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

Documented Institutional Ethics Requirements
Windsor Regional Hospital

Privacy Considerations

Shared external 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 participant's Windsor Regional Hospital electronic medical record (i.e., consent documentation, administration of study drug), please add:
   If you participate in this study, study related information may be added to your Windsor Regional Hospital files and stored in the hospital's electronic medical record system. This information will be accessible to others working at this hospital (i.e., 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 when they access your medical record for clinical purposes.

Obtaining Consent

Permission to Contact:

Windsor Regional Hospital does not permit initial contact with patient 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 future permission to contact for research purposes).

Insurance: Windsor Regional Hospital Principal Investigators

Per the Inter-Institutional Agreement, the Windsor Regional Hospital shall ensure that that the WRH Principal Investigator 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*.**

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

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 Stream, the researcher or delegate must contact the Corporate Office of Research to complete the Research Intake Review process. Please email the Corporate Office of Research at research.office@wrh.on.ca.

Research Intake Review:

Investigators wishing to initiate any studies involving WRH patients, staff, trainees, property and/or data are required to submit the proposed project to the Corporate Office of Research for Intake Review prior to submission to any REB, including through the Stream. Research Intake Review ensures that all research conducted at, or with, WRH complies with relevant laws, regulations, contractual agreements, policies, procedures and guidance. The review also ensures that all hospital leaders and the departments impacted by the study are aware and approve of the proposed hospital resource utilization as operationally feasible, via the Departmental Impact Form, embedded into the intake process. The Research Intake Review ensures that the study is adequately resourced with appropriately trained research staff and an appropriately qualified Principal Investigator (PI) (or co-investigator(s), if applicable) to conduct the study. The Research Intake Review also ensures that the PI (or co-investigator(s)) has completed mandatory clinical research training, and if a physician, has been appropriately credentialed. As a publicly funded healthcare organization, the Research Intake Review additionally 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 Corporate Office of Research at research.office@wrh.on.ca with a copy of your protocol. Studies involving OCREB with the WRH Cancer Program will be triaged to the Cancer Program Clinical Trials team, where applicable.

Approval to Proceed with CTO SRERS:

Prior to opening an application for a new study, or a Participating Site Initial Application, delegation of authority to a CTO Qualified REB must be approved by the local WRH REB chair. WRH REB chair will review project to determine whether the application may proceed for ethics review through the CTO Streamlined System. If the decision is made to submit locally to the WRH REB, the WRH 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 Corporate Office of Research will review research training as part of the Research Intake Review. Please visit the Corporate Office of Research website for more details.

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

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 Corporate Office of Research prior to institutional sign off. Please contact research.office@wrh.on.ca to learn more about this process and if a contract/agreement is needed for your research study. Applications in Stream may be completed concurrently with contract review, with contract signatures complete after REB approval.

Stream:
Collaborators:
The following collaborators must be given a role on all Clinical Trial Initial Application (CTIA), Observational Study Initial Application (OSIA), and Participating Site Initial Application forms.

Email: Ian.Mazzetti@wrh.on.ca
Role: Participating Site Institutional Representative

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

This access is automatically granted when the Participating Site Initial Application (PSIA) is created**. Windsor Regional Hospital should be the centre when creating a PSIA 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 PSIA. When Windsor Regional Hospital is the Lead Applicant site, the research team should immediately create the PSIA for Windsor Regional Hospital or Windsor Regional Hospital Cancer Program (for adult oncology studies) right after creating the new study.** 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.

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

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 PSIA or once the Institutional Administration Requirements listed above have been met.

Institution Representative in application forms

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

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

Title:	**Dr.**
First Name:	**Ian**
Surname:	**Mazzetti**
Organization:	**Windsor Regional Hospital**
Address:	**1995 Lens Avenue**
City:	**Windsor**
Province:	**Ontario**
Postcode:	**N8W 1L9**
Telephone:	**519-254-5577**
Fax:	**N/A**
Email:	**ian.mazzetti@wrh.on.ca**

The Secondary Institution Representative field should be left blank.