewers may raise comments/questions for the researcher to consider but, at the same time, deem the protocol to be ethically acceptable.
2. Full NUREB Review:
- Research ethics review by the full NUREB is the default requirement for research involving human participants with a risk level above minimal.

Regardless of the review strategy, NUREB continues to be responsible for the ethical review and monitoring of all research involving humans within the University's jurisdiction.

NUREB review will focus on the ethics of the research applications. Concerns with quality issues or methodologies are warranted when the research methodology appears to interfere with the participants' rights or researchers' rights (safety, privacy, etc.). Ethical assessment shall not be based on methodological biases, a preference for particular procedures or on the judgment that another approach is possible.

Research Exempt from NUREB Review

Some research is exempt from NUREB review where protections are available by other means. The following are exempt from the requirement of NUREB review (TCPS2, Chapter 2, Articles 2.2 – 2.6):

Research that relies exclusively on publicly available information does not require REB review when:

- a. the information is legally accessible to the public and appropriately protected by law; or
- b. the information is publicly accessible and there is no reasonable expectation of privacy.

REB review is not required for research involving the observation of people in public places where:

- a. it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- b. individuals or groups targeted for observation have no reasonable expectation of privacy; and
- c. any dissemination of research results does not allow identification of specific individuals.

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

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 (TCPS2), and do not fall within the scope of REB review.

NUREB Annual Report

The Chair will submit by the 1st of October an annual report to the Provost and Vice-President, Academic and Research who will present the report to the Board of Governors. The report shall include the number of applications reviewed, a generic description of ethics issues/concerns that have been addressed in the past year and, where necessary, recommendations concerning changes to this policy or to the procedures for conducting an ethics review.

Approval vs. Authorization

Ethics approval is granted by NUREB for a one-year period, renewable three times.

NUREB approval does not, by itself, serve as authorization for the research to begin. Researchers are responsible for determining and complying with any other regulatory or legal requirements that may apply to their research.

Ongoing Review

After NUREB has reviewed and approved a research protocol, review and monitoring continue throughout the project.

Final Reports

Researchers are responsible for submitting a Final Report upon completion of their research. Failure to do so may result in new protocols not being considered for review by the NUREB.

Adverse Event / Unanticipated Issues

Researchers are responsible to report to the NUREB, without delay, any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare that was not approved in the original protocol submission. Unanticipated issues may include unexpected reactions by participants to a research intervention (e.g., unintended stimulation of traumatic memories, unforeseen side-effects of a medication or natural health product), as well as unavoidable single incidents. (Refer to TCPS2, Chapter 6, Article 6.15).

Annual Review and Renewal

Multi-year research is subject to an annual renewal process which consists of the submission of a *Request for Renewal of an Approved Protocol* form.

Research protocols may be renewed a maximum of three times. If additional time is required, a new protocol must be submitted.

Modifications

If a researcher requires modifications to an approved protocol, the researcher must submit a *Request for Modifications to an Approved Protocol*. Once NUREB approves the modifications, the researcher can implement those changes to the research protocol.

Undergraduate and Graduate Research

Undergraduates and graduates undertaking any research project involving human participants, such as a major project, thesis or dissertation, must submit a protocol to NUREB.

Faculty supervisors are expected to review their students' applications for ethical compliance and completeness prior to submitting the protocol to NUREB for review.

All communication from the Ethics Administrator will be to both the student and the faculty supervisor.

Course-based Research/Class Assignments

Ethical review of research carried out by students in course-based research assignments (whereby students are required to collect data from human participants) is delegated to the course instructor (faculty member) following approval by a subcommittee of NUREB. The subcommittee is comprised of the Chair, one NUREB member and the Ethics Administrator. A meeting may be scheduled with the course instructor(s) involved to discuss any concerns. If a protocol is determined to be above minimal risk, the protocol would follow a full NUREB review.

Acknowledging NUREB

In disseminating their research approved by NUREB at conferences, in reports and/or publications, researchers may include the following statement: "This research was reviewed and approved by the Nipissing University Research Ethics Board under protocol [number]."

Similarly, if disseminating research that was authorized by another REB, researchers may include the following statement: "This research was reviewed and approved by the [name] Research Ethics Board under protocol [number]."

Conversely, if disseminating the results of any research-like activity involving human participants that falls under NUREB purview, that either did not seek NUREB approval or was reviewed and did not receive NUREB approval, the researcher shall include the following disclaimer: "This research was not approved by a Research Ethics Board."

In addition, if disseminating results of any research, or research like-activity involving human participants or the secondary use of data obtained from human participants that was exempt from NUREB review, the researchers shall include the following statement: "This research was exempt from Research Ethics Board review, under the Tri-Council Policy Statement2."

Research Involving Aboriginal Peoples/Communities

In accordance with the TCPS2, Chapter 9 is designed to serve as a framework for the ethical conduct of research involving Aboriginal peoples <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/>. It is offered in a spirit of respect. It is not intended to override or replace ethical guidance offered by Aboriginal peoples themselves. Its purpose is to ensure, to the extent possible, that research involving Aboriginal peoples is premised on respectful relationships. It also encourages collaboration and engagement between researchers and participants. For assistance with your plan for community engagement, please contact the Office of Aboriginal Initiatives before conducting any research involving Aboriginal peoples/communities/institutions as participants or prior to submitting a protocol for NUREB review.

NUREB will only consider protocols for research involving Aboriginal peoples/communities where a plan for community engagement has been established and approved.

Multi-Centred Research/Institutional Approval

NUREB will conduct an independent ethics review and provide its decision, either concurrently or sequentially to approval by the other REB(s). If NU is not the host/home institution of the PI, approval is required from their host/home institution prior to NUREB approval. The PI must submit a *Request for Institutional Approval* and include their host/home institutions approved protocol, approval letter and all applicable appendices.

Research in other Jurisdictions or Countries

NUREB is responsible for the ethical conduct of research undertaken by Nipissing University faculty, staff or students regardless of the location where the research is conducted. As with all research, NUREB approval does not constitute authorization. Researchers should consult relevant reliable resources for details about governing laws or policies in the jurisdiction or country where the research will be conducted. Please check the following link to ensure you have obtained the required approvals <http://www.hhs.gov/ohrp/international/index.html>

RECONSIDERATION AND APPEALS

Researchers have the right to request, and the NUREB has an obligation to provide, reconsideration of decisions affecting a research project, through deliberation, consultation or advice. **The researcher and the NUREB must have fully exhausted the reconsideration process**, and the NUREB must have issued a final decision before the researcher initiates an appeal.

Nipissing University has signed a formal Memorandum of Understanding – Ethics Appeal Agreement with a cooperating university.

The application for appeal should include:

- A letter from the Researcher justifying his/her reasons for requesting the appeal;
- The original ethics application submitted; and
- Documentation outlining the NUREB's decision (minutes, REB reviews, etc.).

The Ethics Administrator will be responsible for forwarding the above documentation to the Appeal Committee within thirty (30) days.

Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement 2. The decision of the Appeal Committee shall be binding. The Appeal Committee shall forward a report summarizing their findings and recommendations within 30 days of their decisions to the Ethics Chair of the other institution's REB.

APPROVED