

**University of Prince Edward Island**

Office of the Vice-President, Academic & Research

 January 2017

**ETHICS REVIEW PROTOCOL SUBMISSION FORM**

Submit **one original signed copy** of the submission form and all other application documents including the research proposal or grant application, consent form(s), research instruments, and a certificate of completion for the [TCPS 2 Tutorial](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) to **Research Services, 200 Kelly Building, UPEI** *and* send **one electronic copy** of all application documents to reb@upei.ca. Researchers are urged to consult the [Tri-Council Policy Statement 2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) for more information and guidance.

**\* Submissions are regarded by the REB as strictly CONFIDENTIAL**

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| **SECTION 1: IDENTIFICATION** |
| **Project Title:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. |
| **Department/Faculty:** | Click here to enter text. |
| **Phone:** | Click here to enter text. | **UPEI ID:** | Click here to enter text. |
| **Email:** | Click here to enter text. |
| **\*STUDENT submissions: provide the following information and attach the** [**Confirmation of a Supervisor’s Review Form**](http://research.upei.ca/files/research/confirmation_of_supervisors_review_form_1.pdf)**.** |
| **Supervisors Name:** | Click here to enter text. |  |  |
| **Degree Program:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Project Period:**  | From (MM/DD/YY)  | Click here to enter a date. | To (MM/DD/YY) | Click here to enter a date. |
| Is this project funded? | Yes [ ]  No [ ]   | Funding Agency: | Click here to enter text. |
| Have you signed a Release of Funds Agreement? Yes [ ]  No [ ]  |
| If unfunded, name two possible reviewers: |
| 1. | Click here to enter text. | 2. | Click here to enter text. |
| Does your project involve the use of animals Yes [ ]  No [ ]  |
| Does your project involve biohazards? Yes [ ]  No [ ]  |
| Does this study qualify as involving **MORE THAN MINIMAL RISK**? Yes [ ]  No [ ]  |
| Has this project been reviewed or approved by any other Research Ethics Board? Yes [ ]  No [ ]  |
| If yes, provide the name/s of the other REB and date/s of approval:  | Click here to enter text. |
| **Signature of Local PI attesting that:****a.** I agree to abide by the ethical guidelines and procedures of the University of Prince Edward Island Research Ethics Board (UPEI Research Ethics Policy, current version), of the Tri-Council Policy Statement (current version), of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards**.****b.** I further agree to notify the UPEI REB of any change in the methodology or status of the research project and to comply with requests made by the REB during the life of this research. |
| **Signature:** |  | **Date:** |  |
| **Project Personnel (including students)**  |
| **Name:** | Click here to enter text. | **Name:** | Click here to enter text. |
| **Role:** | Click here to enter text. | **Role:** | Click here to enter text. |
| **Email:** | Click here to enter text. | **Email:** | Click here to enter text. |
| **Name:** | Click here to enter text. | **Name:** | Click here to enter text. |
| **Role:** | Click here to enter text. | **Role:** | Click here to enter text. |
| **Email:** | Click here to enter text. | **Email:** | Click here to enter text. |

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| **SECTION 2: PROJECT INFORMATION** |
| **2.1 SUMMARY** |
| 2.1.1 Briefly describe the rationale and purpose of the study.Click here to enter text. |
| 2.1.2 What new knowledge is anticipated as an outcome of the study?Click here to enter text. |
| **2.2 STUDY DESIGN** |
| 2.2.1 State the Hypothesis or Aim (or research question or research objectives).Click here to enter text. |
| 2.2.2 Provide the justification for the study. Address scholarly/scientific validity of the study and the appropriateness of utilizing human participants.Click here to enter text. |
| 2.2.3 Describe the plan for data analysis in relation to the hypotheses/questions/objectives.Click here to enter text. |
| 2.2.4 Is this intended to be a pilot study, or fully developed project?Click here to enter text. |
| 2.2.5 If a phased review is being requested, describe why it is needed and which phases are contained in this application.Click here to enter text. |
| **2.3 DETAILED METHODOLOGY** |
| 2.3.1 Where will the research be conducted?Click here to enter text. |
| 2.3.2 What will the participants be asked to do? How long will it take to complete each task? Provide the total time required by each participant to complete all tasks. Click here to enter text. |
| 2.3.3 Describe what data will be recorded and what research instruments will be used (attach copies).Click here to enter text. |
| 2.3.4 Describe the roles of the study investigators and research staff.Click here to enter text. |
| 2.3.5 For research involving sensitive issues (e.g. abuse) what ethical qualifications do the research team members have?Click here to enter text. |
| **2.4 RECRUITMENT / PARTICIPANTS** |
| 2.4.1 Total no. of Participants Click here to enter text. |
| 2.4.2 Sources of Participants Click here to enter text. |
| 2.4.3 Describe the method of recruiting participants including who will contact them. Provide a copy of the advertisement and/or recruitment notice/script to be used. Indicate when participants will be approached. Describe the participant inclusion and exclusion criteria. Click here to enter text. |
| 2.4.4 Are vulnerable participants being recruited? (e.g., inmates, patients, etc.) Yes [ ]  No [ ] 2.4.5 If yes who? (specify groups)Click here to enter text. |
| **2.5 RISK AND BENEFITS (only if more than minimal risk)** |
| 2.5.1 If more than minimal risk is involved then discuss the risks of the proposed research to all parties, specifying the particular risks associated with each procedure, test, interview, or other aspect of the protocols. Click here to enter text. |
| 2.5.2 Describe the estimated probability of these risks (e.g., low, medium, high or more precisely if possible).Click here to enter text. |
| 2.5.3 Describe what steps will be taken to mitigate the risks. Click here to enter text. |
| 2.5.4 Describe what risks might exist for communities that are involved in the study.Click here to enter text. |
| 2.5.5 Describe the direct benefits (if any) of participation to participants (not compensation).Click here to enter text. |
| **2.6 INFORMED CONSENT PROCESS**  |
| 2.6.1 Describe the informed consent process (attach a copy of all consent forms).Click here to enter text. |
| 2.6.2 If oral consent is desired, describe why it is necessary and how it will be done (attach a copy of the script).Click here to enter text. |
| 2.6.3 If a waiver of informed consent is sought, please justify.Click here to enter text. |
| 2.6.4 For third party consent (with or without assent), describe how this will be done.Click here to enter text. |
| 2.6.5 Describe the need for, and the plans (if any) for on-going consent.Click here to enter text. |
| 2.6.6 If community consent is needed, describe how it will be obtained.Click here to enter text. |
| 2.6.7 What effort has been made to recruit an inclusive sample?Click here to enter text. |
| 2.6.8 Are the participants competent to consent? Yes [ ]  No [ ]  |
| 2.6.9 If no, who will consent?Click here to enter text. |
| 2.6.10 Are children involved? Yes [ ]  No [ ]  |
| If yes, what age groups?[ ]  Newborn (0-6 months) [ ] Pre-school age (6m to 4y) [ ]  High School (16-18y)[ ] Primary School (5-11 years) [ ] Middle School (12-15 y)  |
| How will the children be recruited?[ ] Through school [ ]  Through another institution\* (Specify) [ ]  Through parents/family [ ] Other (Specify) ***\*\* A letter to the institution asking for permission to conduct the study MUST be attached.*** |
| Will the parent’s/guardian’s consent for the child to participate be obtained? Yes [ ]  No [ ]  |
| If yes, will the child’s assent to participate be obtained? Yes [ ]  No [ ]  |
| If no, please explain:Click here to enter text. |
| If students are being recruited, are they the researchers own students? Yes [ ]  No [ ]  |
| **2.7 DECEPTION / INCOMPLETE DISCLOSURE (if applicable)** |
| 2.7.1 Describe what misdirection will be used (if any) and discuss its justification.Click here to enter text. |
| 2.7.2 Describe what relevant information will not be disclosed to participants and discuss its justification.Click here to enter text. |
| 2.7.3 Describe how participants will be debriefed and given the opportunity to withdraw their data.Click here to enter text. |
| **2.8 CONFIDENTIALITY AND ANONYMITY** |
| 2.8.1 Are the data being collected of a personal or sensitive nature? Yes [ ]  No [ ]  |
| 2.8.2 Describe how the data will be collected, stored and handled in a confidential manner. Who will have access to the data? Click here to enter text. |
| 2.8.3 How long will the data will be retained? What are the plans for their disposal?Click here to enter text. |
| 2.8.4 Is it possible for participants to remain anonymous? If yes, how will this be achieved?Click here to enter text. |
| 2.8.5 Will a waiver of confidentiality be sought from participants? If so, why?Click here to enter text. |
| 2.8.6 How will de-identification be handled in publication of results to minimize the risk of a breech of anonymity?Click here to enter text. |
| 2.8.7 How will confidentiality be maintained in focus groups (if applicable)?Click here to enter text. |
| **2.9 COMPENSATION AND DEBRIEFING** |
| 2.9 1 Describe what compensation will be offered to participants (if any), how it will be provided, and how it will be handled for participants who do not complete the study.Click here to enter text. |
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| 2.9.3 Amount of compensation | Click here to enter text. |
| 2.9.4 Describe your plans for adequate and timely debriefing. Attach a script of the basic debriefing given to participants at the completion of their participation.Click here to enter text. |
| 2.9.5 Describe your plans for informing participants of the results of the studyClick here to enter text. |
| **2.10 CONFLICT OF INTEREST** |
| 2.10.1 What direct or indirect benefits (if any) are you, as PI, receiving as a result of this research?Click here to enter text. |
| 2.10.2 Do you or your collaborators have any affiliation with, or financial involvement in, any organization or entity with a direct or indirect interest in the subject matter or materials of this research? If yes, provide details. Click here to enter text. |
| 2.10.3 Are there any agreements between the investigator(s) and the sponsor(s) of this research that restrict publication of results from this research? If yes, provide details.Click here to enter text. |
| **2.11 HUMAN GENETICS RESEARCH** |
| 2.11.1 Does your research involve human genetic material? Yes [ ]  No [ ]  |
| 2.11.2 If yes, what are the ethical issues involved? (consult section 13 of the Tri-Council Policy statement)Click here to enter text. |

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| **SECTION 3. SUBMISSION CHECKLIST FOR INFORMED CONSENT**  |

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| Complete this checklist and submit with the application. |
|  **Yes Not applicable** |  |
|  [ ]  [ ]   | Identification of document as CONSENT FORM |
|  [ ]  [ ]  | Title of study  |
|  [ ]  [ ]  | Identity and affiliation of researchers |
|  [ ]  [ ]  | Contact information of individual conducting the study |
|  [ ]  [ ]  | Invitation to participate in research |
|  [ ]  [ ]  | Assurance of voluntariness and right to withdraw without repercussions |
|  [ ]  [ ]  | Short description of the purpose of the study |
|  [ ]  [ ]  | Short description of the study design and how many participants are involved |
|  [ ]  [ ]  | Description of inclusion and exclusion criteria |
|  [ ]  [ ]  | Description of what the participant is being asked to do |
|  [ ]  [ ]  | Estimate of the participant’s time commitment |
|  [ ]  [ ]  | Description of where the research will take place  |
|  [ ]  [ ]  | Description of special items or other preparations required of the participant |
|  [ ]  [ ]  | Description of how anonymity will be handled |
|  [ ]  [ ]  | Description of how confidentiality of the data will be assured |
|  [ ]  [ ]  | Description of any necessary limitations of confidentiality protections |
|  [ ]  [ ]  | Description of the nature and probability of risks for participants |
|  [ ]  [ ]  | Description of the benefits and risks associated with participating in this research |
|  [ ]  [ ]  | Description of compensation that will be provided to participants |
|  [ ]  [ ]  | Declaration of any researcher conflict of interest |
|  [ ]  [ ]  | Description of any possible commercial outcomes of the research |
|  [ ]  [ ]  | Description of how participants will review transcripts of interviews  |
|  [ ]  [ ]  | Description of how study results will be provided to participants |
|  [ ]  [ ]  | Permission requested for audio/video taping  |
|  [ ]  [ ]  | Permission requested for use of quotations |
|  [ ]  [ ]  | Permission for future use of data in specified studies |
|  [ ]  [ ]  | Permission to re-contact participant for participation in future studies |
|  [ ]  [ ]  | How assent of participant will be sought when 3rd parties give consent |
|  [ ]  [ ]  | Signature statement indicating that information has been provided |
|  [ ]  [ ]  | Signatures of participant and person obtaining consent |
|  [ ]  [ ]  | Appropriate Reading comprehension level (normally Grade 8)  |
|  [ ]  [ ]  | I understand that I can contact the UPEI Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if I have any concerns about the ethical conduct of this study. |
|  [ ]  [ ]  | I have the freedom to withdraw at any time  |
|  [ ]  [ ]  | No waiver of rights is sought |
|  [ ]  [ ]  | Signature and Date |
|  [ ]  [ ]  | I understand that I can keep a copy of the signed and dated consent form |
|  [ ]  [ ]  | I understand that the information will be kept confidential within the limits of the law |
|  [ ]  [ ]  | I have the freedom to withdraw at any time and/or not answer any question |

**SECTION 4:** **FOR RESEARCH APPLICATIONS THAT MUST ALSO BE REVIEWED BY THE HEALTH PEI REB**

UPEI researchers who wish to conduct research that involves patients, staff, resources or data under the auspices of the Health PEI and the Department of Health and Wellness must submit their UPEI REB application for review by the UPEI Research Ethics Board and the PEI Research Ethics Board before the research begins. **UPEI researchers are no longer required to submit a separate Health PEI REB application to the Health PEI REB.** However, researchers must use the following submission process for review of these files:

1. Submit one e-copy and one hard copy of the following documents to reb@upei.ca, UPEI Research Services, 200 Kelley Memorial Building:

* UPEI REB application;
* All applicable participant consent/assent forms;
* Letter of information to the participant;
* Advertisement and/or other recruitment notice;
* Telephone or other scripts used for participant recruitment;
* Questionnaire/s, measurement instruments or other survey tools;
* Copy of letters of agreement or support from impacted Health PEI services (if applicable);
* Data map/s if the research includes the analysis of one or more large datasets;
* Letter to primary care provider (if appropriate) (contact the Health PEI office with questions);
* CV of the principal investigator;
* Study budget
* Copy of study protocol, if one exists from submission to an alternate REB
* TCPS2 certificate for PI must be included. It is recommended that other team members also complete the tutorial and submit a copy of their TCPS 2 certificate;
* Confirmation of Supervisor’s Review (if applicable)
* Submission checklist

2. The UPEI REB will review the submitted documents for completeness and to ensure that the proposed protocol is in compliance with the UPEI REB policy. Complete applications will be forwarded by the UPEI REB to the Health PEI REB for review by that committee**.**

**Please note that UPEI researchers must send their applications and associated documents directly to the UPEI REB** - **not to the Health PEI REB.**

3. Applications that do not involve more than minimal risk are typically considered appropriate for expedited review by the Health PEI REB. Studies that are eligible for expedited review can be submitted at any time.

Applications that involve more than minimal risk must be reviewed by all members of the Health PEI REB. The Health PEI REB meetings are generally held monthly, with the exception of July and August, when only one meeting may be held. The deadline for full board submissions is approximately three weeks prior to the meeting date. A list of the Health PEI REB meeting dates and submission deadlines can be found at <http://www.healthpei.ca/reb>

4. The Health PEI REB will write to inform the UPEI researcher and the UPEI REB of their decision. UPEI REB will accept the decision of Health PEI REB.

A more detailed explanation of the UPEI/Health PEI REB streamlined review process is available at <http://www.upei.ca/research/research-services/research-certifications/research-ethics-board>

**SUBMISSION CHECKLIST FOR APPLICATIONS TO BE SUBMITTED TO UPEI REB AND TO HEALTH PEI REB**

**Title of Study:**

**PI: PI name**

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| --- | --- | --- |
|  **YES** | **N/A** |  |
| [ ]  | [ ]  | UPEI Research Ethics Board application form |
| [ ]  | [ ]  | Participant Consent forms |
| [ ]  | [ ]  | Letter of Information for participants |
| [ ]  | [ ]  | Advertisement and/or other recruitment notices |
| [ ]  | [ ]  | Telephone or other scripts used for participant recruitment |
| [ ]  | [ ]  | Questionnaire/s, measurement instruments or other survey tools |
| [ ]  | [ ]  | Copy of letters of agreement or support from impacted Health PEI services  |
| [ ]  | [ ]  | Data map/s if the research includes the analysis of one or more large datasets |
| [ ]  | [ ]  | Letter to primary care provider  |
| [ ]  | [ ]  | CV of the principal investigator |
| [ ]  | [ ]  | Study budget |
| [ ]  | [ ]  | Copy of study protocol, if one exists from submission to an alternate REB |
| [ ]  | [ ]  | TCPS2 certificate/s |
| [ ]  | [ ]  | Confirmation of Supervisor’s Review |
| [ ]  | [ ]  | Submission checklist |