WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Windsor Regional Hospital Research Ethics Board

LETTER OF INFORMATION TO INVESTIGATORS

Thank you for your interest in conducting research at Windsor Regional Hospital. All research involving human subjects at Windsor Regional Hospital is reviewed by the Windsor Regional Hospital Research Ethics Board (WRHREB). In order to facilitate this review, it is essential that all the necessary documentation is included in your application. Please see Application Package List below. The Windsor Regional Hospital Research Ethics Board (WRHREB) 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.

For **industry-sponsored research studies**, there is a cost of **$3,000.00 CDN** associated with this review. **Submit the fee with your application**. Cheque should be made payable **to Windsor Regional Hospital (reference: REB Review fee)** and submitted to the Research Ethics Office, Met Campus Room ME1310.

The Project Funding Recoveries Form is to be completed and signed by the Principal Investigator and submitted along with Department Impact Forms. Submit one Impact form for each department affected by the research. As soon as it is available, submit the Clinical Trials Contract to the Research Ethics Office. Once contracts are signed and research ethics approval has been granted, a letter of approval to commence research will be issued.

The WRHREB generally meets on the last Wednesday of each month at 17:00 hours. Principal Investigators are requested to attend the Research Ethics Board meeting and will be given an appointment time. In order to allow sufficient time for research review, **your completed application package must be received at least two weeks before** the meeting date. You will be notified of the REB decision by mail within 10 business days of the meeting and if you so wish, by telephone or email within 3 days following the meeting. Once your research starts, you will need additional REB forms for use when submitting other information for REB review and / or acknowledgement (i.e. Serious Adverse Events; Amendments to Protocol; Investigator's Brochure or Consent and Annual Renewal). It is a requirement that all forms are typed. Please contact the REB office if you have any questions about submission processes.

There is no review fee associated with non-industry funded research. Also note that there is an ethics submission form to be used specifically for archival / secondary use of data (chart abstraction) research.

Application Package to include: (Please submit in individual full sets)

1. Cover letter with detailed information of what is included in the package
2. Ethics Submission Form **(15 copies including signed original)**
3. Informed Consent Document / Letter of Information **(15 copies)**
4. Consent checklist attached for your reference
5. Study Protocol **(4 copies if clinical drug trial – 15 copies other research)**
6. Investigator's Brochure **(4 copies if applicable – clinical sponsored trials)**
7. Departmental Impact Statements; Health Criteria Form - **1 copy for each department impacted)**
8. Certificate in training in Protection of Human Subject Participants (TCPS2) or equivalent – www.pre.ethics.gc.ca. This certificate is required for the Principal Investigator, Co-Investigator(s) and Research Associates (if not previously submitted) – Please note: guidelines are in place for **non-staff** Research Associates. If applicable, please have your associate(s) contact the Research Ethics Office. If this is a Chart Abstraction Study – Please do the Privacy Tutorial on the WRHREB Site.
9. Principal Investigator Curriculum Vitae
10. Any educational materials / advertisements **(15 copies including 1 original)**
11. Signed Privacy Agreement for Principal Investigator and Research Associates
12. There is a requirement that any non-staff research associate be processed through the Research Ethics Office
13. Project Funding Recovery Form and Clinical Trial Agreement (if industry sponsored research)

If you have any questions or require further information, please do not hesitate to contact the Research Ethics Office.

Send Completed Applications to:

Research Ethics Office
Windsor Regional Hospital
1995 Lens Avenue,
Room ME1310
Windsor, ON N8W 1L9
Telephone: (519) 254-5577 Ext 52034
E-mail: erin.link@wrh.on.ca