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
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 used 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

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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).