University of Prince Edward Island
Research Ethics Board
Policy and Procedures

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Preamble

The University of Prince Edward Island endorses the principles set out in the Tri-Council Policy Statement "**Ethical Conduct for Research Involving Humans**" and this document describes how UPEI will apply the Tri-Council policy.

Research is an essential component of the mission of the University of Prince Edward Island and some of this research involves studying human participants. The University has a responsibility to engage in research advancing human knowledge. The use of human beings in the conduct of research confers responsibilities to the investigator(s). It is also the responsibility of the University to promote ethical research.

This policy is intended to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at the University of Prince Edward Island in compliance with the Tri-Council Policy Statement. These ethical standards include respect for human dignity, respect for free and informed consent, respect for vulnerable persons, provision for privacy and confidentiality (for both participants and researchers themselves), respect for justice and inclusiveness, minimizing harm, and maximizing benefit.

Review is available normally only to members of the UPEI research community, researchers in formal collaboration with UPEI members, or for research conducted at UPEI by outsiders. For the purposes of this policy, the term "UPEI research" will be used to refer to all three categories of research. The term "Research" is understood as involving systematic investigation to establish facts, principles, or generalizable knowledge that is intended to be published. It does not include quality assurance studies, performance reviews, or testing within the normal educational requirements, or practicums already covered by professional code of ethics. Developing research skills through activities involving human participants requires departmental level review.

This policy requires that all research projects involving human participants undertaken by members of the university community — including all faculty, staff and students, including students carrying out research as part of class assignments — fall within the jurisdiction of the UPEI Research Ethics Board, irrespective of the source of financial support (if any) and irrespective of the location of the project so long as the investigator represents the work as UPEI research. Research from outside the community that accesses resources or participants at UPEI is also required to undergo review. Review by the Research Ethics Board is also necessary for human remains, cadavers, tissues, biological fluids, etc., taken in routine situations but which are later used for educational purposes.

Research involving naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings would not require REB review if it can be expected that the participants are seeking public visibility.

1.0 Terms of Reference

1.1 Responsibilities:

The University of Prince Edward Island Research Ethics Board (REB) is responsible to the President of the University of Prince Edward Island for:

- developing policies regarding ethical issues relating to the use of human participants in research and experimental teaching protocols;
- reviewing for ethical approval all protocols requiring the participation of human participants;
- reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;
- dealing with matters concerned with human-based research referred to the REB by the President of UPEI;
- preparing an annual report for submission to the President;
- participating in continuing education organized by UPEI research administrators for the University community in matters relating to ethics and the use of human participants

The policies and practices adopted by the UPEI REB will be consistent with the Tri-Council Policy Statement: "**Ethical Conduct for Research Involving Humans**" (current version).

1.2 Composition of REB

The REB shall be made up of no less than 8 members, including both men and women, and include at least:

— two community representatives with no formal affiliation with the University (approximately 1 to 5 ratio)

— five university members with broad expertise in the **methods** or in **areas of research covered by the REB** (research involving human participants or the use of human tissue) in different disciplines.

— one university member with broad knowledge in ethics or experience in the evaluation of ethical implications of research involving human participants.

The balance and composition of the university members on the REB shall be the purview of the President of UPEI.

The Vice-President, Research & Development will serve *ex officio* on the REB.

The REB will have access to a legal expert (other than the University's legal counsel) knowledgeable in the applicable law.

The REB shall require a quorum of at least two thirds of its members (taking into consideration the membership requirements specified above) at all meetings concerned with the ethical approval of research proposals.

The President shall appoint the Chair and determine the length of term for the Chair.

Board members shall serve for three-year terms which normally may be renewed once. Initially, appointments shall range from two to four years to allow for continuity of membership when members are being changed.

The REB membership shall be the responsibility of the President, University of Prince Edward Island, who shall seek advice from the Deans, Vice-President, Research & Development, and the community prior to making appointments to the Board. Members will be selected in accordance with Tri-Council Policy.

1.3 Meetings and Decision-making

The REB shall meet at least once each month to review all protocols requiring the participation of human participants. All research receiving ethical approval through the expedited review process will be reported to the REB by the Chair. Research not delegated to expedited review will be reviewed at the meeting, and the decision to grant ethical approval will be based on a vote. If a vote is not unanimous, the position of those disagreeing will be included in the communication to the researcher. In the event of a tie vote, the matter under consideration will be considered not passed.

An annual schedule of REB meetings will be published.

1.4 Authority

The University endorses the ethical principles cited in the Tri-Council Policy Statement and has mandated its Research Ethics Board (REB) to ensure that all research investigations involving human participants are in compliance with the Statement.

The UPEI REB will have jurisdiction over all research involving human participants. All UPEI research involving human participants will proceed after ethical approval has been

granted by the REB or Departmental Level Ethics Committee in the case of course-based research or assignments that require students to collect information from human participants except practicums already covered by professional code of ethics (see section 2.7).

2.0 Procedural Guidelines for the review of a Research Proposal

2.1 Submission

The basic principle is that all "UPEI research" (as defined in the Preamble) comes under the jurisdiction of the REB. This refers to research involving human participants undertaken by members of the university community — including all faculty, visiting researchers, students, and staff — irrespective of the source of financial support (if any) and irrespective of the location of the project. While it is not necessary for the REB to review a proposal before it is submitted to a funding agency, REB approval must be obtained before the work begins. Visiting researchers should contact the UPEI REB well in advance of the anticipated start date of research. Submissions for review should be submitted to the UPEI REB using the "Ethics Submission Form for Research Involving Human Participants".

2.2 Ethics Review

The effective working of ethics review — across the range of disciplines conducting research involving human participants — requires a reasonable flexibility in the implementation of common principles. This policy, therefore, seeks to express the shared principles and wisdom of researchers in diverse fields. The following standards and procedures will be used by the REB for ethics review:

(a) All research that involves living human participants requires review and approval by the REB in accordance with this policy, before the research is started, except as stipulated below.

(b) Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses should also be reviewed by the REB. Review by the REB is also necessary for such materials taken in routine situations but which are later used for educational purposes.

(c) Research about an individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo

ethics review. Such research only requires ethics review if any participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.

(d) Quality assurance studies, performance reviews or testing within normal educational requirements, or practicum's already covered by professional code of ethics should also not be subject to review.

2.3 Scholarly Review

(a) In case of research proposals that present more than minimal risk, the design of the project must be peer reviewed to assure that it is capable of addressing the question(s) being asked in the research. Sufficient peer review may be considered to be any one of the following:

i. Successful approval by the REB (if research is in the REB's field of expertise).
ii. Successful funding of a grant proposal by a funding agency.
iii. *Ad hoc* independent external peer review reporting directly to the REB.

(b) The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

(c) Research in the humanities and the social sciences which poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

(d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis,* through action in the courts for libel.

(e) Naturalistic Observation: Naturalist observation is used to study behavior in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the human participants do not know that they are being observed, and hence can not have given their free and informed consent. Due to the need for respect for privacy, even in public places, naturalistic observation raises concerns of the privacy and dignity of those being observed. These concerns are accentuated if, for example, the research records permit identification of the human participants, or if the research environment is staged.

(f) In considering research involving naturalistic observation, researchers and the REB should pay close attention to the ethical implications of such factors as: the nature of the activities to be observed; the environment in which the activities are to be observed (in particular, whether it is to be staged for the purposes of the research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the human participants). Naturalistic observation that does not allow for the identification of the human participants, and that is not staged, should normally be regarded as of minimal risk.

2.4 Principle of Proportionate Review

The REB 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.

2.5 Normal Review Process

The REB shall normally meet face to face in order to review submitted research proposals. In case of controversial research proposals, the REB may meet face to face with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but not be present when the REB is making its decision. Minutes will be kept for these meetings by the Office of the Vice President, Research and Development and inserted into the appropriate case files.

The REB shall keep an "open file" in a secure place in the Office of the Vice President, Research and Development for researchers applying for ethical approval. The file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file. It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up to date at all times. When the research project is finished, and the researcher(s) notifies the Office of the Vice President, Research and Development and the UPEI REB, these files shall be "closed" and kept as records demonstrating compliance with the Tri-Council Policy. The files remain the property of UPEI and cannot be removed from the Office of the Vice President, Research and Development by the researchers. These files shall be subject to audit by authorized representatives of UPEI (research administrators), members of Appeal Boards, and funding agencies.

All research receiving ethical approval, whether through the normal or expedited process, as well as that receiving departmental level review shall require a proper file showing compliance with the Tri-Council Policy Statement. Insufficient information in the file is grounds for refusing or delaying ethical approval.

2.6 Expedited Review

Expedited review does not require face-to-face meetings of the REB members. It is usually completed within three weeks of submission of a completed application form. The Chair must report requests for expedited review and results of such reviews to other members of the REB at an appropriate time.

The researcher must choose to apply for expedited or full review and the REB Chair may reject any application for expedited review and refer it to the REB for full review if needed. Expedited review is review by the Chair of the REB and two members rather than the full REB. It is available only in cases which fulfil one of the following criteria:

a) research which obviously involves no more than minimal risk (as defined in the Tri-Council Policy Statement, page *1.5:* "if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk"). Given the heterogeneous nature of subjects, a reasonable person's definition of "minimal risk" as is often employed in the courts concerning subjective harms will also be acceptable to the REB. The researcher is responsible for an acknowledgment of minimal risk to the REB.

b) research projects which have already received approval by the UPEI REB, have complied fully with any requirements, have an up to date file, and the applicant is simply renewing the ethical approval certificate without significant changes to the ongoing research process.

2.7 Departmental Level Review

If human participants are involved in a teaching exercise (i.e., part of an undergraduate or graduate course_ that entails no more than minimal risk, it must be reviewed by a departmental level ethics committee on behalf of the REB and in compliance with the Tri-Council Policy Statement. The Departmental Level Ethics Committee must report results of such reviews to the REB at the end of each academic year.

***Student research deemed to be beyond minimal risk must be reviewed by the REB.

2.7.1 Guidelines for Departmental Honours/ Masters Students

Guidelines were drawn up so as to ensure consistency through Departments at UPEI. Students/Supervisors are required to follow these guidelines for the approval process. All **Honours** students who require ethical approval are required to complete a Departmental review prior to submitting the application to the REB. **Masters** Students are not required to receive Departmental approval prior to submission. **Masters** students however are required to have their ***full*** Thesis Review Committee sign the *Confirmation of Supervisor's Review form* prior to REB submission.

***An exception to the rule exists for Honours Students where at least two members of the Departmental Level review are also on the University REB. In this case students need only submit to the Departmental level review. Currently only the Department of Psychology satisfies this condition.*

2.8 Continuing Ethics Review

(a) Ongoing research shall be subject to continuing ethics review. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers will be asked to include monitoring mechanisms by which the public participating in the research may contact the Chair of the REB. Problems or complaints will be taken seriously by the REB and researchers may be asked to modify their studies in view of such complaints.

(b) Ethics certificates are issued for one year. If the project continues after one year the researcher must submit a completed "Annual Renewal and Amendment Form" to the REB. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue a one-year extension. If in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, re-submission and review by the REB is required.

(c) The REB shall be promptly notified by the researcher when the project concludes.

2.9 REB Conflict of Interest

If an REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making

its decision. In cases of disagreement over conflicts of interest, both the REB member in alleged conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the REB should make a final decision regarding how to proceed.

2.10 Review of Multi-Centred Research

The REB shall review all research proposals as long as the investigator represents the work as UPEI research, regardless of the location where the research is conducted. In multi-centred research, the researcher may wish to distinguish between core elements of the research (which cannot be altered without invalidating the pooling of data from the participating institutions) and those elements that can be altered to comply with local requirements without invalidating the research project. Approval from all centres is required prior to the start of the research project.

2.11 Review of Research in Other Jurisdictions or Countries

Research to be performed outside of the jurisdiction of UPEI or outside of Canada shall undergo ethics review both by the UPEI REB and the REB, where such exits, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

2.12 Review of Research Performed in Emergency Health Situations

The REB will collaborate in the review of Research Performed in Emergency Health Situations with the appropriate hospital research ethics committee where the work is to be conducted. The hospital research ethics committee is best suited to evaluate whether the hospital should support a proposal to use an innovative therapy. They can comment on whether it is the most rational approach for a specific patient (i.e., rather than a proposal to do research per se), and whether sufficient expertise and resources would be in place at the hospital to safely and properly carry out and follow up on the intervention. The REB will collaborate on ethically acceptable consent options for patient enrolment. The REB may allow research that involves health emergencies (as defined in the Consent to Treatment and Health Care Directives Act - Provincial Policy and Guidelines - July 2000) to be carried out without the free and informed consent of the subject only if all the following criteria apply: **a.** There is severe suffering or danger

of bodily harm if the person is not treated **b.** Either the risk of harm is not greater than that involved in standard efficacious

care, or it is clearly justified by the direct benefits to the subject; and **c.** The prospective human participant is unconscious or lacks capacity to understand risks, methods and purposes of the research **d.** There is neither the time nor a method for obtaining consent from a substitute decision-maker; or in the opinion of the health practitioner, the substitute decision-maker has not complied with the principles of how a substitute decision-maker shall act; and **e.** There is no knowledge of a health care directive to suggest that the person

would refuse treatment of the kind that is proposed. **f.** There is approval from the appropriate hospital research ethics committee.

3.0 Decisions of the Research Ethics Board 2.12 Review of Research Performed in Emergency Health Situations

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The REB may allow research that involves health emergencies (as defined in the Consent to Treatment and Health Care Directives Act - Provincial Policy and Guidelines - July 2000) to be carried out without the free and informed consent of the subject only if all the following criteria apply:

a. There is severe suffering or danger of bodily harm if the person is not treated

b. Either the risk of harm is not greater than that involved in standard efficacious care,

or it is clearly justified by the direct benefits to the subject; and

c. The prospective human participant is unconscious or lacks capacity to understand

risks, methods and purposes of the research

d. There is neither the time nor a method for obtaining consent from a substitute

decision-maker; or in the opinion of the health practitioner, the substitute

decision-maker has not complied with the principles of how a substitute

decision-maker shall act; and

e. There is no knowledge of a health care directive to suggest that the person would refuse treatment of the kind that is proposed.

f. There is approval from the appropriate hospital research ethics committee.

3.0 Decisions of the Research Ethics Board

3.1 Reconsideration

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for the decision and give the researcher an opportunity to reply before making a final decision.

UPEI may not override negative REB decisions reached on grounds of ethics without a formal appeal mechanism.

3.2 Appeal

Researchers must apply to the President to appeal a negative REB decision within two months of the date of the decision. A copy of the appeal letter should also be sent to the REB Chair. UPEI shall use a duly constituted REB from another institution as its Appeal Board. Noncompliance with the substance of the Tri-Council Policy Statement is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement. The decision of the Appeal REB shall be final.

4.0 Report of the Research Ethics Board

Certificates of Ethical Approval, signed by the Chair of the UPEI REB will be issued to the Principal Investigator(s) and copies sent to the President and to the Vice-President, Research and Development.

Any decisions by the Chair to approve minor amendments without full committee review will be reported to the committee at the next scheduled meeting.

An annual activity report from the REB will be made to the President of UPEI who will in turn bring the report to Senate for consideration.

5.0 Administration

5.1 Administrative Support

The work involved in the ethical review process should be distributed appropriately among faculty members, staff, researchers, and administrators.

The Office of the Vice President, Research and Development will provide administrative support to the REB including:

(a) Distribution of forms and materials necessary for submission of research proposals to the REB
(b) Collection of submissions and distribution of submissions to REB members
(c) Keeping minutes of REB meetings
(d) Storing submissions and related materials in a secure location
(e) Supporting the REB in its educational activities
(f) Acting as the point of contact for the Secretariat on Research Ethics (CIHR, NSERC and SSHRC), and for Health Canada.
(g) Other duties related to the support of the REB in carrying out its mandate.
(h) Incomplete proposals are not to be date stamped before being reviewed and will be returned to the researcher to complete the proposal before being sent to a reviewer.

Deans of Faculties and Schools will provide significant support to the REB, with respect to:

- educational activities
- management of the system for reporting research
- ensuring that researchers requiring ethical review are submitting their projects to the REB
- advising their faculty members about the need to comply with the Tri-Council Policy Statement.

Individual departments are expected to support and train students so that undergraduate and graduate research projects are ethical, and those that exceed minimal risk may be efficiently reviewed by the REB. Departments should screen student applications for ethical review prior to submission to the REB. The REB may return applications to the

department if they do not conform to the requirements of the Tri-Council Policy. It is advisable that curriculum committees consider including ethics training in the relevant academic programs.

5.2 University Support

UPEI shall provide adequate resources and an annual budget to support the administrative processes and educational activities required by the REB so that the University as a whole remains in compliance with Tri-Council policy.

5.3 Sanctions

The REB Chair shall have the sanction of refusing permission to open a research account or access university controlled funds for researchers who do not comply with the Tri-Council Policy Statement.

The REB will report to the President any cases which undermine UPEI's compliance with the Tri-Council Policy and the President shall decide what sanctions or penalties to impose on the researcher(s).

6.0 Acknowledgement

In preparation of the Research Ethics Policy for UPEI document, the Research Ethics Committee wishes to acknowledge their reliance on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. We also wish to acknowledge our reliance on the Research Ethics Policies used at Queen's University and McMaster University. The "example" for Departmental Ethics Committee Submission Form was modified from the form used by the Department of Psychology, UPEI.

Guidelines for Obtaining Research Ethics Board Approval at UPEI

The UPEI Research Ethics Board (REB) is charged with ensuring that all research using human participants undertaken by anyone employed by or representing the University of Prince Edward Island complies with the Research Ethics Policy for UPEI.

Before faculty, staff, students, and others who are associated with UPEI proceed with funded or unfunded research that involves human participants, they must obtain REB approval evidenced by a current ethics certificate signed by the Chair of the UPEI REB. These guidelines are written to help with the process of obtaining an ethics certificate.

The complete UPEI Research Ethics Policy and all forms required for the submission process can be found at http://www.upei.ca/~research/epolicy.htm. UPEI policy and procedures are intended to implement the Tri-Council policy statement "**Ethical Conduct for Research Involving Participants**" (current version) the text of which can be found at **http://www.pre.ethics.gc.ca/english/tutorial/**

1.0 What Research needs an Ethics Certificate?

All research that involves human participants or human remains requires a current ethics certificate before the work is begun except as follows:

1.1. Work undertaken by undergraduate and graduate students as part of a formal course requirement does not need an ethics certificate from the REB but has to undergo departmental level review (see Section 4.0 below), as long as it poses no more than minimal risk to participants and as long as it is not part of a larger research project. The instructor of the course, however, must obtain departmental level ethics approval for the student project (see Section 4.0).

1.2. Quality assurance studies, performance reviews or testing within normal educational requirements, or practicum's already covered by professional code of ethics are not subject to REB review. However, the REB should be informed of quality assurance studies done by the University Administration.

1.3. All research surveys for external use, including those undertaken by the University Administration, should undergo ethics review by the REB.

1.4. Research about an individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review.

If you are not sure if your research requires REB approval, you should contact Lynn MacPhee, Research Compliance Coordinator in the Office of the Vice President, Research and Development for help.

2.0 When should work be submitted to the REB?

The review process takes time and may result in changes to research methodology or design. It is always best to start the review process as early as possible in the development of a research proposal. Some funding agencies require that a current ethics certificate accompany the application. Other funding agencies receive applications before a certificate is in hand as long as evidence is provided that the work has been or will be submitted for REB review.

Although UPEI allows submission of research proposals to funding agencies prior to an ethics certificate being issued, **in no case can research involving human participants proceed without a current ethics certificate**.

Regardless of the source of funds, a UPEI research account will not be opened to receive funds before an ethics certificate has been issued.

3.0 Levels of REB Review

With the exception of work undertaken by students as noted above (Section 1.1), there are four types of submission for REB approval.

New Submission - Regular Review
New Submission - Expedited Review
Renewal
Amendment

For all levels of review there is a common submission process. The appropriate submission form

must be received by the Office of the Vice President, Research and Development no later than two weeks prior to the next scheduled meeting of the REB. For a list of scheduled REB meeting dates see **http://www.upei.ca/~research/meeting.htm**

New Submission - Full Board Review - more than minimal risk

Complete the ethics approval submission form and return **10 copies** of the submission with **10 copies of your full proposal** to the Office of the Vice President, Research and Development. Submission is on the "Ethics Submission Form for Research Involving Human Participants" available at http://www.upei.ca/~research/epolicy.htm.

If received 21 days prior to the next scheduled monthly meeting of the REB, your submission will be reviewed at the meeting.

New Submission - Expedited Review

If you think that your proposal presents no more than minimal risk to participants, you may request an expedited review. Complete the ethics approval submission form and return **1 original and 3 copies** of the submission with **1 copy of your full proposal** to the Office of the Vice President, Research and Development. Should your request for expedited review not be granted, it will be necessary to follow the procedure for a new submission - regular review- as above.

Renewal

Ethics certificates are valid for one year from date of issue. If no change has been made to the research protocol or if changes are minimal, the Chair of the REB may at his/her discretion renew the ethics certificate for another one year period. Complete the ethics approval submission form and return **1 original and 3 copies** to the Office of the Vice President, Research and Development. Submission is on the "Annual Renewal and Amendment Form" available at http://www.upei.ca/~research/epolicy.htm.

If significant changes have been made to the protocol, or if in the opinion of the REB Chair, changes warrant a review by the complete committee, then the re-submission process is similar to that for a new submission.

Amendment

If in the course of an approved research project there are required changes to the research

protocol, the Chair of the REB may at his/her discretion issue a new ethics certificate for the project. Complete the Annual Renewal and Amendment form and return **1 original and 3 copies** to the Office of the Vice President, Research and Development. Submission is on the "Annual Renewal and Amendment Form" available at http://www.upei.ca/~research/epolicy.htm.

If significant changes to the protocol are required, or if in the opinion of the REB Chair, the proposed changes warrant a review by the complete committee, then the re-submission process is similar to that for a new submission.

4.0 Departmental Level Review of Course-based Research Exercises or Assignments

Many undergraduate and graduate courses include exercises or assignments that require students to collect information from human participants. These are all referred to here as course-based research exercises. The UPEI research ethics policy makes provision for such course-based research exercises that involve human participants and pose no more than minimal risk but requires that these exercises be reviewed by a departmental level ethics committee, unless they are practicums already covered by professional code of ethics. Furthermore, these teaching exercises cannot form part of a faculty member's research project. Faculty research that involves human participants must be submitted to the UPEI Research Ethics Board (see Section 3.0).

Course-based research exercises that involve human participants must be submitted for departmental level review process through the Departmental Chair.

5.0 Serious Adverse Events

In compliance with the Tri-Council Policy Statement, the REB must be informed of serious or unexpected adverse events occurring during the trial and/or study, likely to affect the safety of the participants or the conduct of the trial and/or study. The REB may re-evaluate the ethical aspects of the trial and/or study, as appropriate.

Research Ethics Board Guidelines for Review of Research Proposals

1.0 Initial Approval:

Preparation: Seven days (minimum) prior to the next scheduled meeting all committee members will receive a full copy of proposal(s) and submission form for each proposal to be discussed at that meeting. An external reviewer may also be sent the full documentation should the REB Chair decide that the appropriate expertise is not to be found within the committee membership.

Presentation of the proposal: At the meeting of the committee the REB Chair will present a summary of the proposal. In the case of an external reviewer, he/she may respond in writing or come to the relevant portion of the meeting.

2.0 Criteria for REB Approval of Research:

In order to approve the research the REB shall assess the proposal using as a guide a check list review form - "Committee Review Sheet" (see Appendix 5), and determine that all of the following requirements are satisfied:

Risks: Risks to participants are minimized. (For the purposes of the REB, risks will include not only physical injury but also loss of dignity and self-esteem, guilt and remorse, or feelings of exploitation and degradation.)

i) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and

ii) Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the REB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if

not participating in the research). The REB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility.

Selection of participants is equitable: In making this assessment, the REB will take into account the purposes, aims and setting of the research; in particular,

> (i) the research, where relevant, should strive to achieve a demographically representative sampling, subject to the specific constraints of the research hypothesis;
>
> (ii) if the proposed research involves participants who are vulnerable because they are not competent to give a legally or ethically valid consent, the research must never intentionally or inadvertently, increase or exploit this vulnerability;
>
> (iii) if the proposed research involves participants who are vulnerable because of their relative social or economic powerlessness, the research must never, intentionally or inadvertently, exploit this vulnerability;
>
> (iv) whenever vulnerable people are proposed as participants for research, the REB will determine whether other, non-vulnerable participants would be more, or equally scientifically suitable: vulnerability must never be exploited for expediency.

Informed consent: Informed consent will be sought and obtained from each prospective participant. The consent form must contain the elements listed in the "Committee Review Sheet" (Appendix 5) and be written in a comprehensive manner, intelligible to a lay person, and in a language in which the participant is fluent; in particular,

> (i) for prospective participants who were once competent to give consent, but who are no longer capable of being informed, or of freely exercising their consent, the protocol should take into account advance directives with regard to participation in research, make provision for obtaining substitute consent from the legally recognized substitute decision-maker, and establish a procedure for consulting with the participant should he or she become competent later;
>
> (ii) for prospective participants who are children, every constructive attempt should be made to seek the consent of the child and to ensure, to the fullest extent possible, that the child understands what is to be done; and in addition, where the child is not legally competent to give consent, the protocol must make provision for obtaining substitute consent from the legally recognized substitute decision-maker;

(iii) for prospective participants who have always been, and will likely continue to be incompetent to give consent, every constructive attempt should be made to seek the consent of the person and to ensure, to the fullest extent possible, that the individual understands what is to be done; and in addition, the protocol should make provision for obtaining substitute consent from the legally recognized substitute decision-maker and, where necessary, from the individual's advocate as well;

(iv) in those instances in which prospective participants will not themselves be giving legally competent consent, the protocol must provide a consent form that is suitably addressed to the substitute decision-maker.

Induced Consent and Payment: An over-riding principle in obtaining participants for research studies is that the participants have complete freedom of choice in deciding whether or not to participate in the study.

Pressured consent is unacceptable. These facts must be considered when an investigator is recruiting participants, whether they be patients, "normal" or control participants.

Clinicians must be particularly sensitive to the "freedom of choice" principle if they are recruiting their own patients to a study. It is important, if at all possible, to have another person ask the patients for their decision. In certain situations, laboratory staff, students, or other employees may be "captive" audiences and find it awkward to decline to volunteer for a study. Such groups are very accessible and may be asked repeatedly to volunteer in studies.

Paying participants for participation in a study is appropriate and ethically acceptable when payment is limited to compensation for incurred expenses, e.g. travel, parking, and meals, etc, or as remuneration for time and inconvenience. Any inducement should clearly not distort or influence the freedom of choice.

Informed consent will be appropriately documented (see Appendix 5 for written consent).

The research plan makes provision for monitoring the data collected to ensure the safety of participants. The results of this monitoring should be included in the annual renewal form and in the adverse events.

There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Deception: In general, deception is not acceptable. Under certain circumstances it may be justified, for example **Naturalistic Observation** (see page 7, sections e and f), or where non-deception will clearly impact generalizability, and measures are taken to fully explain the deception afterward, as well as humanely handle any untoward effects of a participant being deceived.

3.0 Decision of the Research Ethics Board

The decision on each protocol will be categorized as follows:

(a) Category 1 Approved

(b) Category 2 Some concern(s) must be addressed before approval is given. The Board endorses protocol with some changes and mandates the Chair to grant approval when the concerns have been satisfactorily addressed.

(c) Category 3 Decision deferred. Based on the documentation provided, the REB is unable to make a decision. The decision is deferred pending receipt of supplementary information or documentation as specified by the REB. The Board will re-review the material.

(d) Category 4 Not approved. The reasons will be provided.

4.0 Report of the Research Ethics Board

In the case of Category 1 approval, a Certificate of Approval form (Appendix 6), signed by the Chair, shall be sent to the Principal Investigator with copy to the President and to the Vice-President, Research and Development. In the case of Category 2, 3, and 4 decisions, the Chair shall inform the Principal Investigator of the REBs concerns by memo or letter.

5.0 Continuing/Annual Review:

The Chair shall make regular reports to the REB on annual renewals received. Those submissions not requiring full review will be issued a Certificate of Approval signed at the discretion of the Chair.

6.0 Amendments:

The Chair has some discretionary ability to approve minor amendments without full review by the REB and will report these approvals to the REB at the next scheduled meeting. Other amendments will require REB review and should be handled using the common submission process.

7.0 Appeals

To assure that proposals which are rejected (Category 4) have received a full review, this will be a two step process. If one or two or all REB members recommend rejection, the proposal will be re-evaluated at the next meeting with review by at least 1 external reviewer. If at this point the committee recommends rejection, the decision will be final.

In the event that an appeal is requested on the grounds that there was an error in process, an Appeal Board will review the request. Their report and recommendations which shall be final will be made directly to the President of UPEI.