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RESEARCH ETHICS BOARD

GUIDELINES

SUBMISSION OF RESEARCH PROJECTS

1. Role of the Research Ethics Board

The mandate of the Research Ethics Board is to safeguard the rights, safety and well being of all research participants.

The REB reviews and approves research projects that meet acceptable ethical and scientific standards and for which adequate facilities and resources are available. The REB also provides advice on the ethical, scientific and technical aspects of planning research projects.

2. General Requirements

What requires REB approval?

All research projects carried out at any and all sites within Niagara Health System require the approval of the Research Ethics Board (REB). *The Tri-Council Policy Statemen : Ethical Conduct for Research Involving Humans (TCPS2)* [a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC)], 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.[1]

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 is not a member of the staff of Niagara Health System there must be named as co-investigator a "Locally Responsible Investigator", who is a staff member and who will be responsible for the conduct of the research. Any project involving medical or surgical treatment must have a licensed physician as a co-investigator and the consent form must be signed by a physician.

Industry-sponsored studies

An administrative fee of $2500 (Cdn) payable to Niagara Health System is required for REB review of all industry-sponsored research projects. For information regarding this fee, please contact the Research Ethics Office at 905 378-4647 Ext 32202.

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3. Role of the Research Ethics Board's Executive Committee

The Executive Committee of the REB reviews and approves minimal risk research projects which meet acceptable ethical and scientific standards and for which adequate facilities and resources are available. The Tri-Council Policy Statement 2 definition of minimal risk helps to guide the selection of projects that can be considered by the Executive Committee (TCPS 2, Chapter 2, Article 2.8 B; and Chapter 6, Article 6.12). **The project must be approved by the full REB at its next meeting for the research to continue**.

The Executive Committee also reviews Adverse Event Reports; Amendment Reports; and Annual Progress Reports of approved projects; as well as Study Completion Reports. Final approval of these activities must be provided by the full REB at its next meeting.

The membership of the Executive Committee is determined by the Research Ethics Board.

4. The Application Process

Applications to the REB must be submitted to the secretary of the REB by **1600 hours ten (10) working days before the scheduled meeting.**

(a) for consideration at the REB meeting held on the first Tuesday of each month.

(b) To be accepted, the application package must include 12 copies (including the one with all required original signatures), consisting of:

- A typed **Application for Review by Research Ethics Board**;
- Consent form/Information sheet;
- Research Protocol (see Section 5 below);
- Letters of approval from hospital/university REBs in other jurisdictions (if applicable);
- Approval letters from Health Canada for new investigational drug or device, of for off-label use of previously approved drug or device, (if applicable – See Sec. A.8 of Application Form);
- A product monograph or investigator's brochure if the study includes an investigational agent not yet approved by Health Canada;
- Approval letters from Infection Control if the study intervention involves use of an infectious agent; or approval letter from Biosafety Committee if the study involves the use of gene therapy or viruses (See Sec. A.9 of Application Form);
- Budget Summary (see Application Form);
- Informed Consent Checklist (see Application Form)
- Copy of certificate of completion for online tutorial of the TriCouncil Policy Statement 2 (TCPS2) – here is the link for the online tutorial:

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http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

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Forward all materials (original documents), including Application for Review and the Information/Consent form(s) to:

Research Ethics Office
Niagara Health System – Welland Site
65 Third Street
Welland, ON
L3B 4W6

Application forms may be obtained as printed forms. Forms may be obtained online at the link below, or from the REB Office at:

Welland Hospital Site
65 Third Street
Welland, ON
L3B 4W6

Online link to REB webpage containing application forms:

http://www.niagarahealth.on.ca/en/research-ethics-board

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

The REB secretary 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 deadline in which to supply the missing information.

(c) Review of Student Research Projects

To assist with processing student research projects in a timely manner, a Sub-committee of the Research Ethics Board (REB) will review all proposed student projects (i.e. non-invasive studies with minimal risk to research participants) at the undergraduate and Masters level. Instructions for the Review of Student Projects and Student Review Form may be obtained as printed forms.

All invasive and Ph.D. projects will be reviewed in full by the Research Ethics Board, requiring students to follow the application process outlined in (a) and (b) above.

5. 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.
- How subjects will be recruited, including advertisements/publicity.
- References.

* Any patient questionnaires that have not been published in a peer reviewed journal must be submitted with the application. Telephone scripts must be provided for telephone interviews/ surveys.

6. 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. Use of verbal consent must be justified in the protocol. Written consent forms must be on Niagara Health System letterhead or bear the heading "Niagara Health System". The research subject must be given a **signed** copy of the completed consent form.

7. Review Procedure

For projects submitted to the REB, the principal investigator may be invited to attend the meeting of the Research Ethics Board and given an appointment time. The REB meets on the first Tuesday of the month. **If the principal investigator cannot represent the project on this date, or cannot delegate this responsibility to a co-investigator, this should be noted at the time of submission.** The project may be deferred to the next scheduled REB meeting if a decision cannot be reached.

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. Research may begin as soon as the principal investigator receives a letter of authorization to proceed from the REB Chair, but approval may be withdrawn (very rarely) by the Medical Advisory Committee or the Board of Trustees. A letter indicating the REB decision will be sent to the principal investigator by the REB Chair, usually within one month of the submission deadline.

If the REB approves the project, it may begin as soon as the investigator has received written approval. ***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.

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

All forms and correspondence submitted to the REB for review and a decision or response from the REB, **must be signed by the principal investigator**.

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REPORT REQUIREMENTS FOR ONGOING RESEARCH

After the project is reviewed and approved, the following reports must be submitted for REB approval (should they apply):

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 enrolment 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 Executive Committee, 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.
  (speak to above two or three points)

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. It is recommended that **annual renewals be submitted six (6) weeks prior to their renewal date** to ensure the continuity of the study.

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. The reasons for cancellation should be stated.

[1] Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans (1998), Section 1, Part H, Article 1.14, *Review of Research in Other Jurisdictions or Countries*:
http://www.pre.ethics.gc.ca/eng/archives/tcps-eptc/section1-chapitre1/#1H