

UNIVERSITY POLICY ON RESEARCH INVOLVING HUMANS

Revised April 2008

Originally Approved by: UNBF Senate 28 November 2000

UNBSJ Senate 29 November 2000

Board of Governors 7 December 2000

This Policy replaces “University Policy on Research and Other Studies Involving Human Participants” of 1975, 1981, 1993 and 1994, and "University Policy on Research Involving Humans" of 1999.

Office of Vice-President (Research)

1. Purpose of this Policy

The purpose of this Policy is to ensure that the rights of human subjects¹ participating in research are respected, and to ensure that such research is conducted ethically.

2. Compliance with Tri-Council Policy

All research within the University which involves human subjects, and all such research directed by University personnel but carried out at other sites, shall comply fully with the standards established by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, as stipulated in the Tri-Council Policy Statement “Ethical Conduct for Research Involving Humans” of 1998², as amended, hereafter referred to as the “Tri-Council Policy”.

Questions concerning compliance shall be referred to the appropriate University Research Ethics Board³ (REB) for consideration: the REB may refer to policy interpretations issued by the Councils, or consult with the National Council on Ethics in Human Research (NCEHR) and/or the Research Ethics Officers of the Granting Councils as needed.

All persons undertaking research involving humans are required to indicate that they have read, and agree to comply with, the Tri-Council Policy.

¹ To facilitate reference to the Tri-Council Policy Statement, the present document uses the terminology adopted in that Statement. See the Tri-Council Policy, endnote to the Introduction, for discussion of the use of the term “subject” in preference to “participant.”

² Copies of the Tri-Council Policy may be obtained from MRC, NSERC or SSHRC: it is available also at the websites of the Councils: www.mrc.gc.ca, www.nserc.ca, and www.sshrc.ca.

³ In previous UNB ethics policies the term used was University Ethics Review Committee.

2.1 Scope of Research Requiring Review

Review and approval by the REB is required before any research involving human subjects is initiated. Details of the scope of research requiring review, and exemptions for certain classes of research, are given in the Tri-Council Policy, Section 1 and Appendix 1. In this context, quality assurance studies, performance reviews or testing within normal educational requirements are not considered to be research.

2.2 Principles

Research involving humans is to be carried out with respect for human dignity, for free and informed consent, for vulnerable persons, for privacy and confidentiality, for justice and inclusiveness, and for the need to balance harms and benefits. For discussion of these principles see the Tri-Council Policy, particularly "Context of an Ethics Framework" Section C "Guiding Ethical Principles", and Section 2 "Free and Informed Consent".

3. Research Ethics Boards

There shall be two Research Ethics Boards, one for the Fredericton campus and one for the Saint John campus. Should the workload for these Boards become excessive, the Vice-President for Research may create additional REBs as necessary, in which case the area of responsibility of each Board shall be specified clearly. The REBs shall make every effort to maintain a common standard, and should meet together from time to time to discuss common concerns.

3.1 REB Jurisdiction Where Research Involves Both Campuses

Faculty research projects will be reviewed by the REB on the campus of the Principal Investigator regardless of where the research will be carried out. Where there are co-investigators on both campuses and no Principal Investigator is listed, the review will be carried out by the UNBSJ REB.

Student research will be reviewed by the REB on the campus of the faculty member supervising the research (or chairing the supervisory committee), regardless of where the research will be carried out.

In all cases, copies of the application and of the review will be provided to the other REB.

3.2 Terms of Reference of the Research Ethics Boards

Research Ethics Boards are established to ensure that research conducted by the faculty, staff and students of the University, and research otherwise conducted under the auspices of the University, respects the rights and assures the well-being of those persons agreeing to be research subjects, and that such research conforms to the Tri-Council Policy.

The REBs shall have full authority, on their respective campuses, to approve, require modification to, or reject proposed research, and to require modification to or cessation of ongoing research, on the grounds of non-compliance with this Policy.

The REBs shall review and assess proposed and ongoing research involving human subjects, to ensure compliance with the Tri-Council Policy. In this activity, the REBs shall follow the procedures and policies specified in Section 1 of that Policy.

Where proposed or ongoing research is deemed not to comply with the Tri-Council Policy, the REBs shall propose appropriate modifications, in consultation with the principal investigator where feasible.

In addition, the REBs shall be responsible for

- monitoring issues and concerns generally relevant to the ethical conduct of research;
- appraising such issues and concerns for their relevance to research at the University;
- apprising the Senate and the Vice-President (Research) of developments relevant to the work of the University; and
- advising the Senate and the Vice-President for Research with respect to the development of appropriate policies and procedures to ensure and support the ethical conduct of research at UNB.

3.3 Appointment of REB Members

The Chair and members of each Research Ethics Board shall be appointed by the Board of Governors upon the recommendation of the Vice-President (Research) and the appropriate

Senate.

3.4 Term of Office

The normal term of office for REB members is three years, with no more than one-third being replaced each year: shorter or longer terms may be necessary from time to time. Members may not serve more than six consecutive years, but are eligible for re-appointment after an interval of one year.

3.5 REB Membership

Each REB shall have at least the following membership (total membership being at least five):

- one member knowledgeable in ethics;
- one member knowledgeable in relevant law;
- two members from faculties normally conducting research involving humans;
- one community representative (two if the total membership exceeds five).

For details of membership requirements see the Tri-Council Policy, Section 1.B2.

3.6 REB Meetings

The REBs shall meet regularly, to review research applications and to discuss issues pertaining to their mandate. Minutes of the meetings shall document clearly all decisions of the REB in reviewing research applications; reasons for rejection of applications shall be recorded with particular care.

3.7 Records

Minutes of REB meetings, as well as processed applications, shall be kept in the Office of Research Services (Fredericton Campus) or the office of the Chair of the REB (Saint John Campus), where they shall be made available to applicants upon request.

3.8 Confidentiality of the Research Ethics Board Process

The proceedings and deliberations of the Research Ethics Board are strictly confidential. Confidentiality shall apply to the following:

- i. Ethics Application forms and their contents
- ii. Attachments (and their contents) to Ethics Application forms
- iii. Oral and written deliberations of the REB
- iv. Oral and written decisions of the REB
- v. REB files
- vi. REB minutes
- vii. Names of applicants
- viii. Correspondence with ethics applicants (i.e., researchers)
- ix. Other matters as may be identified by majority decision of the REB

3.9 Report to Senates

Each REB shall report annually to the appropriate Senate, providing a summary of its work and of major issues which arose during the year.

4. Application Procedure for REB Review of Proposed Research

Applications for REB review of proposed research shall be submitted to the *office of the Chair of the Research Ethics Board on the appropriate campus*.

Each application must be accompanied by an endorsement from the researcher's department or faculty indicating that the proposed research has been reviewed according to procedures approved by the department or faculty and conforms in all respects to the generally accepted standards for the ethical conduct of research in the field or discipline concerned. Where a departmental ethics review committee has been established, the application may be signed by the chair of that committee. Otherwise, the signature of the department chair or faculty dean is required.

Any unresolved issues or concerns identified by the department or faculty must be drawn to the attention of the REB.

5. Review of Proposed Research

5.1 Review Considerations

A primary consideration in reviewing any research involving humans is the adequacy and appropriateness of the procedures used to ensure fully informed choice by potential subjects. This topic is discussed in detail in the Tri-Council Policy, Section 2.

Review of research by the REB also shall involve consideration of the magnitude and distribution of benefit and harm, and the balance between them. In assessing the probable benefit of research which involves more than minimal risk of harm, the REB must satisfy itself that the research design is adequate. For detailed discussion of this aspect of review, see the Tri-Council Policy, Section 1 subsection C2.

5.2 Proportionate Review

The level of review required for research depends upon the risk of harm in that research. **Full REB Review** is required for research where there is greater than minimal risk⁴ and for research which involves deception or incomplete disclosure; **Expedited Review** is allowed where there is no more than minimal risk; and **Departmental Review** is allowed for some research by undergraduate students (see Clause 5.3.4).

5.3 Review Procedures

The REB Chair shall review the application to determine whether it involves more than minimal risk to subjects and whether it involves deception or incomplete disclosure. If not, unless the applicant has indicated a preference for review by the full REB, the application shall be referred for **Expedited Review**. If more than minimal risk, or deception or partial disclosure is involved, copies shall be made and distributed to REB members for **Full REB Review** at the next regularly scheduled REB meeting.

5.3.1 Scholarly Review

"Scholarly Review" in the context of this document refers to the process of determining whether the design of a research project is "capable of addressing the questions being asked in the

⁴ For the definition of minimal risk see the Tri-Council Policy, Section 1, subsection C1.

research", as required by Article 1.5 of the Tri-Council Policy. The procedure for scholarly review will vary depending on the degree of risk and the discipline(s) involved in the proposed research.

Projects that have been approved through a peer review process shall normally be deemed by the Board to meet the required standards of scholarly merit.

For student research projects of no more than minimal risk, the required departmental or faculty approval shall normally be accepted as assurance that the research design is adequate.

Research projects in the Humanities or Social Sciences, which are deemed not to pose more than minimal risk, shall not be subject to scholarly review by the Board.

For faculty research projects in other disciplines, which are deemed not to pose more than minimal risk, and which have not been approved through a peer review process, the adequacy of research design shall be a consideration in the REB review process. When the Board feels a need for advice concerning the research design, it may consult persons with appropriate expertise.

Regardless of the discipline, for research projects deemed to pose more than minimal risk, which have not been approved through a sanctioned peer review process, the applicant shall be asked to recommend two reviewers of suitable competence. The Board shall consult with these and/or other persons to determine whether the research design is capable of addressing the questions asked in the research.

5.3.2 Expedited Review

The person(s) designated by the REB to conduct expedited review (this may be the Chair) shall read the application and determine whether the proposed research is

- (a) acceptable as submitted, in which case approval shall be issued and a summary of the case prepared for REB members and included in the minutes of the next regular meeting of the REB, or

- (b) acceptable with minor modifications, in which case the applicant shall be consulted concerning appropriate modifications and, if these are accepted, approval shall be issued and a summary of the case prepared as above, or
- (c) not acceptable without consideration by the full REB, in which case the application shall be copied and distributed to all members of the REB for consideration at the next regularly scheduled meeting.

An application cannot be rejected without consideration by the full REB.

5.3.3 Full REB Review

Full REB review must take place in a face-to-face meeting of the Board: an exchange of notes or a poll by telephone or e-mail is not acceptable. Full attendance is highly desirable. A quorum shall be defined as attendance that meets the requirements of Article 1.3 of the Tri-Council Policy.

If the applicant has requested an opportunity to meet with the REB, or if any REB member requests that the applicant be present, the applicant shall be invited to attend the REB meeting for initial discussion of the proposed research and to respond to questions by REB members. (The applicant may not be present when the REB is making its decision).

The REB may determine that the proposed research is

- (a) acceptable as submitted, in which case approval shall be issued;
- (b) acceptable with modifications, in which case the applicant shall be consulted concerning appropriate modifications and, if these are accepted, approval shall be issued, or
- (c) unacceptable, in which case the applicant shall be advised and reminded of the right to have an application reconsidered.

Where feasible the REB shall operate by consensus. In the event that consensus cannot be attained, a 2/3-majority vote shall be required to approve or reject a research project. When a decision is reached by voting, the position(s) of those disagreeing with the majority decision shall be communicated to the applicant.

5.3.4 Departmental Review of Undergraduate Research

In accordance with Article 1.4 of the TCP, ethics review of research carried out by undergraduate students is delegated to the department or faculty concerned, **with the following exceptions for which REB review and approval is required:**

- **research involving more than minimal risk,**
- **research which forms a part of a faculty member's research program, or**
- **research for an honours or thesis project.**

Departments shall report annually to the REB, giving details of review procedures used and listing all approved research projects.

5.3.5 Review of Ongoing Research

In accordance with the Tri-Council Policy, Article 1.13, ongoing research is subject to ethics review at a level consistent with the level of risk in the research. Minimally, researchers are required to submit a brief report annually and at the conclusion of their research. These reports shall indicate the number of subjects who have participated in the research, any adverse effects observed, and any request for deviation from the approved protocol. Where there is more than minimal risk, the REB may require a more stringent continuing review process in accordance with Section 1.F of the Tri-Council Policy. The REB shall be advised promptly of the conclusion of a research project.

5.3.6 Approval Period for Ethics Application

Ethical approval of research projects shall be for a period of three years from the date of formal REB notification.

5.4 Modifications to Proposed Research

Any request for modification of proposed research, whether by the REB Chair (Expedited Review) or by the Board (Full REB Review), shall include an explanation of why the modification is required, with specific reference to relevant sections of the Tri-Council Policy. Where feasible, such requests shall be discussed in detail with the applicant. The consultative role of the REBs, in assisting researchers to plan research which meets ethical requirements, should receive high priority in allocating resources.

Applications which have been modified to comply with REB requests shall be reviewed by the REB Chair. If it is determined that the REB request has been met, approval shall be issued and the REB members notified. Otherwise, the Chair shall consult with the applicant to attempt to resolve the difficulty. Should this be unsuccessful, the applicant shall be invited to attend the next REB meeting to discuss the matter with the Board.

5.5 Reconsideration of REB Decisions

An applicant has the right to have a negative REB decision reconsidered. Reconsideration shall be done promptly, by the REB responsible for the original rejection. The applicant shall be invited to be present to discuss the application with the REB, prior to decision making. If the decision of the REB, on reconsideration, remains negative, the applicant may file an appeal with the Research Ethics Appeal Board (see Section 5.6).

5.6 Appeals

The University shall establish a **Research Ethics Appeal Board (REAB)** to review cases in which the REB decision, after reconsideration, remains negative. Members of the REAB shall be appointed by the Senates, on recommendation of the Vice-President (Research). Membership and procedures of this Board shall be equivalent in all respects to those of the other REBs. Present members of REBs within the University shall not be eligible for membership in the REAB.

The REAB may not be an ad hoc body created to deal with a single case. The REAB may sustain, modify or reverse a decision of the REB. The decision of the REAB is final, and shall be communicated promptly to the REB and to the applicant.