

INSTRUCTIONS FOR APPLYING FOR REVIEW OF RESEARCH INVOLVING HUMANS

REVISED FEBRUARY 2009

DO NOT ATTACH THIS SHEET TO YOUR APPLICATION

Application: The application form that follows is an MS Word file that may be edited by the applicant to provide additional space for answers. **It is helpful if material inserted by the applicant is in bold type. Handwritten applications are not acceptable. On the Fredericton campus, completed applications and attachments should be submitted to the Chair, REB, c/o Office of the Vice President (Research); on the Saint John campus, submission should be sent to D.C. Flagel, Chair, UNBSJ REB, Hazen Hall, Rm 100 (506) 648-5645.**

Number of copies required:

- Two (2) copies of the application form;
- One (1) copy of an application for external funding (where applicable);
- One (1) copy of a thesis proposal (where applicable); and
- Two (2) copies of all other attachments.

Applications that do not meet this requirement will be returned as incomplete.

Required attachments: Consult the checklist for a complete list of documents that may be required to be attached to your application.

Electronic Text of Summary: The Research Ethics Board requires submission, by e-mail, of a copy of the Summary of the proposed research (Item 1 on the application form). On the Fredericton campus, this e-mail should be addressed to the Secretary of the REB, Renée Audet-Martel at ethics@unb.ca; on the Saint John campus; it should be addressed to the Chair of the REB, David Flagel flagel@unbsj.ca.

Required Signatures: Please ensure that all required signatures are provided. **In particular, note the requirement for approval by your academic unit.**

Incomplete applications: Incomplete applications will be returned to the applicant without review.

Assistance: For assistance in submitting an application for review consult the Chair of the REB on your campus.

Annual and Final Reports: Forms on which to submit annual and final reports on approved research projects are included at the end of this file. Annual reports are due on 15 January of each year, provided that this date is at least six months after the date of project approval.

A Note about Review Procedures

Applications for research projects which involve no more than minimal risk of harm to research subjects, and which do not involve deception or incomplete disclosure, will normally receive expedited review. Projects ineligible for expedited review, or for which approval was not granted as a result of the expedited review process, are reviewed by the full REB. The status of your application at any time may be determined from the REB secretary on your campus.

FOR REB USE ONLY: **File No.:** _____
Date Complete App'n. Rec'd.: _____
Approved/Approved with.: _____
Modification/Rejected.: _____
Date.: _____

.....

University of New Brunswick
Application for Review of Research Involving Humans

Principal Investigator(s): Name(s); Academic Status (Faculty, Undergraduate Student or Graduate Student); Academic Unit, e-mail Address, Office Telephone, Home Telephone:

Joan Wright, PhD (Joan Wright & Associates), joan@joanwright.ca, (506) 454-7430
 Enrico DiTommaso, PhD (Psychology, UNB, Saint John), rico@unbsj.ca, (506) 648-5636
 Stacey Reading, PhD (Kinesiology, UNB, Fredericton), sreading@unb.ca, (506) 453-4893

Title of Proposed Research:

A Validation of an Experimental Relaxation Protocol: Tension Release Exercises

Commencement Date: June 14, 2011

Completion Date: July 30, 2011

Co-Investigator(s): Academic Unit, e-mail address, Office Telephone

Supervisor(s) (if Principal Investigator is a student); Academic Unit, e-mail address, Office Telephone:

The undersigned parties certify that they have read, and undertake to comply fully with, the Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans."

Principal Investigator(s): _____

Co-Investigator(s): _____

Supervisor(s): _____

The undersigned certifies that the proposed research has been reviewed by, and is acceptable *in all respects* to, the academic unit(s) responsible.

Dean/Director/Chair(s) Typed Name _____

Signature _____

Date submitted to the REB:

1. Summary: Provide here, in approximately 300 words, a summary of the proposed research, indicating clearly the role of the research subjects and any procedures to which they will be subjected.

The proposed research will investigate the effect of Tension Release Exercises (Appendix 1) in accessing the relaxation response by comparing it to an empirically validated progressive muscle relaxation (PMR) protocol pioneered by Goldfried and Davis (1976). PMR has a muscle stretching followed by rest sequence. TRE has a muscle stretching followed by muscle vibration followed by rest sequence. Volunteers will be assessed using the Personality Assessment Screener (Appendix 2) and Medical Questionnaire (Appendix 3). Those with moderate levels of anxiety/stress will be included. Anyone who is using antidepressant or anti-anxiety medication, has muscle or joint ailments or who has a daily practice using either TRE or PMR will not be included as part of the research. They will be offered a mindfulness relaxation protocol for offering to participate. Once the 40 participants have been identified through the screening process, they will be randomly assigned to one of four groups. Group 1 and 2 will each have 10 participants and will receive 5, PMR sessions, one will be led by Robert Jones, MEd, CCC, facilitator A and the other by Diana McLean, MA Psych, Res. In Psych, facilitator B. Group 3 and 4 will each receive 5, TRE sessions, one will be led by facilitator A and the other by facilitator B.

Prior to session 1, after session 3 and following session 5, all participants will be asked to complete the Depression and Anxiety Stress Scale (Appendix 4). For each session, all participants will wear a wrist heart rate measurement device. Measurements will be taken at rest, prior to the exercises and 5 minutes post rest. Likewise, blood pressures will be taken before and after the exercises. In addition, 4 participants will be randomly selected and asked to be monitored by EEG prior to the exercises and following rest.

All sessions will be videotaped from the back of the room to insure privacy for the participants and consistency of adherence to the respective protocols of the facilitators.

Participants will be offered instruction in the relaxation protocol for which they did not receive instruction, following the study.

2. Risk: In your opinion, does this research pose more than minimal risk (Tri-Council Policy, Section 1.C1) to participating subjects? *Yes* *No X*

If yes, provide here a statement that describes in detail the aspects of the research procedure that pose a risk to subjects, and provide your assessment of the risk of harm (probability and severity). Note that not only physical injury but also anxiety or embarrassments are included in the concept of harm. Describe means adopted to minimize risk, and means (such as provision of counseling) to deal with harms, which subjects may experience. Describe as well the potential benefit, which will result from this research, which justifies the above risk of harm.

3. Deception: Does this research involve deception or partial disclosure? *Yes* *No X*

If yes, refer to the Tri-Council Policy, Section 2, specifically Article 2.1(c) and subsequent commentary, and provide here an explanation of how you plan to comply with the requirements of that Section for debriefing. Describe as well the potential benefit, which will result from this research, which justifies waiving the normal requirements for full disclosure.

4. Funding: Has funding been received for this research? *Yes* *No X*

If yes, *from* what agency and for what period?

If yes, *from* what agency and for what period?

5. Research Subjects:

5.1 Number of Subjects: How many subjects will participate in this research? 40

5.2 Recruitment: How will they be recruited, and from what population?

A newspaper ad will run requesting participants, posters will be posted in physicians' waiting rooms, in therapists' waiting rooms and at the local YMCA. We will be accessing an adult population who are experiencing a moderate level of tension/anxiety, who are free of physical ailments of the muscles/joints/bones and who are not taking antidepressants or anti anxiety medication.

(See Appendix 5 for Ad)

6. Informed Consent:

6.1 Informing Subjects: How will the nature of the research be explained to potential subjects, in compliance with Section 2D of the Tri-Council Policy? Attach a copy of any document(s), such as an explanatory letter, to be used for this purpose.

Joan Wright & Associates, in collaboration with the University of New Brunswick (Saint John and Fredericton), are soliciting volunteers to participate in a research project that will assess how two different forms of stretching exercises impact the relaxation response. One type involves stretching/tensing the muscles followed by a rest period. The second type involves stretching/tensing the muscles, followed by vibrating or shaking of leg muscles followed by rest.

We will be asking you to fill out a screening questionnaire to assess your level of tension and stress and a medical questionnaire to assess your physical ability to participate. Following this, you may be assigned to one of the two groups. If you are able to participate, you will be asked to come to five nightly sessions and be led through the exercises. You will be asked to wear a heart rate monitor on your wrist during the sessions so that we can measure your heart rate before and after you do the exercises. Heart rate is a good indicator of how tense or relaxed we are. In addition, before session 1, after session 3 and following session 5, you will be asking you to fill out another questionnaire that will assess your stress. The exercises and filling in the questionnaire will take approximately 1 hour and 15 minutes of your time.

To insure consistency of presentation of the exercises, we will be videotaping the sessions from the back of the room so that only the face of the leader is identified.

Participation is strictly voluntary. You may withdraw at any time. Confidentiality of all results will be preserved during, as well as after, the study. You will only be identified by a number for the purposes of the research to protect your identity. The research results will be kept in a locked filing cabinet for five years after the termination of the study and destroyed thereafter. We are interested in group results only. That is, results will be averaged over all the participants in this study.

Your participation in this study is most appreciated. Should you have any questions, or would like to volunteer to participate, you may contact Dr. Joan Wright at joan@joanwright.ca or 506 454-7430. (see Appendix 6)

6.2 Consent: If written evidence of informed consent will be obtained, attach a copy of the consent form. (See Requirements for Informed Consent Forms.) **If written evidence of informed consent will not be used, explain here, in detail, how you intend to comply**

with the requirements of Section 2A of the Tri-Council Policy: see particularly Article 2.1(b) and subsequent commentary. (See Appendix 7)



EVALUATION OF RELAXATION EXERCISES

Consent Form

Welcome to our study on relaxation. This study is conducted in partnership between Joan Wright & Associates, UNB (Saint John & Fredericton) and the YMCA (Fredericton). The researchers involved in this evaluation are Dr. Joan Wright, Dr. Enrico DiTommaso and Dr. Stacey Read.

This study will look at how two different stretching exercises impact relaxation. One type involves stretching/tensing the muscles followed by a rest period. The second type involves stretching/tensing the muscles, followed by a natural and mild vibration of a leg muscle followed by rest. When the psoas muscle, which is a 13" long muscle anchored in the inner thigh and attaching to the bottom 5 vertebrae, is stretched, a natural vibration results.

You will be asked to attend a pre-screening session to insure that these exercises are safe for you. To determine this, we will ask you to complete a medical history questionnaire and a stress questionnaire. Once it is determined that the exercises are safe for you, you will be assigned to one of the two exercise groups. You will be asked to attend 5 nightly sessions (Monday-Friday) for approximately 1 ½ hours each night.

To compare these types of exercises, we would also like to gather information from several points of view. With your permission, we will administer a brief questionnaire to you before session 1, after session 3, and following session 5. you program, after. We would like to contact you 30 days after the program and have you complete the questionnaire for the last time. The questionnaire will ask about your stress. It will take approximately 10 minutes of your time to complete. For all measures, there is no right or wrong answer and you are free to not answer any question you chose.

Given that stress impacts our heart rate and blood pressure, we will also be asking you to wear a wrist heart monitor (like a wrist watch) to measure your pulse rate during the exercises. Student nurses will be taking your blood pressure before and after the exercises should you give your consent.

Collected information will be stored securely in a locked filing cabinet in the research office of Dr. Joan Wright & Associates. All names will subsequently be removed from the questionnaires once we receive them and these forms will only be identified by means of a random code number. This is to protect your and your confidentiality and privacy.

Only individuals directly involved in collecting and analyzing the data will have access to this information, and only with the permission of the research team. Such individuals will also be required to take an oath of confidentiality prior to accessing the data for evaluation purposes. Five years after the evaluation has been completed, all questionnaires and forms will be destroyed by secure shredding. No personal identifying information will be stored in the database. You have the right to withdraw from participation in the research evaluation at any time.

Because our focus is on evaluating the program, individual results on each person in the program will not be shared because we are not evaluating you as an individual. Our goal is to determine the effectiveness of the new relaxation program. We cannot do this without your help.

If you have any further questions, please contact Dr. Joan M. Wright (506) 454-7430. If you have any concerns about this study and would like to talk to someone not involved in this research, please contact Dr. David Flagel, Chair of the Human Research Ethics Board at the University of New Brunswick-Saint John Campus at (506) 648-5610.

Do you consent to the participation in this study? YES NO

Name: _____

Date: _____

6.3 Children as Research Subjects: If the proposed research involves children as subjects, provide here a statement indicating how compliance with Section 2E, and specifically with Articles 2.5, 2.6 and 2.7 of the Tri-Council Policy, will be achieved.

6.4 Incompetent Adults as Research Subjects: If the research involves adults of diminished competence as subjects, provide a statement indicating how compliance with Section 2E, and specifically with Articles 2.5, 2.6 and 2.7 of the Tri-Council Policy, will be achieved.

7. Inducements: Will any inducements (money, grade points, etc.) be offered to encourage participation? *Yes* *No x*

If yes, indicate here how compliance with Section 2B of the Tri-Council Policy (concerning voluntariness) will be achieved. If academic rewards are to be used, give details of alternative means of achieving equivalent rewards.

8. Private Information: Does the proposed research involve accessing identifiable personal information about subjects by means of surveys, questionnaires, etc.? *Yes x No*

If yes, indicate here, in detail, how you propose to meet the requirements of the Tri-Council Policy, Section 3, specifically Article 3.2. A copy of any questionnaire, survey document or interview schedule to be used should be attached as well.

9. Feedback: Describe the measures, which you propose for providing feedback to research subjects concerning the outcome of the research.

Thank you for taking the time to participate in our research. This study attempted to investigate whether adding muscle vibration to the established protocol of muscle stretching followed by rest, would induce a deeper relaxation. Our main objective was to assess stress levels by self-report measures and heart rate measures to see if vibrating a muscle deep in the inner thigh, the psoas muscle, would lead to a deeper form of relaxation than stretching followed by rest alone.

Stress is believed to contribute to or be the cause of between 60 and 90% of all physicians' visits. The results of this study will help us determine more effective ways to assist people to relax. When people are able to consistently access the relaxation response, they report an increased ability to sleep, eat, think, plan, organize, be social, and feel better.

If you would like more information regarding any aspect of this study, or if you would like to receive a summary report upon its completion, please feel free to contact the researchers. If you have experienced discomfort as a result of your participation, please let the researchers know before you leave or contact them at: (506) 454-7430.

(see Appendix 8 for handout)

10. Data Security: Describe the measures, which you propose for ensuring the security of any identifiable personal data, which will be retained after completion of the research.

All data will be locked in a secure filing cabinet. All data will be identified by a number. The number/name code sheet will be stored in a separate locked filing cabinet.

11. Continuing Review: All research requires brief annual reports and a brief report upon completion of the research. Suitable report forms are included at the end of this file. **Research involving more than minimal risk may require additional measures for continuing review.** If your research involves more than minimal risk, describe here the measures you propose for facilitating continuing review of this research, in compliance with Article 1.13 of the Tri-Council Policy.

12. Additional Information: Please feel free to append any additional information, which you feel may be helpful to the REB in evaluating this application.

Checklist for Attachments to Application for Review of Research Involving Humans

For items that are attached, indicate X; for items that are not applicable, indicate N/A.

Provide the following attachments where applicable:

X or N/A	
N/A	Where the academic unit responsible for the research has a process of formal ethics review , a copy of the approval notice from that process, together with any substantive comments provided by the reviewers.
N/A	If external funding has been sought or obtained for this research, one copy only of the complete application form as well as two copies of any reviewers' comments which have been received.
N/A	For student research , one copy of the full research proposal if one has been submitted to the relevant academic unit.
N/A	A copy of any proposed information letter and/or informed consent form. (Do not duplicate if already included in above material.)
X	A copy of any questionnaire(s), survey documents or interview schedules to be used in the research. (Do not duplicate if already included in above material.)
X	A copy of any debriefing material to be provided to subjects.
X	For research under the jurisdiction of more than one institution , an indication of which other REBs will review the research, and the results of such review if available (see Tri-Council Policy Section 1G).
N/A	For all research (including student research) that exceeds minimal risk, which has not been approved by a sanctioned peer review process , the applicant must recommend two reviewers competent to undertake a "scholarly review" of the proposed research. "Scholarly review" in this context refers to the process of determining whether the design of the research project is capable of addressing the questions being asked in the research.
X	In all cases , a full description of the proposed research, if this is not already contained in the material listed above.
X	In all cases , an electronic text version of the Summary (Item 1 on the application form), via e-mail to ethics@unb.ca on the UNBF campus or to flagel@unbsj.ca on the UNBSJ campus.

Please append this checklist to the application form.

REQUIREMENTS FOR INFORMED CONSENT FORMS

DO NOT ATTACH THIS DOCUMENT TO YOUR APPLICATION

The purpose of an Informed Consent Form is to help to inform the potential research subject about the research and to document the subject's informed agreement to participate. One copy should be given to the research subject, and a copy signed by the subject should be retained in the researcher's files.

An Informed Consent Form must be written in language that the potential subject can understand. It must contain at least the following information:

- A statement identifying the researcher(s). This statement should indicate their affiliation with the University of New Brunswick, and how they may be contacted.
- For student research, the name, affiliation and telephone number of the student's supervisor(s).
- A statement identifying a person not directly involved in the research, for example the Department Chair or Faculty Dean, who may be contacted should the subject have concerns about the research.
- A statement that the reader is being invited to participate in research.
- A clear statement of the purpose of the research.
- A full description of the procedures to be followed in the research (e.g. what is expected of participants, what they will be asked to do, what data will be collected).
- The period of time required for subject participation.
- A statement indicating that participation is voluntary, and that subjects are free to withdraw from the research, and to withdraw any data pertaining to themselves, at any time, without penalty.
- A statement indicating how subjects may receive information as to the outcome of the research.
- Where applicable, a clear description of any potential discomforts and/or risks associated with participation in the research.
- Where applicable, a clear description of the potential benefits of the research, whether to the subject or to others.

- Where applicable, a statement concerning recording of subject participation (audio tape, video tape, photographic records, electronic data recordings, etc.); who will have access to the records, security provisions in storage, possible use in publication, and when they will be erased or destroyed.
- Where applicable, a statement concerning compensation for any injury incurred while participating in the research.
- Where applicable, (for any research involving questionnaires or interviews), a statement informing subjects that they may decline to answer specific questions.
- Where applicable, a statement indicating how confidentiality will be protected.
- Where applicable, a clear explanation of any inducements offered for participation, and of the consequences (if any) on those inducements if the subject withdraws before the research is completed.

Children as Research Subjects:

A parent or legal guardian must provide signed written consent for the participation of children in research. As well, assent of the child is normally required where the child is old enough to understand, and evident dissent is always an indication that the child's participation in the research should be terminated.

When teenaged subjects are considered by the applicant to be competent to consent without parental involvement, the applicant must provide justification for this conclusion.

Incompetent Adults as Research Subjects:

For research involving adults of limited competence, signed written consent must be provided by an authorized third party. As well, assent of the subject is normally required, and evident dissent is always an indication that participation in the research should be terminated.

(A sample consent form consistent with the requirements of the Tri-Council Policy exists on the web site of the National Council for Ethics in Human Research (NCEHR), at www.ncehr-cnerh.org)

University of New Brunswick**Annual Report on Ongoing Research Project Involving Humans**

REB File Number:

Report Date

Project Title:

--

Principal Investigator(s):

Signature(s): _____

Signature(s): _____

Is this Project still ongoing? *Yes* *No*

If yes, what is the estimated completion date?

How many research subjects have participated in this project to date?

Have there been any incidents causing harm to subjects in this project?

(If yes, provide full details for REB consideration).

--

Final Report on Research Project Involving Humans

REB File Number

Report Date

Project Title:

--

Principal Investigator(s):

Signature(s): _____

Signature(s): _____

What was the (approximate) completion date?

How many research subjects participated in this project?

Have there been any incidents causing harm to subjects in this project? *Yes* *No*

(If yes, provide full details for REB consideration).

--

Is it intended that the results be published? *Yes* *No*

(If yes, the REB would appreciate receiving bibliographic data when available).

--

Attach a brief summary of the project. The abstract of a resulting paper, or of a student thesis or report, is acceptable.

UNIVERSITY POLICY ON RESEARCH INVOLVING HUMANS

Revised February 2009

**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 of that research. **Expedited Review** is allowed where there is no more than minimal risk⁴. **Full REB Review** is required for research where there is more than minimal risk, and may be required for research that involves deception or partial disclosure. **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, or whether it involves deception or incomplete disclosure. Applications with more than minimal risk require a **Full REB Review**. Applications with deception or partial disclosure and which do not clearly satisfy the consent procedure outlined in the TCP Article 2.1(c) also require **Full REB review**. 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.

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 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.

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

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.