661 University Avenue, Suite 460
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Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
Windsor Regional Hospital

Privacy Considerations

Shared electronic health systems may not be used as a source for research participant data (i.e. Clinical Connect). For example, if the coordinator for the research study is also a clinical nurse/respiratory therapist treating the patient clinically and has access to the shared electronic health systems to see patient information, they cannot access shared electronic health systems for research purposes.

Informed Consent Form Requirements

Confidentiality section:

1. In the confidentiality section, in the list of authorized representatives that may look at original medical/clinical study records, please include bullet:
   - Representatives of Windsor Regional Hospital to oversee the conduct of clinical research studies at this location.
     Note: Not required if the consent template states: "This institution and affiliated sites, to oversee the conduct of research at this location."

2. If study data will be entered into the participants electronic medical record (i.e. consent documentation, administration of study drug), please add:
   If you participate in this study, the following study related information will be added to your hospital file and stored in the hospital's electronic medical record system: *[describe the study related information that will be put into the participant's medical record, including documentation of consent discussion, consent form, study drug dosing, and results of tests done for study purposes.].* This information will be accessible to others working at this hospital (like your current and future health care provider(s)). Windsor Regional Hospital may also share the patient information stored on its electronic medical records system with other hospitals and health care providers in Ontario so that they can access the information if it is needed for your clinical care. Any of these people may see that you were in this study and the study data listed above when they access your medical record for clinical purposes.

Access to Medical Records and Obtaining Consent

Permission to Contact:

Windsor Regional Hospital does not permit initial contact for research purposes outside of Circle of Care. Initial contact must be made by someone within the Circle of Care and only after the participant agrees to be contacted by the study team can the researchers approach the participant for the consent discussion. Exceptions may apply if prior approval has been obtained from the participant (e.g. REB approved database that includes permission to contact for research purposes).

Insurance: Windsor Regional Hospital PIs

Per the Inter-Institutional Agreement, the WRH shall ensure that that the WRH PI must maintain membership in the Canadian Medical Protective Association ("CMPA"), as appropriate for the duration of the study; and each party shall provide evidence of insurance or CMPA membership as applicable, upon written request of another, and shall provide to the others thirty (30) days prior written notice of modification, cancellation or non-renewal of its coverage. **However at Windsor Regional Hospital, WRH PI may hold membership in CMPA *or equivalent*, and provide evidence of insurance or CMPA membership *or equivalent*.**

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SRERS Administration
Windsor Regional Hospital

Reminder: Institutional Research Administration Requirements:

This SRERS Administration form applies to all studies being opened at any Windsor Regional Hospital (WRH) site including the Windsor Regional Hospital Cancer Program (WRHCP).

The CTO Streamlined System is for ethics review and oversight only. Institutional approval is required for all studies conducted at WRH. Before submitting an application through the CTO Stream, the researcher or delegate must contact the Office of Research to complete the Research Intake Review process. Please email the Office of Research at research.office@wrh.on.ca.

Research Intake Review:

All research studies at WRH must receive institutional approval prior to commencing research activities, including ethics submission, in the form of a Research Intake Review. Research Intake Review ensures that all research conducted at WRH or with WRH complies with relevant laws, regulations, contractual agreements, policies, procedures and guidance, and ensures that all hospital departments/resources impacted by the study are aware and approve of the proposed hospital resource utilization as operationally feasible. The Research Intake Review ensures there the study is adequately resourced with appropriately trained research staff and appropriately qualified Principal Investigator (PI) (or co-investigator, if applicable) to conduct the study and that the PI (or co-investigator) has completed mandatory clinical research training, and if a physician, has been appropriately credentialed. As a publicly funded healthcare organization, the Research Intake Review also ensures that for all research conducted within and/or under the auspices of the organization, where study specific activities that are undertaken within the organization or utilizing resources of the organization that are outside of standard of care, that these activities are reimbursed through study funding.

To initiate the Research Intake Review, please email the Office of Research at research.office@wrh.on.ca with a copy of your protocol to set up a meeting. Studies involving OCREB or the WRHCP will be triaged to the Cancer Program Clinical Trials team where applicable.

Decision to Proceed with CTO SRERS:

Prior to opening a Provincial Initial Application or a Centre Initial Application, delegation of authority to a CTO REB must be approved by the local WRH REB. WRH REB will review the CTO application to determine whether the application may proceed for ethics review through the CTO Streamlined System. If the decision is made to review locally (i.e. through the WRH REB), the Research Ethics Office will notify the study team. This process is embedded into the Research Intake Review process.

Research Training:

All individuals (e.g., investigators, coordinators, and any other personnel conducting research activities including students, trainees, etc.) involved in research activities at WRH (i.e., any involvement at a site, on behalf of a site, with site participants/charts/identifiable data, etc.) are required to complete research training prior to conducting any research activities. The Office of Research will review research training as part of the Research Intake Review. Please visit the Office of Research website for more details.

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Research Contracts/Agreements:
If the study requires a research contract, this must be in place prior to conducting any research activities. All research staff must enter a research confidentiality agreement and document all conflicts of interest. No study can begin in any capacity until all study agreements have been fully executed. Contracts must be reviewed by the Office of Research prior to institutional sign off. Please contact Grace Park at grace.park@wrh.on.ca to learn more about this process and if a contract/agreement is needed for your research study. CTO applications may be completed concurrently with contract review.

CTO Stream:
Collaborators:
The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: Malissa.Gauthier@wrh.on.ca
Role: Institutional Representative

Email: grace.park@wrh.on.ca
Role: Institutional Representative

This access is automatically granted when the CIA is created**. Windsor Regional Hospital should be the centre when creating a CIA for all studies other than adult oncology studies. For adult oncology studies, research teams must select Windsor Regional Hospital Cancer Program as the centre when creating a new CIA. When Windsor Regional Hospital is the Provincial Applicant site the research team should immediately create the CIA for Windsor Regional Hospital or Windsor Regional Hospital Cancer Program (for adult oncology studies) right after creating the PIA in addition to creating the PIA.** This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

Department Approver/Department Head in application forms
The Department Approver/Department Head must be indicated as follows in the applications within CTO Stream:

Title:	Ms.
First Name:	Grace
Surname:	Park
Organization:	Windsor Regional Hospital
Address:	1995 Lens Avenue
City:	Windsor
Province:	Ontario
Postcode:	N8W 1L9
Telephone:	519-254-5577 x 58602
Fax:	519-985-2687
Email:	grace.park@wrh.on.ca

The Departmental Approver/Department Head will only sign off on the CTO PIA or CIA once the Institutional Administration Requirements listed above have been met.

Institution Representative in application forms

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The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title:	Ms.
First Name:	Malissa
Surname:	Gauthier
Organization:	Windsor Regional Hospital
Address:	1995 Lens Avenue
City:	Windsor
Province:	Ontario
Postcode:	N8W 1L9
Telephone:	519-254-5577
Fax:	N/A
Email:	malissa.gauthier@wrh.on.ca

The Secondary Institution Representative field should be left blank.