Prince Edward Island
RESEARCH ETHICS BOARD

Research Protocol Guidelines

1. INTRODUCTORY INFORMATION:

Project Title

Local Principal Investigator, Institution/Department/Divisional Affiliation, Address and Telephone Number, Fax Number, Email Address

Co/Sub/Associate Investigators, Institution/Department/Divisional Affiliation, Address and Telephone Number

Anticipated Duration of Study

Name of Study Sponsor or Funding Agency (if applicable)

Local Site(s) of Research

Version Number and Date

2. SUMMARY:

This section, preferably in lay terms, should include a brief outline of the scientific rationale, hypothesis to be tested, methods of the study, the number of subjects to be studied and the statistical analysis planned.

3. BACKGROUND, RATIONALE AND STATEMENT OF RESEARCH QUESTION(S):

This section should provide the background necessary to understand why the study is being done. A review of current knowledge should be included and referenced. The explanations should be sufficiently clear that a reviewer, who might not be knowledgeable in this area of research, can be convinced that the benefits of the proposed research to the participant or the community at large will outweigh the risk. The primary objectives of the study as well as any secondary objectives (and their proposed usefulness) should be clearly outlined in this section.

For studies of therapies, procedures and interventions, the following must be explained clearly:

- What therapy or therapies represent the currently acceptable ones and which of these is considered "best practice"?
- What are the other treatment options?
- Why is the experimental treatment (drug, device, natural health product or surgery) being proposed?

If a placebo will be used, clearly describe the rationale behind its use. Justification for using a placebo instead of a standard therapeutic agent must be stated clearly.

4. SUBJECT SELECTION:

This section should contain the following information
All inclusion and exclusion criteria for selection of study participants.
Number of participants to be studied (if the study is multi-centered, both the number of participants to be studied locally as well as the number of participants in total should be stated),
Rationale (if not already obvious) for selection of participants.
Planned procedure for recruitment of participants into the study and for obtaining their informed consent must be described clearly. The primary care provider or a designated member of the care team should provide the initials contact to prospective subjects.

Screening procedures should be identified in this section.
If a significant amount of blood is to be withdrawn, criteria for acceptable blood counts for entry into the study should be included. (State the amount of blood to be drawn for screening purposes.)
Procedures to be used to prevent coercion or repeated use of the same subject in research studies should be included.

5. RESEARCH PLAN:

This section should be sufficiently detailed to include all important aspects of the experimental procedure and design including method of assignment to experimental groups, whether participants are randomized (explanation of randomization procedure), whether or not the investigators and/or participants are "blinded" (rationale and explanation of blinding procedures), frequency of subject visits, anticipated time commitment of participants, laboratory testing (identify labs to be used), dose of medications, experimental drugs or natural health products to be used (if applicable). Any additional procedures or tests incurred solely because of the individual's participation in the study should be clearly documented. Information should be provided regarding the reliability and validity of the data collection tools and measures to be used. The rules for stopping the study or withdrawing subjects from the study should be included. If more than one study design is being utilized, the different protocols should be clearly separated.

6. ANALYSIS OF DATA:

The proposed statistical evaluation should be included here. The sample size should be justified by the proposed analysis. The purpose of this section is to convince the reviewer that useable data will be forthcoming to address the primary and secondary objectives of the study. The primary and secondary outcomes should be clearly detailed in this section, as should the corresponding analyses and statistical methodologies for each outcome.

If the research is contractual with a pharmaceutical company or other business, it is preferable to have the data analyzed in an open non-censored manner by an independent analyst.

The REB recommends consulting with a medical statistician or biostatistician regarding appropriate statistical methods and analyses during the study design process, rather than post hoc consultation.

7. RISKS AND BENEFITS:

This section should include all significant adverse experiences which the study participant may encounter and the probability of their occurrence when known. Procedures for adverse event monitoring should be explained. In studies that require blood withdrawal, the amount should be quantified and should conform to the Canadian Blood Services Guidelines (450ml[30tbsp] total per 6 weeks). Potential benefits to the study participants should be described as well as potential benefits to society. In studies of new pharmaceutical agents that are not yet commercially available, it should be stated whether subjects who respond favorably will be able to continue to receive the agent beyond the time frame of the study. The benefits to patients who are randomized to a placebo should be stated, or, if no benefit exists, this should also be stated.

8. CONFIDENTIALITY:

This section should address the following issues:
Where will the data from the study be stored (while the study is ongoing and once the study has ended) and what security measures will be taken to maintain the confidentiality of the study?
Who will have access to the study data?
How long will the data be archived, and under what conditions (eg. in a locked filing cabinet)?
Health Canada requires that data from clinical trials be archived for 25 years. The PEI REB policy is that data from all other trials be archived for a minimum of 5 years from the time of study closure/termination.

9. LIABILITY:

There must be no statements which attempt to limit liability to which investigators, the institution with which they are affiliated, or the sponsoring company (if applicable) would ordinarily be subject.

10. DISCLOSURE OF ANY FINANCIAL COMPENSATION:

Research participants who are patients and who are receiving potential health benefits from participating in a study usually receive no monetary compensation. Reimbursement for direct expenses incurred by participants in the study, such as travel expenses, is acceptable. Participants who are not patients (ie. "normal" volunteers) often are compensated and remuneration for direct or indirect expense is ethically acceptable. The amount of compensation should be stated, and a justification that compensation is not sufficient to induce individuals to participate for monetary reasons should be provided.

11. REFERENCES:

The most recent relevant studies should be noted.

12. APPENDICES:

Questionnaires or measuring instruments and appropriate copyright release (if applicable) should be included as appendices to the proposal when appropriate.

Any advertisements intended for use to recruit participants should be submitted for review.

Please see the General Guidelines (Section 3.11) concerning Advertisements.

Administrative Requirements for Research Protocols:

- Please use a font-size large enough to be legible (12pt Times New Roman font is preferred). Protocols may be returned if this criterion is not met.

- Please include page numbers, as well as a version number and date on your proposal (which must be revised whenever the proposal is amended) and any appended data collection tools or measures.

Additional Considerations:

- Submissions based on a grant proposal (e.g. CIHR, PEI Research Fund), the level of data might not in all instances provide enough information about the methodology to meet the REB's requirements for ethical and scientific review. In these cases the grant proposal should be supplemented by further information based on the guidelines of the this REB.
- All documentation that will be provided to family doctors, participants, participant relatives and caregivers (including study introductory letters) must be reviewed and approved by the REB prior to use.