

University of Prince Edward Island	Policy No. admordgnl0013	Revision No. 1
Policy Title: Research Ethics Board		Page 1 of 9
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1. Purpose

This Policy is intended to ensure that ethical standards in the conduct of research involving humans are maintained at the University of Prince Edward Island ("UPEI") in compliance with applicable laws, UPEI policies, UPEI Research Ethics Board ("REB") procedures and the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans ("TCPS"), as may be amended from time to time. These ethical standards are guided by the three core principles: Respect for Persons, Concern for Welfare, and Justice. The research design should be sensitive to values and perspectives unique to the cultural communities, for instance Indigenous peoples, with which the research is to be conducted.

2. Scope

2.1. This Policy applies to all research involving human participants and/or human biological materials (the "Research") carried out by UPEI faculty, staff, students, and visiting researchers. For clarity, this policy applies irrespective of whether the:

- 2.1.1. Research is funded;
- 2.1.2. Participants are paid;
- 2.1.3. Research is conducted outside the institution;
- 2.1.4. Research is conducted in person or remotely;
- 2.1.5. Information is collected (directly from participants or not);
- 2.1.6. Research is to be published;
- 2.1.7. Research is experimental, correlational or descriptive;
- 2.1.8. Research is a pilot study or a fully developed project;
- 2.1.9. Research is to acquire basic or applied knowledge;
- 2.1.10. Participant from which materials are derived are living or deceased; or
- 2.1.11. Research is for internal use or not.

2.2 The Policy also applies to Research involving human participants carried out by external individuals, groups or organizations that accesses resources or participants at UPEI.

2.3 Certain exceptions to the types of Research requiring ethics review are described in the UPEI Research Ethics Board (REB) Standard Operating Procedures (SOP).

3. Definitions

- 3.1 **Authorized third party** means any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to decide whether to participate or to continue to participate in a particular research project.
- 3.2 **Capacity to consent** means an individual's ability to decide for themselves whether to participate in research based both on their decision-making capacity (defined in the TCPS, Chapter 3, Section C, as ability of prospective or actual participants to sufficiently understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not participate with respect to the nature of a particular research project, and the risks, consequences, and potential benefits associated with it) and alignment with any laws governing research participation.
- 3.3 **Certificate of Ethical Approval** is the document issued by the REB to the Principal Investigator when an REB protocol has been approved. The Certificate of Ethical Approval is signed by the REB Chair.
- 3.4 **Conflict of interest** holds the meaning provided in UPEI Conflict of Interest Policy and the TCPS.
- 3.5 **Core principles** means the three core principles of the TCPS that together express the overarching value of respect for human dignity: respect for persons, concern for welfare, and justice.
- 3.6 **Course-based research** means Research conducted through undergraduate and/or graduate courses for pedagogical purposes and which cannot form part of a faculty member's research.
- 3.7 **Institutions** means the universities, hospitals, colleges, research institutes, centres and other organizations eligible to receive and manage Tri-Council grant funds.
- 3.8 **Justice** is one of the core principles of the TCPS that refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research nor denied the benefits of the knowledge generated from it.
- 3.9 **Minimal Risk research** means Research in which the probability and magnitude of possible harms implied by participation in the Research are no greater than those encountered by participants in the aspects of their everyday life that relate to the research.
- 3.10 **Ongoing research** means Research that has received REB approval and has not yet been completed.
- 3.11 **Participant** means an individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a Research question; also referred to as "human participant", and in other policies/guidance as "subject" or "research subject".

- 3.12 **Principal Investigator (PI)** means the faculty member responsible and accountable for conducting the proposed research. The Principal Investigator assumes full responsibility for the adherence to UPEI policies and procedures and the integrity of research data and results. The PI must be a UPEI faculty member or be a person who is otherwise approved by the REB to hold a REB permit.
- 3.13 **Reciprocal REB review** means an official agreement between two or more Institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's Research Ethics Boards.
- 3.14 **Research Ethics Board ("REB")** means a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an Institution to review the ethical acceptability of all Research involving humans conducted within the institution's jurisdiction or under its auspices. In this Policy, unless otherwise noted, REB refers to the UPEI **REB** established under Section 5.7.
- 3.15 **REB Standard Operating Procedures (REB SOP)** means the reference document issued and administered by the REB, detailing procedures and guidelines related to the operation of and applications to the UPEI REB.
- 3.16 **Respect for persons** is one of the core principles of the TCPS that recognizes the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy.
- 3.17 **Senior Administration** includes the UPEI President, all Vice-Presidents, all Deans, the UPEI Librarian, and the Chief Information Officer.
- 3.18 **Welfare** means the quality of a person's experience of life in all its aspects. Welfare consists of the impact on individuals and/or groups of factors such as their physical, mental, and spiritual health, as well as their physical, economic, and social circumstances.
- 4. Responsibilities**
- 4.1 This Policy is authorized by the Board of Governors.
- 4.2 The development and maintenance of this Policy is the responsibility of Vice-President, Academic & Research (VPAR).
- 4.3 The administration of this Policy is the responsibility of UPEI REB.
- 4.4 The REB is responsible for:
- a) Reviewing, approving, rejecting, proposing modifications to, or terminating any proposed or ongoing Research;

- b) Promoting awareness and understanding of research ethics involving humans within the university community;
- c) Reviewing policy and procedures regarding ethical issues relating to Research to ensure that policies remain current;
- d) Engage into reciprocal REB review agreements with other Institutions;
- e) Being available to members of the UPEI community for consultations on matters relating to ethics of Research; and
- f) Preparing an annual report for submission to the President (or delegate), who will in turn bring the report to the Board of Governors for their consideration, in accordance with the REB SOP.

4.5 The UPEI Vice-President Academic & Research is responsible for:

- 4.5.1 Supporting the recruitment of appropriate REB members in accordance with the TCPS and in consultation with UPEI Deans and the President (or delegate);
- 4.5.2 Ensuring the REB is provided with necessary and sufficient ongoing financial and administrative resources to fulfill its duties (e.g., REB coordination, support in policy development and interpretation, record keeping).
- 4.5.3 Informing the President of any non-compliance of research ethical standards reported under the *Responsible Conduct of Research, Scholarly and Creative Work Policy*.

4.6. Principal Investigators are responsible to the REB for:

- 4.6.1 Adherence to this Policy and associated procedures and other relevant policies including the TCPS;
- 4.6.2 Providing an annual report summarizing current Research findings and a final report summarizing all Research findings;
- 4.6.3 Submitting, when necessary, timely renewal and amendment applications.

4.7 Responsibilities of members of UPEI are defined in the *Responsible Conduct of Research, Scholarly and Creative Work Policy*.

5. Policy

5.1. All Research, as outlined in 2.1 and 2.2 is subject to ethics review by the REB and should be submitted for this review in accordance with the REB SOP.

5.2 The REB will arrive at one of the following three possible decisions for each proposal:

- 5.2.1. Approval: the proposal is approved and a Certificate of Ethical Approval is issued.
- 5.2.2. Deferred: decision is deferred pending revisions and/or receipt of supplementary information or documentation as specified by the REB, at which time the proposal will be re-assessed.
- 5.2.3. Not approved: the proposal is not approved and may be revised and resubmitted as a new submission in accordance with the REB SOP.
- 5.3. Certificates of Ethical Approval are valid for one year from the date of issue but can be renewed if no change has been made to the research protocol, and the renewal is made in accordance with the REB SOP.
- 5.4. Ongoing Research is subject to continuing ethics review. The Chair of the REB must be notified of any significant proposed changes to the research plan or research protocol before such changes are implemented, in accordance with the REB SOP.
- 5.5. An appeal of an REB decision to reject a research proposal may only be brought by a Principal Investigator and in accordance with the REB SOP.
- 5.6. Research to be performed across multiple jurisdictions, outside of the jurisdiction of UPEI and/or outside of Canada shall undergo ethics review both by the UPEI REB and the REB of the respective external jurisdiction, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done and in accordance with the REB SOP.
- 5.7. UPEI REB
 - 5.7.1. The mandate of the REB is to review the ethical acceptability of Research in accordance with the TCPS and on behalf of the university, including approving, rejecting, proposing modifications to, and/or terminating any proposed or ongoing Research.
 - 5.7.2. The REB shall be made up of at least five (5) UPEI members and one member from the community, including people of all genders, of whom:
 - a) At least two (2) members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
 - b) At least one (1) member is knowledgeable in ethics;
 - c) At least one (1) member is a community representative who has no formal affiliation with the University;
 - d) The inclusion of one (1) undergraduate student member and one (1) graduate student member on the REB committee is desirable.

- e) The inclusion of at least one (1) member knowledgeable in law is desirable.
- f) The inclusion of at least one (1) person who identifies as Lnu or other Indigenous person is desirable.

5.7.3. The recruitment and appointment of the REB Chair and committee members shall be completed through consultation with the UPEI President (or delegate) and the relevant Dean(s) and in accordance with the TCPS and the REB Standard Operating Procedures.

5.7.4 To ensure the independence of REB decision-making, members of UPEI Senior Administration shall not serve on the REB.

5.7.5 UPEI recognizes that the REB must operate independently in its decision-making related to Research ethics approval.

5.7.6 The REB must avoid and manage any real, perceived, or potential Conflicts of Interest which may arise in the course of its decision-making related to Research ethics approval, in accordance with the *UPEI Conflict of Interest Policy* and the REB SOP.

5.7.7 In their assessment of the acceptable threshold of risk and in determining whether research is minimal risk, the REB has special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability.

5.7.8 In determining appropriate methods to obtain informed consent and REB review processes, the REB must consider potential participants' capacity to consent and the risk level of the proposed research.

Regarding individuals who have not yet attained the age of majority in the applicable jurisdiction as participants in research, and the requirement of authorized third party (e.g., parental/guardian) consent in particular:

5.7.8.1 For research otherwise deemed **minimal risk** where **individuals aged 16-18** would be recruited, authorized third party consent is **not** required, and the delegated reviewer process outlined in the REB SOP would be employed.

5.7.8.2 For research that is **greater than minimal risk** where **individuals aged 16-18** would be recruited, authorized third party consent will normally be required, and the full board review process outlined in the REB SOP would be employed.

When a waiver of authorized third party consent is sought, in such cases a full board review, as outlined in the REB SOP, is required to determine whether authorized third party consent is required or not. Justification for an authorized third party consent waiver should be provided in the REB application form and should satisfy the REB that **all** of points (b) through (e) of TCPS Article 3.7A (see Section 5.7.8.3 below) are met.

5.7.8.3 For **any research** involving **individuals aged under 16**, an authorized third party consent is normally required.

For research deemed **minimal risk** where **individuals aged under 16** would be recruited, authorized third party consent is normally required and the delegated reviewer process outlined in the REB SOP would be employed.

When a waiver of authorized third party consent is sought by the PI, a full board review as outlined in the REB SOP is required to determine whether authorized third party consent is required or not. Justification for an authorized third party consent waiver should be provided in the REB application form.

A waiver of authorized third party consent will only be considered by the REB for research falling under Section 5.7.8.3. of this Policy, when the conditions of TCPS Article 3.7A are met and documented by the PI:

*“The REB may approve research that involves an alteration to the requirements for consent set out in [TCPS 2] Articles 3.1 to 3.5 if the REB is satisfied, and documents, that **all** of the following apply:*

- a. the research involves no more than minimal risk to the participants;*
- b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;*
- c. it is impossible or impracticable (see TCPS 2 Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;*
- d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and*
- e. the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with [TCPS 2] Article 3.7B.”*

For research deemed **greater than minimal risk** where **individuals aged under 16** would be recruited, authorized third party consent is required, and the full board review process outlined in the REB SOP would be employed.

5.7.9 An REB committee may be formed at the faculty/department level, in accordance with the REB SOP, for the specific purpose of reviewing Course-based Research as outlined in Section 5.8.

5.8. Course-based Research

5.8.1. This Policy makes provision for Course-based Research that normally would fall under this Policy in accordance with Section 2, but that poses Minimal Risk, allowing for the ethics review to occur through a faculty/departmental level ethics committee.

5.8.2. Course-based Research must be submitted for review and approval prior to the research beginning in accordance with the REB SOP.

5.8.3. Course-based Research deemed to be beyond Minimal Risk must be reviewed by the REB.

5.8.4. Course-based research activities do not include research conducted for Honours and/or Graduate student theses.

5.8.5. UPEI Deans of Faculties are responsible for providing annual reports detailing course-based research activities involving humans.

6. Compliance

6.1. All research activity must also be carried out in accordance with the *UPEI Responsible Conduct of Research, Scholarly and Creative Work Policy*.

6.2. In no scenario can Research, as outlined in Section 2, proceed without a current ethics approval permit.

6.3. In the event of non-compliance with this Policy or the REB SOP, the REB has the authority to suspend a permit. Additionally, the *Responsible Conduct of Research, Scholarly and Creative Work Policy* outlines reporting requirements for research misconduct and the responsibilities for determining the initiation of a formal investigation for Research misconduct. Details on investigations of research misconduct are outlined in the "Procedures for Addressing Allegations of Misconduct in Scholarly Activity at UPEI".

6.4. The REB will inform the President (or delegate) of any cases of non-compliance and recommend sanctions or penalties.

7. Review

7.1. This Policy is to be reviewed every five (5) years. The VPAR is responsible for initiating that review.

8. Relevant Policies

8.1 Conflict of Interest Policy

8.2 Responsible Conduct of Research, Scholarly and Creative Work Policy

9. References

9.1. Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans

9.2. Research Ethics Board Standard Operating Procedure