

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 health care provider.

Privacy Policy

1. Please note that shared electronic health systems such as 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.

Informed Consent Form Requirements

1. **Reproductive Risks**

If there are potential or known reproductive risks associated with the research, the following text must be as the template for the centre consent forms in the 'What are the reproductive risks' section:

If there are risks related to being or becoming pregnant or getting someone pregnant:

The effects that the study drug(s) may have on eggs (ova), sperm, or on 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 are able to become pregnant or produce sperm must agree to both of the following while taking the study drug(s) and for 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**

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.

If study data will be entered into the participant's medical record:

Adding information into your Unity Health Toronto medical record

Your participation in this study will be recorded in your [Unity Health site name](#) 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 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.

Compensation/Reimbursement

If compensation or honoraria will be processed through the Unity Health Toronto Finance Department:

In order 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 requirements.

Permission to Contact

If recruitment will occur at a Unity Health Toronto (UHT) site (rather than centrally by the lead site): UHT 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 unless prior approval has been obtained from the participant (e.g. REB approved permission to contact for research purposes database).

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.

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

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/>