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Documented Institutional Ethics Requirements
University Health Network (UHN)

IMPORTANT: QI/QA projects and projects that are solely to establish the creation of a database/biobank/registry must not be submitted through CTO Stream. They must be reviewed via a different mechanism at UHN.

Informed Consent Form Requirements (Not applicable to studies reviewed by OCREB)

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:

1. **"How will participant information be kept confidential?**" section:

   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. Since we do not fully understand how COVID-19 affects different people, it may be a meaningful factor to consider in this study.

   It is your choice whether you agree to allow your results to be shared with the study sponsor, and your decision will not affect whether you can still participate in the study. You will be given an option to decide at the end of this form.

2. Include the following on the "**Signatures"** section of the ICF:

   - ☐ I **agree** to allow my COVID-19 test results to be shared with the study sponsor as described in this consent form.
   - ☐ I **do not agree** to allow my COVID-19 test results to be shared with the study sponsor as described in this consent form.

3. **Emergency Contact Number**: Clearly provide instructions for whom to contact (e.g. the Principal Investigator, Co-investigator, "Ask for the study doctor"). The contact person must be knowledgeable about the study. For Phase 1 studies, the contact MUST be a physician knowledgeable in the study.

4. "**What is the background information for this study?**" section: It is the Principal Investigator's (PI) responsibility to ensure this section describe the current standard of care at UHN.

5. "**How will participant information be kept confidential?**" section:

   When the statement "A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart" is present in the provincially-approved consent form template, it must be deleted from the UHN consent and replaced with the following language:

   "Research Information in Shared Clinical Records
   If you participate in this study, information about you from this research project may be stored in your hospital file and in the University Health Network (UHN) computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any

questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca)."

6. In the list of organizations who may have direct access to original (identifiable) medical/clinical study records, include the following bullet:

    - This institution and affiliated sites, to oversee the conduct of research at this location

    NOTE: this bullet must replace alternate wording (e.g., "*insert research site name*, to oversee the ethical conduct of research at this site") present in the provincially-approved consent form.

7. "**Are study participants paid to be in this study**?" section:

    When the statement "In the case of research-related side effects or injury, medical care will be provided by your doctor" (or variations of it) is present in the provincially-approved consent form, it must be deleted from the UHN consent and replaced with the following language:

    "If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost"

8. **Permission to contact via UHN EPIC**
    If you are utilizing the 'Okay to Contact' feature through the UHN EPIC system for current or new studies as part of a recruitment strategy to screen and contact patients for research activities, this needs to be outlined in the study recruitment plan of the UHN Centre Initial Application form (specifically, **Section 3.0 – Informed consent/assent information)** and submitted to the REB of Record for review. Use of the 'Okay to Contact' feature in EPIC must be conducted in accordance with the Clinical Research Guidance and Policy on UHN's Clinical Research Hub

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SRERS Administration
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CTO and CAPCR: Institutional Research Administration Requirements

All research involving humans performed at UHN requires Institutional Authorization (IA) prior to the conduct of the research. For this reason, all studies using an external board of record model such as Clinical Trials Ontario (CTO), must still submit an Institutional Authorization application in CAPCR (Coordinated Approval Process for Clinical Research), in addition the REB application submitted to CTO.

IA is granted on a per-protocol basis by the Executive Vice President of Science and Research or designate once all requisite approvals have been obtained. Please see http://www.uhnresearch.ca/service/approval-process for additional details.

Initiating a Study at UHN

There are 2 things required before research teams may begin study activities at UHN:

- ✓ **CTO REB of Record Approval for the UHN Centre**
  Note: The study team will be required to attach the UHN Site's CTO Centre Approval Letter to the initial CAPCR application, prior to Institutional Authorization being issued (the Approval Letter does not need to be attached to 'submit' CAPCR, but is required for CAPCR to be authorized)

- ✓ **Institutional Authorization (IA) has been granted from the Coordinated Approval Process for Clinical Research (CAPCR) system**

Contacts for Questions about the UHN CTO Process

As UHN has a large number of studies using CTO, there are 2 contacts for support. If research teams have questions about the process for CTO studies at UHN, please contact:

- ❖ **Non-Oncology Studies:** boardofrecord@uhnresearch.ca
- ❖ **Oncology Studies:** BOR-CCRU@uhn.ca

Setting up the Provincial Initial Application (PIA) and Centre Initial Application (CIA) in CTO Stream

To allow appropriate oversight and approvals at UHN, select users at UHN, referred to as 'Collaborators' are added to the CIA by CTO. The Collaborators should also be added to the PIA, when UHN is the Provincial Applicant. If UHN is the PIA, the study team should create the PIA and CIA submission in parallel, to allow the Collaborator permissions to be granted by CTO. In cases where the CIA is not created at the time of the PIA, the study team will have to manually assign the Collaborator permissions. Below is a table of the required Collaborators.

Collaborator Name	Collaborator e-mail	Collaborator Role
Paul MacPherson	paul.macpherson@uhn.ca	Institution Representative
Menaka Pulandiran	menaka.pulandiran@uhn.ca	Institution Representative
Shahjereen Shahidullah	shahjereen.shahidullah@uhn.ca	Institution Representative
Evette Gad Elrab	evette.gadelrab@uhn.ca	Institution Representative

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Collaborator Name	Collaborator e-mail	Collaborator Role
Anita Sengar	anita.sengar@uhn.ca	Institution Admin
Alex Karabanow	alexander.karabanow@uhn.ca	Institution Admin
Heather Cole	heather.cole@uhn.ca	Institution Admin
Krystal Internicola	krystal.internicola@uhn.ca	Institution Admin
Gillian Parker	gillian.Parker@uhn.ca	Institution Admin
Daeniell Miller	daeniell.miller@uhn.ca	Institution Admin
Shrutakirti Kulkarni	shrutakirti.kulkarni@uhn.ca	Institution Admin
Amadeus Chui	amadeus.chui@uhn.ca	Institution Admin
Ana Motta	ana.motta@uhn.ca	Institution Admin

Institution Representative in application forms

The Institutional Representative is required to approve all CIA prior to the application being sent to the REB of Record for review. At UHN, the primary Institution Representative must be indicated as follows in the applications within CTO Stream:

CTO CIA Field	Primary Institutional Representative	Secondary Institutional Representative
Title	Mr.	*Leave the Secondary Institutional Representative blank*
First Name	Paul	
Surname	MacPherson	
Organization	University Health Network	
Address	700 University Avenue	
Address	4th Floor, Room 4-133	
City	Toronto	
Province/State	Ontario	
Postal Code/Zip	M5G 1Z5	
Telephone	416 581-8573	
Fax	*Leave blank*	
E-Mail	paul.macpherson@uhn.ca	

NOTE: If Mr. MacPherson is absent, signature requests for the Institution Representative in CTO Stream can be sent to Mr. Alexander Karabanow (alexander.karabanow@uhn.ca).

When sending a signature request to the UHN Institution Rep, please keep in mind the following is required before they will sign the CIA in CTO Stream:

- CAPCR application is submitted
- Division/Department Head in the CTO Stream and CAPCR applications match
- Centre PI signs the CIA in CTO Stream

If the above requirements have been met and you are still waiting for a signature for the UHN Institution Rep, please contact boardofrecord@uhnresearch.ca.