Version 6: Dated April 2022

Prince Edward Island
RESEARCH ETHICS BOARD

General Guidelines

1. PURPOSE

It is the responsibility of the PEI Research Ethics Board (REB) to safeguard the rights, safety and well being of participants in all human subjects research involving the PEI Department of Health patients, staff, resources or data. Research is reviewed to ensure that it is ethically acceptable, scientifically valid and that it will conform to the ethical guidelines of the Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans" (TCPS), as well as other ethical guidelines, applicable legislation and regulatory requirements.

The opinion of the REB should be sought whenever there is any doubt about the applicability of PEI Research Ethics Board review of any project.

Research is defined as:
"A class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference."

Your study **must be reviewed and approved** by the REB if your research involves:

- human participants;
- biological materials, including materials from deceased individuals;
- patients, staff, resources or data within Health PEI's jurisdiction;
- engaging in data collection within Health PEI's jurisdiction that has already received ethical approval from another Research Ethics Board; and/or
- the secondary use of data that was originally collected from human participants for another purpose.

Quality improvement studies, performance reviews or testing within normal educational requirements are not normally required to be reviewed by the REB, unless they contain an element of research. However, if you wish to publish your study, it should be submitted to the REB for review and approval.

Review and approval by the REB must be obtained prior to the start of any research.

Please note that approval by the REB does not indicate any commitment of personnel, material resources or space of Health PEI or the Department of Health and Wellness for any proposal.

RESEARCH	Yes/No	QUALITY ASSURANCE	Yes/No
The goal of the project is to test an hypothesis		The goal of the project is to improve service delivery	
You are using scientific methods (e.g. controls, blinding, randomization) and the outcome of the project is uncertain		The project has a reasonable expectation of success	
The planned procedures deviate from normal clinical care		There is no change in normal clinical care	
Your expect to draw generalizable conclusions		The findings will be used to improve the PEI Department of Health patient service delivery only	
You expect to publish your findings in a scientific journal		Publication is not intended	

2. SUBMISSION REQUIREMENTS

Submissions must be complete, with all the appropriate documentation included. Required documentation is identified on the PEI Research Management System, peirebsyntosolution.com Incomplete submissions or submissions not conforming to REB requirements will be returned for revision and resubmission.

The Research Ethics Coordinator reserves the right to defer from review by the REB any submission that is lacking information critical to the deliberations of the Board.

The following information is intended to assist investigators in preparing their proposals for the Research Ethics Board.

- Covering Letter
  Please provide background information on the following points:
  - why this study is important
  - a brief description on the current standard of care
  - how this study differs from the current standard of care
  - do you have access to the appropriate participant population
  - ethical issues and the manner in which such issues will be dealt with

- Recruiting and Consenting Step-By-Step Process
  - Describe how, and by whom participants will be recruited and the process by which informed consent will be obtained from the study participant.

- Research Protocol
  - The Research Protocol, including all appendices and any applicable amendments/revisions to
  - date (if they have not been incorporated in the latest version of the protocol).

- Consent Form(s)
  - Consent Forms must comply with the REB's Consent Form Guidelines and be at a reading level of Grade 8 or below.

- Investigator's Brochure and/or Product Monograph, or Device Manual
  - Please provide any license numbers, if available.

- Safety Updates
    - Any safety report or additional safety information that has not yet been included in the Investigator's Brochure, Product Monograph or Device Manual.

- Questionnaires or Measurement Instruments
    - Provide any questionnaires or measurement instruments that were not previously appended to the protocol. As well, provide copies of any web-based questionnaires or measuring instruments

- Written Information for Participants e.g. Diaries, Brochures, Pamphlets, Leaflets, Kits
    - If any rating scale is embedded in the case report form, a copy of the relevant pages must be submitted for review.

- Telephone Scripts
    - If participants will be contacted via telephone.

- Advertisements
    - Any advertisement intended for the use to recruit participants must be submitted for review.
    - Advertisements to be distributed to the public (by mail, newspaper, radio, television, bulletin boards, websites) must receive REB approval before placement. A description of where the advertisement is to be placed (and for how long) should be provided with the proposed ad. Please include a version number and date on all draft advertisements submitted for review.

The following guidelines should be followed in writing the text:
- The information in the ad should match the approved protocol
- For clinical trials, use of the term "treatment" should be avoided.
- Investigational or experimental drugs/devices/procedures should be clearly noted as such.
- No statement of direct benefit should be made.
- The availability of compensation (but not specific amount) can be noted.

- Budget
    - Per patient amount with breakdowns (Study Coordinator, Lab, DI, Pharmacy, Miscellaneous)
    - Should note number of expected participants.

- Health Canada "<u>Letter of No Objection</u>"
    - For clinical trials of investigational drugs or approved drugs being tested for a new indiction a "Letter of No Objection" is required from the Therapeutic Products Directorate
    - For clinical trials of investigational natural health products, a "Letter of No Objection" from the Natural Health Products Directorate is required.
    - For clinical trials of medical devices, a "Letter of No Objection" from the Medical Devices Bureau is required.

- Current Curriculum Vitae for Principal Investigator and License

- Please inform the REB of any restrictions that might apply to your license or that of the sub/co-investigator(s). For out-of-province investigators, written assurance that appropriate liaisons have been established is required.

- Letters of Support and/or Letters of Agreement
    - Letter of Support, for collaborative support from other services or departments where no compensation is involved. There should be some indication of the impact on non-study participants who may require this service.
        - Letter of Agreement, for "fee for service" arrangements with services or departments. There should be some indication of the impact on non-study participants who may require this service.

- Contact Information for Invoice (for Contractual Studies only)
    - Please provide the name, mailing address, telephone number, fax number and email address for the individual to whom the invoice for the REB Review is to be sent.

4. FORMAT OF SUBMISSIONS

The REB's guidelines are designed to assist investigators in preparing research proposals and consent forms for use in research that falls under the REB's jurisdiction. While the REB will consider submissions using different formats, investigators should be aware that the presentation in different formats may make the material less readily comprehensible to Board members. In general, the better the REB understands a submission, the less likely it will need further explanation and perhaps revision.

5. REVIEW PROCESS

The REB meets once a month, if necessary, with the exception of July and August when only one meeting may be held. The deadline for submission to the REB is approximately three weeks prior to the meeting date.

Submissions are reviewed for ethical and scientific acceptability according to the standards of the Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans" (TCPS) and other regulatory and ethical guidelines as applicable. In some cases the REB may solicit an external peer review (in consultation with the investigator) if additional input is considered necessary for appropriate review of the protocol.

Investigators will be invited to be in attendance to discuss their study at the REB meeting. Following review the submission will be given one of three ratings.

"Full Approval"	Satisfaction with the protocol, consent form or other study documents. The investigator has ethical approval to proceed with the study.
"Conditional Approval"	Questions remain about the protocol; documentation may not be present; major revisions are required to the consent form. This rating does not indicate permission to commence the study. Revisions must be submitted to the REB Chair, and possibly one other REB member, for review and approval prior to commencement the research study.

"Not Approved"	Major ethical and methodological questions exist. The requested clarifications and changes must be resubmitted and reviewed by the REB.

The Principal Investigator will be notified in writing of the REB's decision as well as the reasons for the rating. Requests for additional information or clarification regarding outstanding issues or concerns may be sought at that time.

6. EXPEDITED/DELEGATED REVIEW

A portion of the proposals submitted to the REB are eligible for expedited/delegated review. This review is conducted by the Chair and one other Board member. The term "expedited review" refers to the fact that this makes the review process more expedient for the REB as a whole; it does not mean that proposals are reviewed more quickly than when reviewed by the full Board.

Proposals which are typically considered appropriate for expedited review include:
- Studies involving "minimal risk" to participants
- Extensions of previously approved proposals
- New studies which involve only minor modifications to a previously approved proposal

Proposals under expedited review will be forwarded to the full REB for review if it is deemed necessary by the Chair or Board member conducting the expedited review.

Minimal Risk is defined as:
"When 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 the relevant aspects of his or her everyday life."

Proposals submitted for expedited review must meet all the standards outlined in the guidelines.

7. RESOURCES

Approval by the REB does not indicate any commitment of personnel, material resources or space of the PEI Department of Health to any proposal.

The investigator must identify the impacted services of the PEI Department of Health and secure Letters of Support and/or Agreement. Copies of which must be submitted to the REB.

8. CONTINUING REVIEW REPORTING REQUIREMENTS

To fulfill the REB's responsibilities for continuing oversight of ongoing research (as mandated by the local, national and international standards), after the initial submission and review by the REB, Investigators are required to:

- Inform the REB immediately when it is believed that the risks of research participation have changed, or an unanticipated scientific or ethical concern has been raised by the research staff or participants.

- Complete and submit a **Request for Annual Approval form** for all ongoing research, on a yearly basis. Renewal of REB Approval is required on an annual basis, after a proposal is granted Full Approval by the REB. The Request for Annual Approval form should be received by the REB in advance of the Anniversary Date for your study (indicated in the REB's Full Approval Form), but

no more than 30 days in advance of the Anniversary Date. Submit the form far enough in advance to allow time for processing without your approval expiring. The REB will grant continued approval in writing. In some instances the REB may request that progress reports be submitted every 3, 4 or 6 months depending on the study.

- Submit changed and/or revised Protocols and Consent Forms for approval prior to implementation (except deviations from, or changes to the protocol to eliminate immediate hazards to the trial subjects, or when the changes involve only logistical or administrative aspects of the trial). It is very helpful when a rationale or justification for the changes is provided in a cover letter to the REB, along with a list of the major amendments. Major amendments deal with issues concerning patient safety such as inclusion/exclusion criteria, new tests or procedures, new study methodologies, confidentiality, contraception or research related clauses. All changes both major and administrative, are to be highlighted in the revised consent form. Any impact on subjects should be described. Any changes to the potential harms/benefits should be described. The REB will provide written approval for any revised protocol and/or consent forms.

- Complete and submit an **Updated Investigator's Brochure and/or Product Monograph form** when updated/revised versions are received. Revised brochures/monographs must be accompanied by a document that summarizes the changes that have been made. The REB will acknowledge receipt of updated documents in writing.

- Report all serious adverse events (and additional safety information) from external sites in a timely fashion to the REB. The REB will acknowledge receipt of safety information in writing.

- Report all serious and unanticipated adverse events that occur at the local site within 48 hours to the REB. The REB will review any recommendations and evidence from the investigator and sponsor regarding these events in terms of the implications for participant safety and whether or not any changes are required to the protocol or consent form. The REB will acknowledge receipt of the local safety report in writing.

- Complete and submit a **Reporting a Study Closure or Early Termination form** when a study has been closed. This form should not be submitted when study recruitment closes, but when all study activities at the local site terminates. The REB will acknowledge a site closure in writing and request that a final report/publications be submitted for information.

- Request Protocol Exception(s) prior to implementation. A protocol exception (waiver) is defined as any temporary protocol deviation that is approved by the REB prior to implementation. An exception to an eligibility criterion would be an example of a protocol deviation that should be approved by the REB prior to implementation. If a protocol deviation is implemented prior to its approval by the REB, it will be considered a major protocol violation. The REB will provide written approval of all protocol exceptions.

- Report All Major Protocol Violations to the REB. A major protocol violation is defined as any investigator- or sponsor-initiated protocol deviation that was not approved by the REB prior to implementation and that impacts the safety of trial participants, affects the integrity of the trial data, and/or affects the willingness of any trial participants to continue their participation in the trial. A couple of examples of major protocol violations are: obtaining informed consent with an approved version of the informed consent form that is not the most recent REB approved version; obtaining informed consent with a version of the informed consent form that has not been approved by the REB; not obtaining informed consent before initiating the study procedures; enrolling a new trial

participant without continued REB approval (i.e. - during a lapse in annual approval); The REB will acknowledge receipt of major protocol violations in writing.

- Report All Minor Protocol Deviations to the REB. A minor protocol deviation is defined as any protocol deviation that was not approved by the REB prior to implementation and that does not impact the safety of the trial participants, affect the integrity of the trial data, and/or affect the willingness of any trial participants to continue their participation in the trial. Deviations initiated (accidentally or intentionally) by the research team or sponsor need to be reported. Minor protocol deviations can be grouped and reported every 3 months after a study receives full approval. A couple of examples of minor protocol deviations are: scheduling participant visits outside of visit windows due to research staff holidays (if this does not affect the safety of the participants); not obtaining an investigator's signature on an informed consent form within 14 days of obtaining informed consent.

- Notify the REB of any planned audits by an external regulatory agencies (ie. Health Canada, the FDA). A copy of the audit report shall be sent to the REB within 2 weeks of receipt by the investigator.

- Notify the REB of any planned audits by the sponsor. A report of any substantive findings shall be sent to the REB within 2 weeks of receipt by the investigator. This requirement refers to full site audits by the sponsor, not the on-going monitoring visits performed during the course of the study.

- Notify the REB of any of the following changes:
  - Addition of a Co/Sub-Investigator (need address and contact information)
  - Removal of a Co/Sub-Investigator
  - Addition of Study Coordinator (need contact information)
  - Removal of a Study Coordinator
  - Change in Principal Investigator (need name address and contact information of the new PI).
  - Change in where research visits are to occur (in total or in part)
  - Change in research contact numbers
  - Change in mailing address and contact information
  - Change in status of practicing license for Medical Doctors

  Update the Consent Form as appropriate and submit for approval. This Board will provide written acknowledgment and/or approval for any changes to previously reported information.

NOTE: All documents/information submitted to the REB must be accompanied with a cover letter.

9. QUALIFICATIONS TO BE AN INVESTIGATOR

Education: The investigator has read and understands the principles behind
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- PEI Research Ethics Board Guidelines
- ICH Good Clinical Practice (if applicable)
- Health Canada Division 5 Regulations for Clinical Trials (if applicable)

Training: The investigator has adequate training in the discipline in which the research will be undertaken.

In addition, the REB requires the investigators and research staff to complete the free, online Introductory Tutorial for the Tri-Council Policy Statement 2nd Edition: Ethical

Conduct for Research Involving Humans (TCPS2). Those who complete the tutorial are required to submit the certificate to the REB.

Experience: The investigator has adequate experience in the discipline in which the research will be undertaken.

10. INQUIRIES

All submissions and inquiries should be directed to:

PEI Research Ethics Board
c/o Health PEI
16 Garfield Street
PO Box 2000
Charlottetown, PE C1A 7N8

Tel: 902-569-0576
Fax: 902-368-4969
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