CLINICAL TRIALS ONTARIO

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# 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.