CLINICAL TRIALS ONTARIO

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

Documented Institutional Ethics Requirements
Unity Health Toronto
Providence Healthcare, St. Joseph's Health Centre and St. Michael's Hospital

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 Unity Health Toronto to oversee the conduct of clinical research studies at this location.

   Note: if the consent template includes the statement "This institution and affiliated sites, to oversee the conduct of research at this location", the above bullet point language is not required.

For studies where COVID-19 test results will be/may be provided to the sponsor, it is the Principal Investigator's responsibility to ensure the following language is added to the consent form (Not applicable to studies reviewed by OCREB):

3. **"How will participant information be kept confidential?**" section:

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COVID-19 Information

If you are tested for COVID-19 before or at any time during this study, the study sponsor may want to know the results of this testing, whether the result is positive or negative. Since we do not fully understand how COVID-19 affects different people, it may be a meaningful factor to consider in this study.

Please be aware that if you have a serious side effect or other medical issue during the study, your COVID-19 status (if known) may be included in a report sent to the sponsor and/or regulatory agencies for safety reasons.

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SRERS Administration
Unity Health Toronto
Providence St. Joseph's and St. Michael's Healthcare

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 all sites, this form can be obtained by emailing Ms. Elizabeth Huggins at Elizabeth.Huggins@unityhealth.to
- 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.

Privacy Policy

Providence St. Joseph's and St. Michael's Healthcare 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: Ori.Rotstein@unityhealth.to
Role: Institutional Representative

Email: Elizabeth.Huggins@unityhealth.to
Role: Institutional Representative

Email: Karen.Ung@unityhealth.to
Role: Institutional Admin

This access is automatically granted when the Centre Initial Application is created. **When** Providence St. Joseph's and St. Michael's Healthcare **is the Provincial Applicant site the research team should immediately create the CIA for the participating Providence St. Joseph's and St. Michael's Healthcare 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 Providence St. Joseph's and St. Michael's Healthcare must be indicated as follows in the applications within CTO Stream:

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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:	(blank)
Email:	Ori.Rotstein@unityhealth.to

The Secondary Institution Representative field should be left blank.

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 all site CIAs contact Ms. Elizabeth Huggins (Elizabeth.Huggins@unityhealth.to)