WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Windsor Regional Hospital Research Ethics Board

GUIDELINES for the Submission of Research Projects

1. Role of the Research Ethics Board

The mandate of the Windsor Regional Research Ethics Board is to safeguard the rights, safety and well being of all research participants. The Research Ethics Board carries out its functions in accordance with ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2).

The REB reviews and approves research projects that meet acceptable ethical and scientific standards and for which adequate facilities and resources are available.

2. General Requirements

What requires REB approval?

All research projects carried out at all sites within Windsor Regional Hospital require the approval of the Research Ethics Board (REB). The Tri-Council Policy Statement further requires that research to be performed outside the jurisdiction or country of the institution which employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the REB, 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.

Chart reviews and other reviews of clinical practice conducted solely for the purpose of quality assurance monitoring do not require ethics review. However, quality assurance or quality improvement projects that contain a research element should be submitted to the REB.

Credentials of the Principal Investigator

If the Principal Investigator does not have affiliation with Windsor Regional Hospital, there must be named a "Locally Responsible Person", who is a staff member or has affiliation and who will be responsible for the conduct of the research. Any project involving medical or surgical treatment must have a licensed physician as an Investigator and the consent form must be signed by the Investigator.

Industry-sponsored studies

A review fee of $3,000 (CDN) payable to Windsor Regional Hospital is required for REB review of all industry-sponsored research projects and must be submitted with research application. There is also an annual research renewal fee of $500.00 (CDN). For further information regarding fees, please contact the Research Ethics Office at (519) 254-5577 Extension 52034.

3. Delegated Ethics Review

Minimal risk research projects which meet acceptable ethical and scientific standards and for which adequate facilities and resources are available may receive a delegated ethics review. Delegated review designation is at the call of the Chair. The TCPS2 definition of minimal risk helps to guide the selection of projects that can be considered for delegated review (TCPS2, Chapter 6; Article 6.12). The full REB is notified at its next meeting of the research designation following delegated approval and decision is recorded in the meeting minutes.

Delegated review is comprised of the Chair and two members from within the full membership and is determined by area of expertise necessary for that particular research and on a rotation basis.

4. Primary Reviewers

Two Primary Reviewers from within the full membership are assigned to each Clinical Drug Trial. The Primary Reviewers review Adverse Event Reports; Amendment Reports; general notifications such as Deviation alerts and DSMC reports. Full membership reviews Annual Progress Reports of approved projects; as well as Study Completion Reports. The Primary Reviewers report their opinion and final approval of these activities must be given by the full REB at its next meeting.

5. The Application Process

Applications to the REB must be submitted to the Research Ethics Office (Room ME 1310 – Metropolitan Campus) 2 weeks prior to meeting for consideration at the REB meeting held that month. REB meetings are held on the last Wednesday of each month at 17:00 hours. Principal Investigators are asked to attend the meeting to discuss their research proposal. If distance / circumstances prevent the Investigator from attending in person, telephone conference may be considered.

For **research requiring full board review**, the application packages must be submitted in complete sets which include copies (including one with required original signatures), consisting of:

- Cover letter to REB listing all attachments for submission;
- **1** signed copy of Research Ethics Board Submission Form for Research Involving Human Participants;
- **1** copy of the Consent Form and / or Letter of Information
- **1** copy of study protocol, if drug trial
- **1** copy of any educational materials / advertisements
- **1** copy of the Investigator's Brochure (if applicable – drug trials)
- **1** copy of each completed Departmental Impact Statement
- **1** copy of Privacy Agreement signed by Researcher
- **1** copy of Privacy Agreement signed by each Research Associate
- **1** copy of CV for Principal Investigator (do not resubmit if previously submitted)
- **1** *Certificate of successful completion of training in Protection of Human Subject Participants. Provide a certificate for Principal Investigator(s), **and for each** on site Co-Investigators, Research Associates(s) and / or study nurses. (Excellent tutorial courses, which issue a certificate when complete and take approximately 1-2 hours are available on-line at www.pre.ethics.gc.ca. or http://phrp.nihtraining.com/users/login.php - **(DO NOT RESUBMIT CERTIFICATE IF PREVIOUSLY SUBMITTED)**

Please note: All sections of the application form must be completed. It is not enough to refer to sections of the protocol.

The REB Coordinator will review each application for completeness. If there are elements missing, the investigator will be notified and will be given 24 hours grace period after the submission deadline in which to supply the missing information.

6. Protocol Requirements

The research question and methodology must be presented in sufficient detail to permit evaluation of the scientific merit of the project. The protocol should include:

- Study purpose and rationale
- Description of the population to be studied, inclusion and exclusion criteria
- Sample size (and how sample size was determined)
- Design and detailed description of methodology
- Definition of end-point(s)
- Measurements and measurement instruments.* Data Collection forms (when available)
- Data analysis plan including confidentiality / privacy and protection plan
- How subjects will be recruited, including advertisements / publicity
- References

* Any patient questionnaires must be submitted with the application. Telephone scripts must be provided for telephone interviews / surveys.

7. Consent Form Requirements

Consent forms and patient information sheets may be combined or written separately. Readability should be at a Grade 8 level. The text of the consent form must include the items specified in the **Informed Consent Checklist**, which is contained in the Application. If investigators propose to study recipients of their therapeutic care, invitations to participate in the research should ideally be made by persons on whom the subjects have no dependency. It must be documented on how consent was obtained. Use of verbal consent must be justified in the protocol. The WRHREB Logo guidelines for consent forms must be followed. The research subject must be given a **signed** copy of the completed consent form.

8. Review Procedure

While all REB members read all of the applications, two members are assigned to each application to review it in greater detail. The Chair will call upon these reviewers to lead the questioning of the investigator and the discussion that follows.

The REB may vote to approve the application as submitted, to approve with conditions, to defer a decision with recommendations for (usually major) changes, or to disapprove the application. If the REB approves the project, it may begin as soon as the investigator has received written approval. Written approval is not given until project funding, Clinical Trial Agreement (or applicable research contract) and Department Impact sign-offs have been satisfied. If the approval is conditional on modifications being made, research may not begin until these modifications have been verified and approved by the REB Chair and a letter of final approval has been issued.

The process of delegated review is similar, but does not require the presence of the principal investigator.

All Ethics Submissions **must be signed by the Principal Investigator**.

9. Appeal of Research Ethics Board Decision

The REB is guided by principles of natural justice in its decision-making. Such principles include providing a reasonable opportunity to the researcher to be heard, written explanation of the reasons for opinions or decisions, opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions.

To this end, the REB encourages ongoing discussion with researchers prior to the submission of new human ethics protocols and during the review process, with provision for reconsideration of a decision affecting a research project. When a researcher and the REB cannot reach agreement, the decision of the REB may be appealed by the researcher. The onus is on the researcher to justify the grounds on which they request an appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision.

The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before the researcher initiates an appeal. (TCPS 2 Chapter 6; Article 6.18 to 6.20).

REPORT REQUIREMENTS FOR ONGOING RESEARCH

After the project is reviewed and approved, the following reports must be submitted for REB approval.

1. Amendments to Protocol or Consent Form

a) Any changes in the study protocol or information sheet/consent form must be detailed on an **Amendment Form**. If, in the investigator's opinion, these changes could affect a subject's willingness to participate, or adversely affect the risk/benefit ratio, an amended consent form must be submitted and further enrollment must be halted until the investigator has written approval to continue. In some cases, re-consenting of all study subjects may be necessary;
b) Advertisements for recruitment purposes not submitted at the time of initial application must be approved by the REB prior to use;
c) Any changes in reimbursements or incentives must be approved prior to implementation.

2. Serious Adverse Event Reporting

A **Serious Adverse Event (SAE)** is any adverse occurrence or response to a drug/intervention, whether expected or not, that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity that is life threatening or that results in death.

Local Serious Adverse Events:

- **Use the *Local Serious Adverse Event Report* form.**
- All ***local*** Serious Adverse Events, whether expected or not, must be reported ***promptly*** to the Research Ethics Board, if in the opinion of the investigator the event may be related to the study drug/intervention.
- ***Prompt*** reporting of all locally occurring serious adverse events, drug-related or other, which requires reporting as follows:
  a) If it is neither fatal nor life threatening, **within 15 days** after becoming aware of the information; and
  b) If it is fatal or life threatening, **within 48 hours** after becoming aware of the information.
- The reporting of SAEs may **not** be deferred to the Annual Progress Report.
- In addition, local SAEs must be reported by the Locally Responsible Investigator to the study Sponsor or appropriate federal government agencies (e.g. Health Canada).
- If the local site is part of a multi-centre study, the Locally Responsible Investigator must also append the most recent *Data Safety Monitoring Board (DSMB) or a Sponsor-generated Safety Report* summarizing Serious Adverse Events to-date and any implications for the risk/benefit ratio, as described below.

Non-local Serious Adverse Events:

- If the *local site* is part of a *multi-centre study*, the Locally Responsible Investigator is responsible for providing regular (2 to 3 times per year) **DSMB or Sponsor-generated Safety Reports** to the REB Office, as described below.

Data Safety Monitoring Board (DSMB) and Sponsor-generated Safety Reports:

- All DSMB Reports must be forwarded as soon as they are available and must be accompanied by a letter from the Locally Responsible Investigator indicating that s/he accepts the findings and recommendations of the DSMB.
- Sponsor-generated reports must contain the following information:
    - Total number of participants;
    - Total number of serious adverse events;
    - Total number of serious adverse events likely related to the study drug/intervention;
    - Whether the study should continue.
- The Sponsor-generated report must be accompanied by a Cover Letter from the Locally Responsible Investigator indicating his/her assessment of the seriousness and causality of the side effects and whether in his/her opinion they alter the risk/benefit ratio and/or require changes to the Information/Consent documents, Protocol, or other study documents.

3. Annual Progress Reports

A detailed progress report must be submitted every year to the REB until the project is completed. The report must include the items detailed in the **Annual Progress Report** form and the results of any interim analyses or safety committee reports. The Annual Progress Report form should be accompanied by a list of all publications arising as a result of the research project.

For high risk studies and other circumstances, more frequent reporting may be required.

4. Unusual Events

The attending physician of the research subject must be notified in the event that unusual or unexpected results are obtained in the study as a whole or in a single subject. A copy of the letter of notification should be sent to the REB.

5. Study Completion Report

It is the investigator's responsibility to notify the REB using the **Study Completion Report** form when the study has been terminated, or if the study is cancelled after REB approval has been received. If study is cancelled, the reasons for cancellation should be stated.