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

Documented Institutional Ethics Requirements
Halton Healthcare

Missions and Values

At Halton Healthcare we believe in pushing the boundaries of traditional healthcare by engaging in cutting-edge clinical research. Our goal is to enhance patient outcomes, provide innovative treatment options, elevate the current standard of care and make a meaningful difference in the lives of those we serve.

Privacy Considerations

Shared electronic health systems such as Connecting Ontario, PRO, RM&R, OLIS, HDIRS, eCHN, DPV, and IAR do not permit access for research purposes. Shared electronic health systems may not be used as a source for research participant data. Access to Shared Clinical Systems is restricted to the sole purpose of providing or assisting in providing care. Halton Healthcare aligns research privacy standards with PHIPA.

Informed Consent Form Requirements

Halton Healthcare's informed consent requirements align with the N2 SOP for Informed Consent.

In the confidentiality section, please add the following bullet to the list of representatives that will have access to study data for the purpose of quality assurance:

- Representatives of Halton Healthcare to oversee the conduct of clinical research studies at this location.

NOTE: this bullet must replace alternate wording (e.g., "insert research site name, to oversee the ethical conduct of research at this site") present in the provincially-approved consent form.

Access to Medical Records and Obtaining Consent

Permission to Contact: Halton Healthcare 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.

Insurance: Halton Healthcare Hospital PIs

Per the Inter-Institutional Agreement, Halton Healthcare shall ensure that that the Halton Healthcare 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.

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SRERS Administration
Halton Healthcare

Reminder: Institutional Research Administration Requirements

This SRERS Administration form applies to all studies being opened at Halton Healthcare in which the sponsor of the study has engaged CTO. The CTO Streamlined System is for ethics review and oversight only. Institutional approval is required for all studies conducted at Halton Healthcare. 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 adperez@haltonhealthcare.com.

Research Intake Review:

All research studies at Halton Healthcare 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 Halton Healthcare or with Halton Healthcare 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 coinvestigator) 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 adperez@haltonhealthcare.com with a copy of your protocol to set up a meeting.

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 Physician Program Director of Clinical Research at Halton Healthcare.
If the decision is made to review a particular study locally (i.e. through the Halton Healthcare REB), the Physician Program Director of Clinical Research will notify the study team.

Research Training:

All individuals (e.g., investigators, coordinators, and any other personnel conducting research activities) involved in research activities at Halton Healthcare (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.

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. CTO applications may be completed concurrently with contract review.

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Sites that are under Halton Healthcare include:

- Oakville Trafalgar Memorial Hospital
- Milton District Hospital
- Georgetown Hospital

CTO Stream

Collaborators:

The following collaborators must be given a role on the initial study-wide application, called the Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) and the Participating Site Initial Application (PSIA):

Email:	mheffernan@haltonhealthcare.com	Email:	Ipreyra@haltonhealthcare.com
Role:	Institutional Representative	Role:	Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **When Halton Healthcare is the Lead Applicant site the research team should immediately create the PSIA for Halton Healthcare (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 CTIA/OSIA prior to submission.

Institution Representative in application forms

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

Title:	Dr.
First Name:	Michael
Surname:	Heffernan
Organization:	Halton Healthcare
Address:	3001 Hospital Gate – Oakville Trafalgar Memorial Hospital
City:	Oakville
Province/State:	Ontario
Postcode/Zip:	L6M 0L8
Telephone:	905-845-2571
Fax:	905-815-5127
Email:	mheffernan@haltonhealthcare.com

The Secondary Institution Representative must be indicated as follows in the applications within CTO Stream when there is a conflict for the Primary Institution Representative:

Title:	Dr.
First Name:	Ian
Surname:	Preyra
Organization:	Halton Healthcare
Address:	3001 Hospital Gate – Oakville Trafalgar Memorial Hospital
City:	Oakville
Province/State:	Ontario
Postcode/Zip:	L6M 0L8
Telephone:	905-845-2571
Fax:	905-815-5127
Email:	Ipreyra@haltonhealthcare.com

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