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

IMPORTANT: Projects that are solely to establish the creation of a database/biobank/registry must not be submitted through CTO Stream.

Missions and Values

Unity Health Toronto is a Catholic academic healthcare provider. Research conducted at Unity Health must comply with the Catholic Health Alliance of Canada Health Ethics Guide.

Privacy Policy

1. **Use of Shared Systems**

   Please note that shared electronic health systems such as Care Everywhere, ConnectingOntario, 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. 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.

2. **Permission to Contact**

   If recruitment will occur at a Unity Health Toronto (UHT) site (rather than centrally by the lead site):

   As of February 01, 2025, Unity Health will permit researchers and research staff to make initial contact with potential participants in specific circumstances. Unity Health Privacy Office approval is required for any initial contact by research teams.

3. **Pre-Screening**

   Unity Health permits researchers and research staff to pre-screen charts to identify potentially eligible participants in specific circumstances and with REB approval. Unity Health Privacy Office approval is required for any pre-screening by research teams.

Methods of Obtaining Consent

1. **e-Consent via Epic**

   At Unity Health, e-consent via Epic or MyChart (Unity Health's clinic-facing and patient-facing medical record system) ***cannot*** be used for Health Canada or FDA-regulated research studies.

Informed Consent Form Requirements

1. **Reproductive Risks**

   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 the study drug(s) may have on eggs (ova), sperm, or an unborn baby (fetus) are unknown/detail the known risks. You should not become pregnant or get someone pregnant while taking the study drug(s).

   Participants who can become pregnant or produce sperm must agree to both of the following while taking

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the study drug(s) and for specify length of time afterward: i) not to get pregnant or get someone pregnant and ii) to use an appropriate family planning method as discussed and decided upon in consultation with a study investigator.
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. Privacy and Confidentiality

a) 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.

b) In the confidentiality section, the following statements must be included:
In addition to the study team, other authorized employees of Unity Health Toronto may have access to your personally identifying information so that they can carry out regulatory or institutionally required duties. Unity Health Toronto may also store personally identifying information collected or used for these duties for a period of time, in accordance with regulations and institutional policies.

c) If the study will involve Unity Health patients as participants, the following paragraph is required:

Adding information to your Unity Health Toronto medical record

Your participation in this study will be recorded in your Unity Health medical record. 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 clinical tests done for study purposes.
Unity Health Toronto shares 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.

3. Compensation/Reimbursement

If compensation or honoraria will be processed through the Unity Health Toronto Finance Department, the following paragraph must be included:

To process your reimbursement/honoraria, the Finance department at Unity Health Toronto will be provided with list the information that will be provided to the Finance Department. The department will use this information for the sole purpose of processing your compensation and will retain this information in accordance with the department's requirements.

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SRERS Administration
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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.

Unity Health Toronto Institutional Approval Form

Please note that the institutional signature will not be requested until the Institutional 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

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: Ori.Rotstein@unityhealth.to
Role: Institutional Representative

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

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

This access is automatically granted when the Centre Initial Application is created. **When** a Unity Health Toronto site **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.

Institutional Representatives in application forms

The Primary Institutional 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

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Postcode/Zip: M5B 1W8
Telephone: (416) 864-5637
Fax: N/A
Email: Ori.Rotstein@unityhealth.to

The Secondary Institution Representative field should be left blank.

Institutional Representative Signature on the CIA
Prior to requesting the Institutional Representative signature on the CIA, please contact the individual below outside of CTO Stream (e.g., via regular email) to submit the Institutional Approval Form to confirm that the application is acceptable and may proceed with signature requests:

- Ms. Elizabeth Huggins (Elizabeth.Huggins@unityhealth.to)

To Submit a Research Contract
Please complete a Contract Document Tracking Form and follow the instructions found at http://stmichaelshospitalresearch.to/staff-services/research-contracts/contact-us/