WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Windsor Regional Hospital Research Ethics Board

Research Ethics Submission Guidelines

Contents

Role of the Research Ethics Board

The mandate of the Windsor Regional Hospital Research Ethics Board (WRH REB) is to safeguard the rights, safety and well-being of all research participants. WRH REB is constituted and operated in accordance with the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2), Canadian Food & Drug Regulations, Division 5 (Clinical Trials), ICH Good Clinical Practice Guidelines E6, Personal Health Information Protection Act, 2004 (PHIPA), U.S. Code of Federal Regulations Title 21 & 45. The WRHREB also holds a Federal Wide Assurance Registration with the U.S. Office of Human Research Protection. All research involving human subjects at Windsor Regional Hospital is reviewed by the WRHREB.

The REB reviews and approves research projects that meet acceptable ethical and scientific standards and for which adequate facilities and resources are available. In order to facilitate this review, it is essential that all the necessary documentation is submitted to the REB for review. Please see Application Checklists below.

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.

Examples of research studies requiring REB approval:

- Research involving live human participants
- Research involving human remains, cadavers, tissues, biological fluids, or embryos
- Research involving the secondary use of data such as the use of patient chart abstractions

REB review exemptions

Case Reports: Case reports are considered a description of some or all of the diagnosis, treatment and follow-up of an individual patient. Projects may be considered a case report if they include **3 or less** patients. Case Reports are not generalizable or scientifically rigorous. They are considered educational based on the limited number of interesting cases, and that patient(s) are treated as clinically indicated, not by a research protocol or intervention.

Quality Improvement: Quality improvement projects focus on improving a program, process or system and should not increase risk or cause excessive burden to patients or staff. Chart reviews and other reviews of clinical practice conducted solely for the purpose of quality assurance/improvement (QA/QI) monitoring do not require ethics review (i.e. QA/QI that assesses the performance of an organization or its employees or students). Quality improvement/assurance studies and program evaluations which address a research question require REB review. It is recommended that QA/QI projects be submitted to the REB to confirm if the project qualifies as QA/QI prior to accessing data. If the chair deems the project as QA/QI, an exemption letter will be issued.

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" (i.e. WRH Site Investigator), 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 with active privileges at WRH as the Principal Investigator.

Industry-sponsored studies

A review fee of $3,000 (CDN) payable to Windsor Regional Hospital is required for REB review of all new industry-sponsored research projects. There is also a fee of $500.00 (CDN) for annual renewals and major amendment submissions. Fees must be submitted with your application along with the REB Review Recovery Form. Cheques should be made payable to Windsor Regional Hospital (reference: REB Review fee) and submitted to the Corporate Office of Research, Met Campus. For further information regarding fees, please contact the Research Ethics Office (see contact information below).

Training

All investigators and team members named on the application are required to complete research ethics training courses. Training includes completion of:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)
- WRH REB Privacy Tutorial for Researchers

Additional research training courses that may be required depending on type of research being performed is:

- Good Clinical Practice (applicable if research is a clinical trial)
- Health Canada, Division 5 Training
- Transportation of Dangerous Goods

For information on accessing the additional training, contact research.office@wrh.on.ca. Completion records of the research ethics training courses and additional research training courses should be submitted online: https://redcap.link/WRH_researchtraining.

Delegated/Expedited Ethics Review

New research projects that involve no more than **minimal risk**, and meet acceptable ethical and scientific standards and for which adequate facilities and resources are available **may** receive a delegated/expedited ethics review. To be associated as **minimal risk**, the potential risk(s) from research related activities to the participant is **not greater** than what the participant is exposed to in their day-to-day activities and life.

Delegated/expedited review designation is determined by the Chair. The TCPS2 definition of minimal risk helps to guide the selection of projects that can be considered for delegated/expedited review (TCPS2, Chapter 6; Article 6.12).

Examples of projects that **may** qualify for delegated/expedited review include:

- Retrospective chart review research
- Research utilizing secondary or archival data

- Projects that have received formal approval from the University of Windsor REB and are being submitted to the WRH REB under the reciprocal review agreement

Please note, any submissions made within **2 weeks** prior to the normal scheduled REB meeting will be reviewed at the Full Board meeting.

Other submissions may also qualify for delegated/expedited review such as: translations of previously approved documents, additions of new research team members, or continuing annual reviews of approved minimal risk research where there has been no changes to the research as previously approved.

Delegated/expedited review submissions are reviewed outside of the REB meeting schedule by the entire board. Once a quorum is received on the submission, a decision letter is issued. All offline decisions are documented and shared for reference in the subsequent REB meeting and recorded in the meeting minutes.

The Application Process for New Project Submissions

Prior to submitting your application to the REB, your research project must first undergo a new project Intake Review assessment by the Office of Research. This process includes facilitating the review and sign off of Departmental Impact form(s), Clinical Trial Contracts, Project Funding Recoveries Form and any other institutional reviews and approvals. The study protocol and/or draft ethics submission submitted to the Office of Research **prior** to WRH REB application submission at research.office@wrh.on.ca. Following successful intake by the Office of Research, a No Objection Letter will be issued, which must be included as part of your application to the REB.

Once review is completed with the Office of Research, applications to the REB must be submitted to the Research Ethics Office by email to research.ethics@wrh.on.ca by the posted deadline for consideration at the REB meeting held that month. The REB Administrator will review each application package 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.

All Ethics Submissions must be reviewed and signed by the Principal Investigator.

REB meetings are held on the last Wednesday of each month at 17:00 hours. Principal Investigators (or an approved delegate) are asked to attend the meeting to discuss their research proposal and will be given an appointment time. Principal Investigators will have 10 minutes allocated to their project, a few minutes to provide a brief overview, and the remainder of the time to be used to answer questions from the REB members. At this current time, all meetings are held virtually, an access link will be provided before the meeting.

Required Application Documents for New Project Submissions

Research Involving Humans

Ethics applications for **research involving humans** must include the following applicable documents (all study documents should have a version date and/or number):

- Completed and signed checklist (cover page of application form), listing all attachments for submission;

- Office of Research's No Objection Letter
- Research Ethics Board Submission Form for Research Involving Human Participants;
- Study protocol – all studies under this application category **must** have a study protocol
- Consent Form and/Letter of Information
- Study recruitment materials
- Study instruments (i.e. surveys, interview guides, data collection forms, CRF)
- Permissions/Approvals (i.e. other REB clearances)
- Investigator's Brochure (if applicable – drug trials)
- Health Canada NOL (if applicable – drug trials)
- Departmental Impact Form for each department impacted
- Privacy Agreement signed by **each** Researcher (PI and Co-PIs)
- Privacy Agreement signed by **each** Research Associate (all research team members)
- CV for Principal Investigator (not required to resubmit if previously submitted within 5 years)
- **Each member** of the research team must complete the Windsor Regional Hospital Privacy Tutorial available here: https://redcap.link/wrhreb_privacytutorial (to be completed every 5 years). You do not need to attach the PDF copy to the application.
- **Each member** of the research team must complete the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2) training and submit completion certificate to https://redcap.link/WRH_researchtraining. Certificate copies do not need to be included in the application.
- REB Review Fee Recovery Form and payment (if industry sponsored research)

Research Involving Archival/Secondary Data

Ethics applications for **research involving archival/secondary use of data** must include the following applicable documents (all study documents should have a version date and/or number):

- Completed and signed checklist (cover page of application form), listing all attachments for submission;
- Office of Research's No Objection Letter
- WRH Ethics Submission Form for Archival/Secondary Use of Data
- Study protocol – recommended in case an amendment is needed in the future.
- Consent Form and/or Letter of Information
- Data collection tools (i.e. CRFs, data collection forms)
- Permissions/Approvals (i.e. other REB clearances)
- Departmental Impact Form
- Privacy Agreement signed by Researcher
- Privacy Agreement signed by **each** Research Associate
- CV for Principal Investigator (not required to resubmit if previously submitted within 5 years)
- **Each member** of the research team must complete the Windsor Regional Hospital Privacy Tutorial available here: https://redcap.link/wrhreb_privacytutorial (do not complete again if done within 5 years). You do not need to attach the PDF copy to the application.
- **Each member** of the research team must submit the most recent completion of training from Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2) to https://redcap.link/WRH_researchtraining. Certificate copies do not need to be included in the application.

Consent Form Requirements

Consent forms and patient information sheets may be combined or written separately. Readability should be at a **Grade 8 level** or less, depending on your patient population. If investigators propose to study recipients under their therapeutic care, consent to participate in the research should be completed by persons on whom the subjects have no dependency. It must be documented on how consent was obtained. The WRH logo should appear on the consent forms. The research subject must be given a signed copy of the completed and signed consent form. If requesting verbal consent, use of verbal consent must be justified in the protocol.

Data Storage Requirements

Privacy, security, and confidentiality are of the utmost importance to Windsor Regional Hospital and the WRH REB. The easiest way to protect participants is through anonymized data, although this may not always be possible. It is the ethical duty of both the researcher and the REB to ensure there are appropriate measures to minimize risks and safeguard information.

Windsor Regional Hospital requires that all data be stored with physical safeguards (for example, files in a locked cabinet, administrative safeguards (i.e. only approved individuals may access such information) and a number of technical safeguards, including the use of computer passwords, password protecting files with personal information or personal health information, storing files on protected network folders where only authorized users have access, and encrypted storage devices.

Details of how data will be stored and destroyed **must** be documented in your submission to the REB. Should there be any changes in how sensitive data is stored (for example, moving to REDCap platform) this must be detailed and submitted to the REB in an amendment.

Data must be stored by researchers for a minimum of 7 years following publication or study closure, or 15 years from the end of study, in line with Health Canada regulations.

Application Review Procedure

While all REB members read all of the applications, two primary reviewers are assigned to each application to review it in greater detail. The reviewers are assigned based on their respective area of expertise. At the meeting, 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. If the REB approves the project, it may begin as soon as the investigator has received written approval and all other required approvals are obtained (i.e. REBs for other jurisdictions). 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. As discussed above, delegated review is conducted off-line and the submission is provided to all REB

members. Once a quorum amount of responses is received, a decision will be issued to the principal investigator.

You will typically be notified of the REB decision by e-mail within 10 business days of the meeting. However, depending on the nature of the review, some responses may take longer.

There are four types of decision letters that may be issued:

Designation type	**Definition**
Category A – Full Approval	You may begin research as your submission is fully approved.
Category A – With Notes	You must acknowledge/address the comments from the WRH REB in a response letter however, resubmission of all documents is not required. WRH REB will review your response letter and if satisfied, your project will be designated as a Category A – Full Approval and new letter issued.
Category B – With Concerns	With a Category B designation, you must respond to the comments from the WRH REB (see notes below) in a separate **letter and re-submit any amended documents with tracked changes.** The WRH REB will review your response and if satisfied, your project will be designated as a Category A – Full Approval and new letter issued.
Category C – Decision Deferred	With a Category C designation, you must respond to the comments from the WRH REB (see notes below) **in a separate letter and re-submit any amended documents with tracked changes**. The WRH REB will review your response and if satisfied, your project will be designated as a Category A – full approval and new letter issued. **Due to the level or number of concerns from the REB, you may also be required to present your submission again at a subsequent REB meeting.**

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).

Required Ongoing Reporting for Approved Research

After the project is reviewed and approved, the following ongoing reporting is required to be submitted for WRH REB approval. Without WRH REB approval on the following reports, your research project will be deemed inactive and you will be unable to conduct the research project activities until the required approvals are obtained. Should the original Departmental Impact be amended in the ongoing reporting, the Office of Research should be consulted with prior to REB submission.

Amendments to Protocol or Study Documents

Any changes to the study from the originally approved submission must be submitted to the WRH REB for review on the Amendment Request Form. No changes should be implemented until REB approval is received. Changes should not be made on the original application form. Changes should be made only to the protocol and supporting documents and should be submitted as tracked changes.

The following are examples of changes to the study that would require an Amendment Request Form to REB. This list is not exhaustive; if the investigator is unsure if the change requires an amendment, they should connect with the REB for guidance.

- Any changes in the study protocol and consent form/letter of information. If, in the investigator's opinion, the changes could affect a subject's willingness to participate, or adversely affect the risk/benefit ratio, an amended consent form is required to be submitted. Depending on amendment requested, re-consenting of all study subjects may be necessary, and details of re-consent should be identified in the application;
- Changes or new recruitment materials;
- Any changes in reimbursements or incentives;
- Changes to data collection variables or storage;
- Changes to, or addition of, research team members;

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:

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. Reporting is completed on the Serious Adverse Event Reporting Log.

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 **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.

Annual Renewal Reports

A detailed annual renewal must be submitted every year to the REB until the project is completed. The report must include the items detailed in the Annual Renewal Request Form and the results of any interim analyses or safety committee reports. The Annual Renewal Request 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.

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.

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. It is imperative that the study completion form is as detailed as possible and includes a list of all publications and presentations associated with the project. Study completion reports should only be submitted once data analysis is complete.

Outstanding Documents

It is the investigator's responsibility to ensure all submissions are complete and up-to-date. Should there be other materials outstanding, such as annual renewals or missing training, any new submissions from the investigator may not be accepted until all outstanding documents are received.

REB Meeting Schedule and Submission Deadlines

The WRH REB meets monthly on the last Wednesday of every month, excluding December. Submission deadlines are two Mondays prior to the meeting date. The full meeting schedule and deadlines can be found on the WRH REB website.

Contact Information

A list of the current WRH REB committee members is available on the WRH REB website.
All applications and reporting documents should be submitted to:

research.ethics@wrh.on.ca
519-995-0184
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