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):

   Initial contact by research teams at Unity Health is only permissible if all of the following are true:
   - The person(s) making initial contact with potential participants is an employee or registered personnel (e.g., volunteer, physician, student, resident, etc.) of Unity Health.
   - Contact will not be made with potential participants who have indicated they do not wish to be contacted about research.
   - Contact by the research team will be limited to Unity Health patients.
   - The Board of Record has determined that initial contact by the research team is appropriate for the specific study and study population.

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 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 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. Participant Responsibilities

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 responsibilities of study participants' section:

- You must check with your study doctor about how to ensure you do not get pregnant or not get someone pregnant during the study, and for *(insert time in months/years)* after you have completed the study (*or the last dose)*.

3. Other Reproduction-Related Language

As a Catholic academic healthcare provider, language in the consent form must comply with the Catholic Health Alliance of Canada Health Ethics Guide. Any other sections of the consent form referencing the reproductive considerations of the study may require revision as directed during Unity's institutional review of the study.

4. 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.

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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.

5. 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.

6. Signature Page

If e-consent is being obtained, the following bullet point must be added to the signature page:

- I understand my electronic signature is equivalent to my written signature