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## University Policy on Research Involving Humans

Office of Research Services

Policy

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### 1.0 Purpose

- 1.1 The purpose of this Policy is to ensure that the rights of humans participating in research are respected, and to ensure that such research is conducted ethically.
- 1.2 To facilitate reference to the Tri-Council Policy Statement 2<sup>nd</sup> edition (2010), the present document uses the terminology adopted in that Statement. In particular, it uses the term “participant” in preference to “subject”.

### 2.0 Applicability

- 2.1 University-wide

### 3.0 Definitions

- 3.1 For the definition of minimal risk see the Tri-Council Policy, Chapter 2.B. Any unresolved issues or concerns identified by the department or faculty must be drawn to the attention of the REB. [http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)

### 4.0 Implementation

- 4.1 COMPLIANCE WITH TRI-COUNCIL POLICY: All research within the University which involves human participants, 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 second edition of the Tri-Council Policy Statement “Ethical Conduct for Research Involving Humans” of 2010, as amended, hereafter referred to as the “Tri-Council Policy”.
  - All persons undertaking research involving humans are required to indicate that they have read, and agree to comply with, the Tri-Council Policy.
- 4.1.1 SCOPE OF RESEARCH REQUIRING REVIEW: Review and approval by the REB is required before any research involving human participants is initiated. Details of the scope of research requiring review, and exemptions for certain classes of research, are given in the Tri-Council Policy, Chapter 2, Section A. In this context, quality assurance studies, performance reviews or testing within normal educational requirements are not considered to be research.
- 4.1.2 PRINCIPLES: Research involving humans is to be carried out with respect for human dignity, for free and informed consent, for vulnerable persons, for privacy

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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 "Ethics Framework" (Chapter 1).

- 4.2 RESEARCH ETHICS BOARD: 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.

4.2.1 REB JURISDICTION WHERE RESEARCH INVOLVES BOTH CAMPUSES:

- 4.2.1.1 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.
- 4.2.1.2 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.
- 4.2.1.3 In all cases, copies of the application and of the review will be provided to the other REB.

4.2.2 TERMS OF REFERENCE OF THE RESEARCH ETHICS BOARDS

- 4.2.2.1 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 participants, and that such research conforms to the Tri-Council Policy.
- 4.2.2.2 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.
- 4.2.2.3 The REBs shall review and assess proposed and ongoing research involving human participants, to ensure compliance with the Tri-Council Policy. In this activity, the REBs shall follow the procedures and policies specified in Chapter 1 of that Policy.

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- 4.2.2.4 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.
- 4.2.2.5 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
- 4.2.3 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.
- 4.2.4 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.
- 4.2.5 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, Articles 6.4, 6.5 and the commentary.
- 4.2.6 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.

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- 4.2.7 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.
- 4.2.8 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:
- Ethics Application forms and their contents
  - Attachments (and their contents) to Ethics Application forms
  - Oral and written deliberations of the REB
  - Oral and written decisions of the REB
  - REB files
  - REB minutes
  - Names of applicants
  - Correspondence with ethics applicants (i.e., researchers)
  - Other matters as may be identified by majority decision of the REB
- 4.2.9 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.
- 4.3 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.
- 4.3.1 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
- 4.3.2 Any unresolved issues or concerns identified by the department or faculty must be drawn to the attention of the REB.
- 4.4 REVIEW OF PROPOSED RESEARCH
- 4.4.1 REVIEW CONSIDERATIONS: A primary consideration in reviewing any research involving humans is the adequacy and appropriateness of the procedures used to

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ensure fully informed choice by potential participants. This topic is discussed in detail in the Tri-Council Policy, Chapter 3, Section A.

- 4.4.1.1 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, Chapter 1.C and Chapter 2.B.
- 4.4.2 **PROPORTIONATE REVIEW:** The level of review required for research depends upon the risk of harm of that research. **Expedited Review** is allowed where there is no more than minimal risk. **Full REB Review** is required for research where there is more than minimal risk. **Full REB Review** may be required for research that involves deception or partial disclosure, research in which participants lack capacity to decide to participate (Tri-Council Policy Article 3.9), or research that includes participants who have not reached the Age of Majority (nineteen in the Province of New Brunswick). **Departmental Review** is allowed for some research by undergraduate students (see Clause 4.4.7).
- 4.4.3 **REVIEW PROCEDURES:** The REB Chair shall review the application to determine whether it involves more than minimal risk to participants. Applications with more than minimal risk require a **Full REB Review**. Applications involving deception or partial disclosure and which do not clearly satisfy the consent procedure outlined in the Tri-Council Policy, Article 3.7 also require **Full REB Review**. Applications posing no more than minimal risk, but involving participants who may lack capacity or who have not attained the Age of Majority, will be referred for **Full REB Review** if the Chair has reason to believe that participants cannot provide fully informed consent or the procedures for obtaining third-party consent (Tri-Council Policy, Article 3.11) do not appear to meet the standards of Tri-Council Policy, Article 3.11. Decisions reached by the full Board in such cases shall be taken with due regard for issues of capacity described in Tri-Council Policy Articles 3.9 and 3.10, for privacy considerations as discussed in Tri-Council Policy, Articles 5.1 – 5.7, and available interpretations and applications of these articles. The chair may refer all other applications to **Expedited Review**. However, if the applicant requests a **Full REB Review** it will be granted. For a **Full REB Review**, copies of the application shall be made and distributed to the REB members for review, normally at the next scheduled REB meeting.
- 4.4.4 **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

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addressing the questions being asked in the research", as required by Article 2.7 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.

4.4.4.1 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.

4.4.4.2 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.

4.4.4.3 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.

4.4.4.4 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.

4.4.5 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:

- 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
- 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
- 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.

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- 4.4.5.1 An application cannot be rejected without consideration by the full REB.
- 4.4.6 FULL REB REVIEW
- 4.4.6.1 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 6.9 of the Tri-Council Policy.
- 4.4.6.2 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
- acceptable as submitted, in which case approval shall be issued;
  - acceptable with modifications, in which case the applicant shall be consulted concerning appropriate modifications and, if these are accepted, approval shall be issued, or
  - unacceptable, in which case the applicant shall be advised and reminded of the right to have an application reconsidered.
- 4.4.6.3 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.
- 4.4.7 DEPARTMENTAL REVIEW OF UNDERGRADUATE RESEARCH
- 4.4.7.1 In accordance with Article 6.12 of the Tri-Council Policy, 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.

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- 4.4.7.2 Departments shall report annually to the REB, giving details of review procedures used and listing all approved research projects.
- 4.4.8 REVIEW OF ONGOING RESEARCH: In accordance with the Tri-Council Policy, Article 6.14, 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 participants 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 Article 6.14 of the Tri-Council Policy. The REB shall be advised promptly of the conclusion of a research project.
- 4.4.9 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.
- 4.4.10 MODIFICATIONS TO PROPOSED RESEARCH
  - 4.4.10.1 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.
  - 4.4.10.2 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.
- 4.4.11 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



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decision of the REB, on reconsideration, remains negative, the applicant may file an appeal with the Research Ethics Appeal Board (see Section 4.5.7).

### 4.4.12 APPEALS

4.4.12.1 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.

4.4.12.2 The REAB may not be an ad hoc body created to deal with a single case.

4.4.12.3 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.

<http://www.ncehr-cnerh.org/>

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

## 5.0 Interpretation and Questions

- 5.1 Questions concerning compliance shall be referred to the appropriate University Research Ethics Board (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.