



## **RESEARCH ETHICS BOARD**

### **TERMS OF REFERENCE**

The Nipissing University Research Ethics Board (NUREB), as created by the Board of Governors of Nipissing University, is responsible for overseeing all matters related to research involving human participants undertaken by the members of the University community for teaching and/or research purposes. Nipissing University endorses the principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (1998)* (TCPS).

The guiding ethical principles of NUREB are, respect for free and informed consent, protection of vulnerable persons, privacy and confidentiality, justice and inclusiveness, and balancing harms and benefits (assessing minimal risk of research). They reflect shared fundamental values that are expressed in the duties, rights, and norms of those involved in research. Research participants reasonably expect that their rights shall be equally recognized and respected, regardless of the discipline.

#### **A) PURPOSE**

The purpose of the NUREB is:

1. 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-Council (CIHR, NSERC and SSHRC) and contained in the TCPS. The Councils only provide funding to individuals and institutions which certify compliance with this policy.
2. 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.
3. To review and recommend policies and procedures to the Administration on research involving human participants, including policies concerning conflict of interest and academic integrity, ensuring that policies remain current.
4. To serve as an advisory board to the Vice-President, Academic and Research on matters related to ethical conduct in research and academic activities.

5. To serve the research community as a consultative body and to contribute to education in research ethics.
6. To prepare at the end of the academic year an annual report for submission to the Board of Governors.

## **B) AUTHORITY OF THE NUREB**

Authority for ethics review follows from this policy document as approved by the Board of Governors of Nipissing University within the Office of the Vice-President, Academic and Research. NUREB is empowered by the Board of Governors to ensure that all research involving human participants is carried out according to the ethical principles adopted by Nipissing University. Nipissing University is accountable for the research carried out in its own jurisdiction or under its auspices.

NUREB has jurisdiction over all research<sup>1</sup> involving human participants undertaken by faculty including visiting and part-time researchers, as well as over all course-based research or class assignments that require students to collect information from human participants. NUREB approval is required for all research involving humans that is conducted by any of its employees, at any time, whether or not that research involves University resources and whether or not it occurs under the auspices of Nipissing University.

All research projects involving human participants must be formally approved by the NUREB prior to undertaking. NUREB can also reject, propose modifications to, or terminate any proposed or on-going research that does not meet the required standards of ethics in accordance with the University policy. Nipissing University may not override NUREB decisions reached on the grounds of ethics. Following NUREB decisions, 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 do not comply with this policy.

Nipissing University may not override negative NUREB decisions reached on the grounds of ethics without recourse to the designated appeal board. Nipissing University is accountable for the research carried out in its own jurisdiction or under its auspices.

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<sup>1</sup> Research is any original and systematic investigation undertaken in order to increase knowledge and understanding and to establish facts and principles. It comprises the invention of ideas and generation of knowledge that lead to new and substantial improved insights and/or the development of new materials, devices, products and processes. It should have the potential to produce results that are sufficiently relevant to increase knowledge. Good reflective inquiry produces theories and hypothesis and benefits any intellectual attempt to analyze facts and phenomena. This search for individual facts or data requires an open-ended question for which there is no ready answer. Data is gathered through experiments, surveys or other methodologies.

## **C) APPOINTMENTS AND TERMS OF SERVICE**

Nipissing University Board of Governors appoints NUREB members on the recommendation of the Vice-President, Academic and Research. NUREB members shall serve for three-year terms that may be renewed once. Members may be eligible for re-appointment after an interval of one year. Initially, appointments shall range from two to four years to allow for continuity of membership. NUREB membership is the responsibility of the Vice-President, Academic and Research.

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.

## **D) MEMBERSHIP**

The NUREB shall consist of at least eight (8) members to include the following:

- Six (6) faculty members with broad expertise in the methods or in the areas of research covered by NUREB, and representing both genders
- At least one (1) community representative with no formal affiliation with the University
- The Director of Research Services (ex-officio, non-voting)
- NUREB Coordinator (non-voting)

Each NUREB member is asked to propose the name of another faculty member who could be, if need be, recommended for nomination by the Vice-President, Academic and Research in the case that the NUREB member is unable to carry on his/her duties. Alternates are usually selected considering past experience with ethics review. They have served on NUREB or on another university Research Ethics Board. They do not replace NUREB members time to time at a meeting. Only in exceptional circumstances are they replacing a member (on sabbatical year/half year, long term illness) since some members do not want to resign while on sabbatical or ill.

The Chair will be appointed by the Vice-President, Academic and Research on the recommendation of the NUREB members, for a two (2) year term, renewable twice.

At least one (1) member should be knowledgeable in the field of ethics. All NUREB members are required to complete the *Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* located at [www.pre.ethics.gc.ca/english/tutorial/](http://www.pre.ethics.gc.ca/english/tutorial/). The NUREB shall have access to a legal expert who will sit on the NUREB only for specific research projects. The institution's legal counsel could not be a member of the NUREB. The NUREB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that on the NUREB.

For details on membership requirements see the TCPS, Section 1 (Article B2).

The Vice-President, Academic and Research may forward to the Board of Governors a NUREB recommendation for the dismissal of a NUREB member if it is determined that the member is unable to carry out his/her duties and responsibilities. The criteria that NUREB would use for dismissal are:

- Unexplained absences to the meetings
- Review of protocols not done in due time for the meeting
- Omit to disclose conflict of interest
- Systematic and repetitive obstruction of the NUREB review process

## **E) MEETINGS AND ADMINISTRATIVE SUPPORT**

NUREB shall meet at least ten times a year to review all ethics applications. Face-to-face meetings are essential for adequate discussion of research proposals and for collective education of the NUREB. Deadline dates to submit applications should be posted on the ethics web site as well as the schedule of the NUREB meetings. NUREB meetings should take place no later than 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. Where feasible the NUREB shall operate by consensus. A quorum will consist of 60% of the board members and a majority vote will determine decision, with the chair only voting in the case of a tie.

Minutes of all NUREB meetings shall be prepared and maintained by the NUREB Coordinator. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes shall clearly document the NUREB decisions and any dissents, and the reasons for them. Failure to do so may expose researchers and institutions to legal liability. The proceedings and deliberations of the NUREB are strictly confidential. Confidentiality shall apply to NUREB files including application forms, attachments and their content, names of applicants and correspondence with applicants.

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

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:

- Collection of submissions and distribution of applications to NUREB members
- Keeping minutes of NUREB meetings
- Operational costs of the NUREB meetings, including travel costs for the community member or any external experts required
- Storing submissions and related materials in a secure location
- Supporting attendance to CAREB annual meeting and NCEHR conference for the Chair (and/or any other member) of the NUREB

## **F) CERTIFICATION PROCESS**

### **Proportionate Approach to Ethics Assessment:**

The NUREB will use a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research, and correspondingly more protection given to the human participants. Refer to TCPS, Section 1, (Article.1.6).

In practice, proportionate review implies different levels of NUREB review for:

- Research protocols involving no more than minimal risk
- Research protocols that raise ethical concerns or ethical issues
- Renewals of the ethical approval certification for on-going research projects without significant change
- Renewals of certification for courses without significant change

The NUREB members will normally focus on discussing the ethics of the research protocols. They will be concerned with quality issues or methodologies when the research methodology appears to interfere with the participants' rights or researchers' rights (safety, privacy, etc.). Ethical assessment would not be based on methodological biases, a preference for particular procedures or on the judgment that another approach is possible. Scholarly merit, quality and method of a research project will enter NUREB deliberations only for research above the minimal risk level.

The NUREB Coordinator verifies that protocols are complete before sending them to the Chair who makes a first general assessment of the protocols. The Coordinator then forwards the completed protocol(s) involving no more than minimal risk to two members for review. Protocols involving more than minimal risk are sent to all NUREB members. The members send their comments after reviewing the protocols and the comments are included in the minutes of the full NUREB meeting. At the meeting the reviewers present their comments and after discussion NUREB members make the decision to approve, ask the applicant for more information/changes or reject the protocol. The NUREB may invite the researcher to participate in such discussions, as they are an essential part of the educational role of the NUREB. The formal decision on whether to allow the research or to require modifications is often preceded by extensive discussion of ethical concerns. In the event that a minority within the NUREB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be

made to reach consensus. When the NUREB is considering a negative decision, the NUREB Coordinator will provide the researcher with all the reasons for doing so and NUREB will give the researcher an opportunity to resubmit a modified protocol and/or to reply before a final decision is made at the next NUREB meeting. If NUREB members recommend approval the NUREB Coordinator will then prepare a certification letter for the Chair to sign.

**Letters of Certification:**

All letters of certification are signed by the Chair of the NUREB and are issued upon NUREB approval. Letters of Certification are valid for one (1) year and indicate the expiration date in which the *Final Report* or *Request for Renewal* is due.

**Annual Reviews and Renewals of Certification:**

Ongoing research is subject to an annual renewal process which consists of the submission of a *Request for Renewal of an Approval Protocol* form to [ethics@nipissingu.ca](mailto:ethics@nipissingu.ca). Renewals are discussed at full NUREB meetings.

**Modifications:**

If the research plan or research protocol requires changes/revisions/modifications, submission of a *Request for Modifications to an Approval Protocol* form to [ethics@nipissingu.ca](mailto:ethics@nipissingu.ca) is required.

**In Principle Review:**

NUREB can issue “in principle” approval of research protocols for activities up to the start of the work involving human participants. Researchers should subsequently inform the NUREB of the date on which they anticipate commencing work with human participants and seek the appropriate ethics approval by submitting a full protocol.

**Procedures for Class Assignment:**

In accordance with the TCPS, Section 1, B3 (Article 1.4), ethics review of research carried out by students in a course-based research or assignment that requires students to collect information from human participants is delegated to the Faculty concerned, with the following exceptions for which NUREB review and approval is required:

- Research involving more than minimal risk
- Research which forms part of a faculty member’s research program
- Research for an honours or thesis project

The **Faculty Ethics Review Committee (FERC)** (a subcommittee of the NUREB) shall be composed of no fewer than four (4) members including the following:

- Chair of the NUREB
- NUREB member from the Faculty
- NUREB Coordinator
- And the course instructor

The FERC is consistent with regular NUREB committee meetings, follows the same procedures and is in compliance with the TCPS.

The instructor completes a protocol for the class assignment, and submits it to the NUREB Coordinator at [ethics@nipissingu.ca](mailto:ethics@nipissingu.ca) who will forward it to the Chair. The Chair forwards the protocol to one other NUREB committee member for review. The Coordinator will schedule a meeting for the Chair, NUREB member, course instructor, and the NUREB Coordinator to discuss any concerns with the protocol for the course assignment. If a protocol was determined to be above minimum risk, the protocol would go for full NUREB review. *The NUREB Chair is to facilitate this without compromising the comprehensiveness of the review.* Minutes are taken by the NUREB Coordinator and records are kept following the same procedures that apply to the full NUREB.

### **Student Research:**

Students undertaking research involving human participants for the purpose of completing an Honours thesis or a Master's degree must submit a protocol to the NUREB.

*Faculty supervisors must screen their students' applications for ethical review and completeness prior to submission to NUREB.* Any incomplete application(s) or application(s) that does not conform to stipulated requirements will not be sent for review to the NUREB members. Students' protocols follow the same certification process as used for researchers' protocols.

When the NUREB is considering a negative decision or requires changes to a protocol, the NUREB Coordinator will provide both the student and the supervisor with all the reasons for doing so. The NUREB will give the student an opportunity to resubmit a modified protocol and/or to reply. If NUREB members recommend approval the NUREB Coordinator will then prepare a letter of certification for the Chair to sign.

### **Review of Multi-Centered Research:**

To facilitate coordination of ethics review between NUREBs, the researcher should distinguish in the protocol between the shared core elements of the research project and those elements that are specific to his/her research and need to comply with his/her own institution's requirements.

### **Review of Research in other Jurisdictions or Countries:**

Nipissing University is responsible for the ethical conduct of research undertaken by its faculty, staff or students regardless of the location where the research is conducted. Thus, review by NUREB of research involving human participants is required in addition to review by any agency having jurisdiction over the site of the research.

## G) RECONSIDERATION AND APPEAL BOARD

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.

In cases when researchers and NUREB cannot reach agreement through discussion and reconsideration, Nipissing University will permit review of the NUREB decision by the Appeal Board. Researchers must apply in writing to the Vice-President, Academic and Research within two (2) months of a NUREB negative decision. The Vice-President, Academic and Research may refuse to grant an appeal for non-compliance of the proposal with the substance of the TCPS. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS.

Considering the small size of the institution, Nipissing University has signed with Laurentian University a formal ethics appeal agreement (January 2008) in order that the appropriately constituted Research Ethics Board/Committee of one institution can act as the Appeal Board/Committee for the other institution.

**Acknowledgment:** this policy was prepared using excerpts from the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. We also acknowledge our reliance on the Research Ethics policies of Wilfrid Laurier University, UOIT, Laurentian University, UPEI and UNB.