

## Nipissing University Terms of Reference For Research Ethics Board

<b>Office of Accountability:</b>	Board of Governors
<b>Office of Administrative Responsibility:</b>	Vice-President, Academic and Research
<b>Approver:</b>	Board of Governors
<b>Scope:</b>	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
<b>Approval Date:</b>	June 2012
<b>Renewal Date:</b>	June 2014
<b>Last Reviewed:</b>	
<b>Policy Number:</b>	NU-RES-2011.08

### PRINCIPLE

The Nipissing University Research Ethics Board (NUREB) operates under the nominal oversight of the Vice-President, Academic and Research 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 (2010) (TCPS2)*.

### 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, sanction 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. Researchers do not require institutional approval, so long as participants are advised that the research has not received such approval and are warned of any consequent risks.

## **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 contribute to 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 Office of the Vice-President, Academic and Research shall provide 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 meetings, including travel costs for the community member(s) or any external experts required;
- 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.

The Vice-President, Academic and Research has the authority to refuse permission to open a research account, to access university controlled funds or to impose any other sanction to researchers who are not compliant with this policy or the TCPS2.

### **TCPS Tutorial Requirement**

Effective August 31, 2012, any new research protocol submitted to NUREB must include proof that the researcher has completed the *Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)* located at <http://tcps2core.ca/welcome>. Effective August 31, 2012 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 on the recommendation of the Vice-President, Academic and Research. 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 of at least five members, including both men and women, of whom:

- at least two members have expertise in relevant research disciplines, fields and methodologies covered by NUREB;
- at least one member is knowledgeable in ethics;
- at least one member is knowledgeable in the relevant law (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
- at least one community representative who has no affiliation with Nipissing University.

Each NUREB member is asked to propose the name of a substitute NUREB member for nomination by the Vice-President, Academic and Research so that the NUREB can continue to function in the case of an extended absence (e.g. sabbatical, illness, parental leave).

The Chair is appointed by the Vice-President, Academic and Research on the recommendation of the NUREB members, for a two-year term, which is renewable twice.

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 Vice-President, Academic and Research:

- Unexplained absences to meetings;
- Protocol reviews not completed in a timely manner;

- Fails to disclose conflict of interest;
- Systematic and/or repetitive obstruction of NUREB review processes.

## **MEETINGS AND ADMINISTRATIVE SUPPORT**

NUREB shall meet a minimum of ten (10) times per academic year to discharge its responsibilities. These meetings will normally be face-to-face, but participation via videoconference or teleconference or other technologies is permitted, where necessary.

NUREB meetings shall take place approximately two (2) weeks after submission of applications.

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 a majority vote will determine each decision. The Chair may only vote in the case of a tie.

The Ethics Coordinator 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, including risks to researchers, the potential benefits and the ethical implications of the project. NUREB uses a proportionate approach to review based on the general principle that the more invasive the research, the greater the care in assessing the research, and correspondingly more protection given to human participants.

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 by electronic means.

## **Levels of Research Ethics Review**

1. Delegated Review:
  - Where the risk level of the research is minimal, 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. Where delegates consider a negative decision (i.e., one that would refuse ethics approval), the decision shall be referred to the full NUREB for review and endorsement before communicating the decision to the researcher.

- Where both reviewers approve the protocol, it is approved without waiting for a meeting of the full REB.
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.

### **NUREB Annual Report**

The Chair will submit by the 1st of October an annual report to the 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.

### **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 three times.

## **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 screen their students' applications for ethical compliance and completeness prior to submitting the protocol to NUREB for review.

The NUREB Coordinator will correspond with 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 the Faculty Ethics Review Committee (FERC). FERC is a subcommittee of NUREB, comprised of the Chair, one NUREB faculty member and the Ethics Coordinator. A meeting is 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. Discussions are recorded by the REB Coordinator.

## **Acknowledging NUREB**

In disseminating their research at conferences, in reports and/or publications, researchers shall 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 shall 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 REB purview, that either did not seek REB approval or was reviewed and did not receive REB approval, the researchers 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 REB review, the researchers shall include the following statement: "This research was exempt from research ethics board review, under the second edition of the Tri-Council Policy Statement."

## **Quality Assurance, Quality Improvement, Program Evaluation, Testing**

Certain research-like activities are exempt from REB approval.

Where such data are later proposed for research purposes (as secondary use of data), researchers shall first obtain NUREB approval.

### **Research Involving Aboriginal Peoples/Communities**

Researchers are required to contact the Office of Aboriginal Initiatives <http://www.nipissingu.ca/departments/aboriginal-initiatives/Pages/Contact-Us.aspx> before conducting any research involving Aboriginal peoples/communities/institutions as participants.

When submitting a protocol for ethics review, researchers are required to include the following:

- acknowledgement from the Office of Aboriginal Initiatives;
- Aboriginal community/institutional authorization;
- Intellectual Property Agreement (where deemed appropriate by the Aboriginal community/institution).

NUREB will only consider protocols for research involving Aboriginal peoples/communities that include the above items.

Any *Request for Modification* to an approved protocol involving research with Aboriginal peoples/communities/institutions as participants requires prior acknowledgement from the Office of Aboriginal Initiatives and additional Aboriginal community/institutional authorization.

### **Multi-Centered Research**

NUREB will conduct an independent ethics review and provide its decision, either concurrently or sequentially to approval by the other REB(s).

### **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.

### **RECONSIDERATION AND APPEAL BOARD**

Nipissing University may not override a NUREB decision to reject a research protocol.

Researchers have the right to request, and the NUREB has an obligation to provide, reconsideration of decisions affecting a research project. This includes a reasonable opportunity to meet with the NUREB, an explanation of the reasons for opinions or decisions, and written grounds for the decisions.

When a researcher does not receive NUREB approval or where the researcher has legitimate grounds for opposing NUREB's conditions of approval, the researcher has the right to appeal.

In such cases, researchers must notify the Ethics Coordinator, who shall provide a name and contact information for the Appeal Board.

Nipissing University has signed a formal ethics appeal agreement with a cooperating university in order that the Research Ethics Board of that institution can act as the Appeal Board.