

University of Prince Edward Island		Version: No. 1
Procedure:	Research Ethics Board Standard Operating Procedures	
Associated Policy:	Research Ethics Board Policy	
Effective Date: 5 April 2022		
Authority:	VP Academic & Research	
Responsibility	UPEI REB	

1. REB Approval Process

1.1. When to start the ethics review process

The review process takes time and may result in changes to research methodology or design. Principal Investigators (PI) are advised to start the review process as early as possible in the development of a research proposal.

Some funding agencies require that a current ethics approval permit accompany the application. Other funding agencies receive applications before an approval permit 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 approval permit being issued, in no case can research involving human participants proceed without a current ethics approval permit.

1.2. Guidelines for application submission

The following refers to applications submitted for all types of review:

- All application forms, including new applications, renewal and amendment forms are available electronically on the UPEI Researcher Portal database. The forms, must be completed and submitted through the UPEI Researcher Portal;
- Applications should be submitted well in advance of the anticipated start date of research;
- Applications involving more than minimal risk, and that do not involve patients, staff, resources or data under the auspices of the Health PEI and the Department of Health and Wellness must be received no later than the last Friday of the month. These applications will be reviewed at the next UPEI REB monthly meeting. Applications received after the monthly submission deadline will be held for review at the following monthly meeting;
- Applications involving more than minimal risk and where the research protocol involves patients, staff, resources or data under the auspices of the Health PEI and the Department of Health and Wellness must be submitted to the UPEI REB at least three weeks prior to the Health PEI REB meeting date. PIs are advised to check the Health PEI REB website for information about meeting dates;
- Students conducting interviews, administering tests or collecting data on each other;

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- Students conducting interviews, administering tests or collecting data on each other and compiling this information for presentation or dissemination;
- Students conducting interviews/distributing questionnaires to individuals outside the classroom environment;
- Students conducting research projects (research question formulation, data collection from human participants, data analysis/compilation, data presentation);
- Students and/or participants in course-based research activities administering tests or procedures which may cause psychological distress, anxiety, embarrassment or discomfort for students and/or participants.
- Course-based research deemed to be beyond minimal risk must be reviewed by the UPEI REB.

All faculty members who wish to include course-based activities involving the use of human participants must submit the appropriate information, including the course name and number, a summary of the nature of the research activity and the instructions given to the class, to their departmental or faculty level ethics committee for review and approval. This information must be submitted in a timely manner to allow the departmental or faculty ethics committee sufficient time for the review and approval process.

Faculty members who wish to conduct this type of research must consult the Chair of their department or faculty ethics committee for the appropriate forms.

It is the faculty member's responsibility to ensure that ethical approval is obtained before the research activity begins. The faculty member's signature on the departmental ethics application form attests to his/her/their commitment to ensuring that the research activities described will be undertaken in conformity with the ethical principles outlined in the UPEI REB policy.

Ethical approval for course-based research activities will be granted for a minimum of one semester. If changes are made to the course following approval by the departmental or faculty ethics committee then a memo outlining the revisions must be sent to the Chair of the relevant ethics board committee for review and approval. All forms related to the ethical approval of each course must be kept by the faculty member for the purpose of any audits that may be required.

If a departmental or faculty ethics committee decision is deferred or a course-based research activity involving human participants is not approved, then the Chair of the departmental or faculty ethics committee shall inform the Principal Investigator of the reasons for the decision in writing. The faculty member may request that the departmental or faculty ethics committee reconsider its decision or the faculty member may appeal the decision. These requests must be made to the departmental or faculty ethics committee responsible for the original review and decision. If the faculty member cannot reach agreement with the departmental or faculty ethics

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committee then he/she/they can forward the request to the UPEI REB, using the processes noted above in Section 1.3.5.4.

2. Honours student and Graduate student REB applications

As per the UPEI REB policy 5.8.4, course-based research activities do not include research conducted for Honours and/or Graduate student theses.

All research to be conducted by Honors students and/or Graduate students must be submitted to the UPEI REB for review and approval, as per section 1.2 (above). Faculty supervisors are responsible for the completion and submission of these applications and they must be named as the Principal Investigator as per the UPEI REB policy 3.9.

3. Review of Multi-Jurisdictional Research

The REB shall review all research proposals as long as the Principal Investigator represents the work as UPEI research, regardless of the location where the research is conducted. In multi-jurisdictional research, the Principal Investigator 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 institutions is required prior to the start of the research project.

4. Exceptions to Research Ethics Board (REB) approval process

- Research involving human participants undertaken by undergraduate and graduate students as part of a formal course requirement that has been reviewed and approved at the department or faculty level ethics committee (see Section 2 above). Note: Research that involves more than minimal risk and/or is part of a larger project must be submitted for a formal UPEI REB review;
- Quality assurance studies, performance reviews or testing within normal educational requirements, or practice already covered by a professional code of ethics. The REB should be informed of quality assurance studies done by the University Administration;
- 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;
- Research that relies exclusively on publicly available information when the information is legally accessible to the public and appropriately protected by law or the information is publicly available and there is no reasonable expectation of privacy;
- Research involving the observation of people in public places where it does not involve any intervention staged by the research or direct interactions with the individuals or groups, or the individuals or groups targeted for observation have no reasonable expectation of privacy;

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- Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes.

5. Governance of UPEI REB

The work involved in the administration of the UPEI REB should be distributed appropriately among faculty members, staff, Pls, and administrators.

5.1 Administration of REB files

REB files will be stored indefinitely in a secure, online database such as the UPEI Researcher Portal. It is the responsibility of the Principal Investigator to address all the recommendations made by the REB and keep the file complete and up to date at all times. Upon notification to the UPEI REB that the research project has been completed the online file will be closed and kept to demonstrate compliance with the TCPS. These files shall be subject to audit by authorized representatives of UPEI (research administrators), members of Appeal Boards, and funding agencies.

5.2 Administrative 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 the TCPS.

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

- Maintenance of forms and materials necessary for submission of research proposals to the REB;
- Making submissions available to REB members;
- Keeping minutes of REB meetings;
- Maintenance of submissions and related materials in the secure, online database;
- Supporting the REB in its educational activities;
- Acting as the point of contact for the Secretariat on Research Ethics (CIHR, NSERC and SSHRC), and for Health Canada;
- Other duties related to the support of the REB in carrying out its mandate.

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

- Educational activities;

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- Management of the system for reporting research;
- Ensuring that PIs requiring ethical review are submitting their projects to the REB;
- Advising their faculty members about the need to comply with the TCPS;
- Ensuring that PIs conducting research complete the TCPS Tutorial Course on Research Ethics (CORE) and obtain their certificate of completion;
- Conducting internal departmental ethics reviews if the student research is: (a) for the requirements of a course, (b) is of minimal risk, and (c) the findings of the research are not disseminated outside the course;
- 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. It is advisable that curriculum committees consider including ethics training in the relevant academic programs.

5.3 Appointment of REB Chair and Members

Before taking up an appointment, the REB Chair and members must take the TCPS CORE Tutorial and provide a certificate of completion. The Chair will serve for a three-year term. Faculty and community committee members will serve for a three year term, initially staggered to ensure continuity. The graduate student will serve for a two-year term. Membership in the committee may be renewed.

5.4 Conflict of Interest

If the REB is reviewing research in which a member of the Board has a personal interest or has a directly competing interest, 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, the REB member in alleged conflict and/or the Principal Investigator 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.

5.5 Meetings and Attendance

The REB shall meet regularly to allow for adequate discussion of, and effective decision making on REB research ethics applications for the collective education of the REB. Normally, meetings will take place throughout the year on a monthly basis, with the exception of July and August. A quorum will consist of 5 members, including the Chair or Chair's designate, at all meetings concerned with the ethical approval of research ethics applications. A schedule of REB meetings and the names of REB committee members will be published on the UPEI website. Minutes will be kept for these meetings by the Research Compliance Coordinator, Office of the Vice-President, Academic and Research.

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5.6 Department or Faculty Level ethics committees

Members of the department and faculty level ethics committees do not need to be members of the UPEI REB but must have appropriate experience, expertise, training and resources. The number of committee members, and length of term on the committee, may vary by department or faculty. Deans of Faculties and/or Department Chairs are responsible for appointing departmental or faculty ethics committee members.

6. Acknowledgements

In preparation of the UPEI Research Ethics Policy, the Research Ethics Committee wishes to acknowledge its reliance on the Tri-County Policy Statement: Ethical Conduct for Research Involving Humans.