

Documented Institutional Ethics Requirements Providence St. Joseph's and St. Michael's Healthcare

Missions and Values

Providence St. Joseph's and St. Michael's Healthcare is a Catholic academic health care provider.

Privacy Policy

1. Please note that shared electronic health systems such as ConnectingOntario, PRO, RM&R, OLIS, HDIRS, eCHN and IAR do not permit access for research purposes.

Shared electronic health systems may not be used as a source for research participant data. 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

1. If there are potential or known reproductive risks associated with the research, the following text must be used as the template for the centre consent forms in the 'What are the reproductive risks' section:
The effects that *insert name of product/agent/device* may have on an unborn baby (fetus) are unknown. You must not become pregnant or father a baby *specify period e.g., while taking [insert name of product/agent/device] and for [identify post-intervention period] after the last dose*. The study doctor will discuss family planning with you to ensure that you do not become pregnant or father a baby during the study.
If there are known interactions or contraindications with specific methods, they should be included.

(NOTE: For studies reviewed by the Ontario Cancer Research Ethics Board (OCREB), the template OCREB wording for reproductive risks must be used instead)

2. In the confidentiality section, in the list of organizations with direct access to participant records for quality assurance and data analysis, please include the following bullet:
 - Representatives of **St. Michael's Hospital OR St. Joseph's Health Centre OR Providence Health Care** to oversee the conduct of clinical research studies at this location.
Note: The PI will select the name of the site where the research is being conducted.

SRERS Administration Unity Health Toronto

Providence Healthcare, St. Joseph's Health Centre and St. Michael's Hospital

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

Study Impact Approval Form

Please note that the institutional signature will not be requested until the Study Impact Approval form is completed.

- For research conducted at the St. Michael's Hospital site, this form can be obtained by emailing Ms. Elizabeth Huggins at hugginsel@smh.ca.
- For research conducted at St. Joseph's Health Centre site, this form can be obtained by emailing Ms. Laura Tomat at lTomat@stjoestoronto.ca.
- For research conducted at both St. Michael's Hospital and St. Joseph's Health Centre, a Study Impact Approval Form must be completed for **each** site. The forms can be obtained by emailing both Elizabeth Huggins and Laura Tomat.

Privacy Policy

Unity Health Toronto does not permit the release of full date of birth (i.e. dd-mmm-yyyy) or personal health information (PHI) for research purposes without justification.

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: RotsteinO@smh.ca
Role: Institutional Representative

Email: HugginsEl@smh.ca
Role: Institutional Representative

Email: LTomat@stjoestoronto.ca
Role: Institutional Representative

Email: UngK@smh.ca
Role: Institutional Admin

This access is automatically granted when the Centre Initial Application is created. **When Unity Health Toronto is the Provincial Applicant site the research team should immediately create the CIA for the participating Unity**

Health Toronto site(s) (right after 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 Representatives in application forms

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

Title: Dr.
First Name: Ori
Surname: Rotstein
Organization: Unity Health Toronto
Address: 30 Bond Street
City: Toronto
Province/State: ON
Postcode/Zip: M5B 1W8
Telephone: (416) 864-5637
Fax: N/A
Email: RotsteinO@smh.ca

The Secondary Institution Representative field should be left blank.

NOTE: For applications where signatures were requested prior to May 1, 2019, Dr. Patricia O'Campo may be identified as the Institution Representative within the application form.

Institutional Representative Signatures on the CIA

Prior to requesting Institution Representative signature on the CIA, please contact one of the individuals below outside of CTO Stream (e.g., via regular email) to submit the Study Impact Approval Form and to confirm that the application is acceptable and may proceed with signatures:

- For St. Michael's Hospital CIAs contact Ms. Elizabeth Huggins (HugginsEl@smh.ca)
- For St. Joseph's Health Centre CIAs contact Ms. Laura Tomat (LTomat@stjoestoronto.ca)
- For research conducted at both St. Michael's Hospital and St. Joseph's Health Centre, please contact both of the individuals listed above

REB of Record Study Agreement

CTO will send the REB of Record Study Agreement to the PI for signature.

For OCREB studies: The study team will complete the PDF fillable Agreement template (ask CTO if your team does not already have a template) with the information from CTO Stream and send the Agreement to the PI for signature.

To obtain Dr. Rotstein's signature on this agreement, the study team will be required to submit a Contract Document Tracking Form to Researchcontracts@smh.ca along with Schedule E. Once signed, the study team will send a scanned copy of the agreement to CTO (streamline@ctontario.ca), who will then obtain signatures from the REB Host Institution. Fully executed agreements will be disseminated by email and through CTO Stream.

Questions about REB of Record Study Agreements can be directed to:

Elizabeth Huggins - hugginse@smh.ca or 416-864-6060 x77689 (for St. Michael's Hospital)

Laura Tomat – ltomat@stjoestoronto.ca or 416-530-6486 x3039 (for St. Joseph's Health Centre)

To Submit a Research Contract (including a REB of Record Study Agreement)

Please complete a Contract Document Tracking Form and follow the instructions found at
<http://stmichaelshospitalresearch.ca/staff-services/research-contracts/contact-us/>