Research Ethics Board
Guidelines for Completing the Research Study Application

General

These guidelines are available to assist in completing the application form. The answers to all questions must be detailed on this form (it is not adequate to refer to other documents for this purpose). The form is available from the Research Ethics Office and must be typed in 12 point font.

Submission

Submissions to the REB must be complete with all appropriate documentation attached. All submissions are required to include:

- The Research Study Application completed by the applicant and endorsed by the applicants Department/Division Head. All research proposals are to be submitted by the applicant to the Head of the Department/Division whose patients will be under study. Signature from the Department/Division Head indicates agreement that the Department supports the project and that the Investigator is qualified to conduct the study.
- Supporting Documentation as outlined on the application checklist provided in the application form. These items include:

(1) Final research protocol
(2) Informed consent document
(3) Investigational Drug Brochure/Product Monograph
(4) Case Report Forms/ Data Collection Forms
(5) Questionnaires/diaries/wallet cards
(6) Advertisements for recruiting purposes
(7) Letters of Support
(8) Health Canada Qualified Investigator Undertaking (QIU) (if applicable)
(9) Research Ethics Board Attestation (REBA) (if applicable)
(10) TPD NOL (Division 5 trials only)
(11) Study Budget- All multi-party contracts are required to be submitted for review and approval through Research Services.
(12) A Curriculum Vitae and copy of medical license for PI

INSTRUCTIONS FOR COMPLETING THE FORM

Please note that unless an item is 'not applicable' for your study (which must be clearly indicated) ALL sections must be completed.

When completing the form, **please use the "tab" key when moving between data fields.** If this is not done the formatting of the document will be altered and some information will become lost/hidden in the form. If you require assistance or have any questions, please contact the Research Ethics Office.
I

Box 1

The Research Ethics Office will regularly publish lists of approved projects. Provide the complete title of the study/protocol that will be used in public reports of approved projects. If the title contains proprietary information, provide an abbreviated title that the sponsor has agreed to release through a contractual arrangement with Research Services. If the trial has been registered, please provide the registration number. Please refer to the following website for additional information on clinical trial registration http://www.clinicaltrials.gov/. The Horizon Health Network REB strongly supports the recommendations of the International Committee of Medical Journal Editors (ICJME) regarding the requirement to register all clinical trials on a publicly accessible and recognized registry.

Box 2

Indicate the location of the study population and from which facilities participants will be recruited

Box 3(a)

Provide the name of the Principal Investigator (PI) with current contact information. For clinical trials, one Qualified Investigator (QI) per clinical trial facility must be identified as medically responsible for a clinical trial according to Division 5 of Health Canada regulations. A QI refers to a physician or dentist in good standing of a professional medical or dental association.

Box 3(b)

Any PI not on active staff is required to collaborate with a member of the active staff of Horizon Health Network. The active staff member will assume responsibility as the contact or the Principal Investigator for the applicant in the study to ensure proper conduct of the study locally, protect the privacy of the patients, to maintain confidentiality of hospital records and to be clinically responsible for any risks related to the research study.

Box 4

Provide the name(s) of co-Investigator (s) with current contact information. The signature of each co-Investigator is required as evidence of their agreement to participate in the trial.

Box 5

Provide Research Coordinator current contact information. If this person is not an employee of this Institution, please contact the Research Services Office in your facility for further information.

Box 6
(6.1-6.3) Please provide administrative contact information as indicated on the form.

Box 7
Potential Conflict of Interest
Please complete as indicated on the form. As per the Tri-Council Policy Statement Article 7.4, "Researchers shall disclose to the REB real, potential or perceived individual conflicts of interests, as well as any institutional conflicts of interests of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interests" Please see http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/chapter7-chapitre7/#toc07-1c for additional information.

Box 8
Departmental Support and Awareness
Please complete as indicated on the form.

Box 9
Funding
Please complete as indicated on the form
.
Box 10
Sponsor Contact Information
Sponsor refers to any private or public/government agency that has agreed to provide full or partial funding for the study.

Box 11
REB Fees
Please complete as requested

Box 12
(12.1) Indicate what phase for clinical trials.
(12.2)Investigators should detail the plan for safety monitoring by the sponsor or DSMB (e.g., how often will safety data be analyzed; how often safety reports will be produced).According to the Tri-Council Policy Statement Article 11.3,"Researchers shall provide the REB with an acceptable plan for monitoring the safety of trial participants, including a plan for the tabulation, analysis and reporting of safety data in a form that permits REBs to interpret and act upon the data".
(12.3 a-b) Provide information regarding the costs of drugs/devices.
(12.4) Emergency code break information must be provided for blinded studies.

Box 13
Research Protocol Information
(13.1.1-13.1.5) Complete as requested
(13.2)Specific exclusion of any group (e.g., women, elderly) must be justified scientifically, or for safety reasons.

(13.3)Standard of care is defined as normal and/or expected treatment at facilities throughout Horizon Health Network. Procedures should be described in enough detail so that it can be compared with details in the protocol for the REB to understand how participation in this study changes the normal treatment procedures (e.g., different drugs, visits, assessments, tests, etc.).
(13.4)Specify which tests, procedures and visits are research-related and how they differ from standard of care. This information must be transferred to the consent form in such a way that the subject understands how participating in the research may be different from the treatment normally received with standard care.
(13.5) List any additional visits, procedures, or data collection (including collection and banking of blood and/or tissue) for the purpose of the study.
(13.6) Follow-up care following the end of a treatment study should describe what appropriate referral arrangements will be made.
(13.7)The outcome of previous reviews by another REB should be provided.
(13.8)Investigator's should be aware of any statements in the contract which appear to prohibit the right to notify research subjects, other investigator's, physicians, the REB, regulatory agencies or the scientific community of newly identified risks during the conduct of the study.
(13.9)The language in the contract should not contain an agreement that would prohibit an investigator's final ability to publish. However, it is recognized that some delay in publication by local investigators in a multi-center trial may be requested by the sponsor for the purposes of an initial publication of the entire study, or for review of the material

Box 14
Informed Consent Process
(14.1) The informed consent procedure should be described following the three questions outlined in this section. Note that it is the policy of the REB that the initial contact of a potential research subject should be by a member of the health care team. A researcher not on a health care team may only contact the patient after the patient has agreed to be approached.
(14.2) Any expected limitations to consent should be described (e.g., if subject population is likely to include individuals with limited capacity or individuals with special needs who might not be able to see or hear). If the capacity to consent changes during the course of the study how the issue of will informed consent be handled.
(14.3) Refer to the Tri-Council Policy, Section 2, Article 2.1(c) and describe the potential benefits which will result from this research which justifies waiving the normal requirements for full disclosure.
(14.4) Refer to the Institutional policy on consent from Substitute Decision Makers which lists individuals who may qualify as a temporary substitute decision maker.

Box 15
Other Ethical Issues
A placebo-controlled trial must be justified by using ***specific reference*** to the circumstances outlined in the Tri-Council Policy, Article 11.11 This document can be viewed at: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/chapter11-chapitre11/#toc11-1g. Some studies are conducted in order to

satisfy requirements for Health Canada or FDA approval. This is not a sufficient ethical justification for the study. Ensure that a more precise justification is provided which explains why additional studies are needed and warranted.

For clinical trials, information should provide evidence of *clinical equipoise*, which is defined as "...a genuine uncertainty on the part of the expert medical community about the comparative therapeutic merits of each arm of a clinical trial." The justification must include the differences between what is considered the current 'standard of care' and the experimental intervention.

Box 16
Privacy and Confidentiality
(16.1-16.4) Please complete as requested. This section collects information as required by federal and provincial privacy laws.

Box 17
Research Summary
The summary should include the following information:
(i) **Hypothesis/Research Question -** This specifies the precise research questions being evaluated in the study.
(ii) **Objectives-** This includes the specific outcomes/endpoints of the research.
(iii)**Research Method -** This should include a description of the target population and/or sample, sample size, sampling method (e.g. randomization), type of research design (e.g., experimental parallel group or cross-over design) and the statistical analysis plan. It should also include a justification for the use of deception or placebo or for the need to carry out research in emergency health situations, if applicable.
(iv) **Proposed Benefits/Potential Risks -** Specify the benefits to the subjects and if there are no benefits, state this explicitly. Information on harms must be included and must be consistent with the information on harms provided in the protocol and Investigator's Brochure. **Purpose -** This is the main reason that the study is being conducted (e.g. to determine efficacy, equivalence, safety, dosage levels, effectiveness) and should include the direct implications/applications of the research. Specify whether or not optional studies that may be part of a protocol are being conducted at the local site. This should also include background evidence that explains the need for the study. In particular this section should explain what is unique about the study and what new research questions can be answered in order to support the ethical tenet that the proposed research has value.

Box 18
All supporting documentation as outlined in the checklist must be appended to the application.

Box 19
The Principal Investigator for a study is responsible for adhering to the TCPS and other relevant guidelines and regulations, and indicates this by signing the application form.

Box 20
The Principal Investigator's Department Head must also sign the application form to indicate that the Principal Investigator has the qualifications, experience, and facilities to carry out their research.

Complete applications are then submitted to:
Dept. of Ethics Services, 5DN
Saint John Regional Hospital
400 University Avenue – PO Box 2100
Saint John, NB, Canada E2L 4L4
Telephone: (506) 648-6094

Submission Deadlines

The REB normally meets every four weeks on Wednesdays with the exception of August. The deadline for submission is two weeks prior to the meeting date. Submissions must be received in the Research Ethics Office by 4:00pm on the deadline date.

When a study submission is received, it is reviewed by Research Ethics Office for completeness. The Research Ethics Office will contact the Investigator to obtain any further information required or resolve any protocol or consent form related issues in order to facilitate the review process. Any issues and /or resolutions will be reported to the REB at the time of review. The Research Ethics Board reserves the right to defer any submission that is lacking information critical to the deliberations of the Board.