661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
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www.ctontario.ca

Documented Institutional Ethics Requirements
The Ottawa Hospital

IMPORTANT: Projects that are solely to establish the creation of a database/biobank/registry without a discrete, time limited, research question must not be submitted through CTO Stream.

TOH will not participate in projects submitted through CTO Stream where the only purpose of the project is for the establishment of a repository/database/biobank and there is no research question associated with the project. Please request a huddle meeting with OHSN-REB Manager and Chair for guidance on these initiatives by contacting REBAdministration@ohri.ca.

Scope

These requirements apply to researchers from The Ottawa Hospital (TOH)/Ottawa Hospital Research Institute (OHRI)

Privacy Policy

True Initials and Full Date of Birth

The Ottawa Hospital does not permit the release of true initials or full date of birth (i.e.: year/month/day) for research purposes. These must be replaced with pseudo- initials and partial date of birth (e.g.: Month/Year) on any data released from the institution.

ConnectingOntario ClinicalViewer, OLIS and eHealth

ConnectingOntario ClinicalViewer, OLIS, eHealth must **not** be used 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 system to see patient information, they cannot access shared electronic health system for research purposes.

Pre-Screening Medical Records

As per The Ottawa Hospital (TOH) privacy policy, research personnel are permitted to pre-screen potential participant medical records. The plan for pre-screening medical records must be described in the REB application.

Permission to Contact (PTC) Process

At the Ottawa Hospital (TOH), permission to contact (PTC) for research is obtained by someone within the patient's circle of care or by an agent of the HIC (Health Information Custodian). At TOH, PTC is typically obtained at the time of registration by the registration clerks or by the patient themselves during registration in MyChart. It may also be obtained by a member of the patient's circle of care or an agent of TOH. OHRI research staff are agents of TOH and authorized to obtain PTC. OHRI research staff must follow the institutional guidelines for obtaining PTC. The guidelines are found on the Clinical Research Administration page of IRISGuide.

Translation Requirements

CLINICAL TRIALS ONTARIO

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The Official Languages Policy for TOH remains in effect for all investigators submitting their studies in CTO Stream. The Official Languages policy applies to all TOH patient facing documents (e.g., recruitment materials, consent forms, questionnaires, wallet cards, etc.).

Clarification for when an exemption for translated patient documents applies:

- Short term recruitment (recruitment will be completed within 3 months of Institutional Approval)
- Study does not involve patient participants from TOH.
- Purpose of the study is to create a validated survey/tool in English only

Process for Translation in Initial Applications:

- Once the Investigator receives the Provincial and/or Centre Initial Application approval letter in CTO Stream, the approved English documents must be submitted immediately for translation via one of the options indicated in the study's Clinical Research Registration Form (CRRF) in IRIS (e.g.: Third Party translation services, OHRI Coordinated Translation).
  - If the translation service provider is OHRI Coordinated Translation, then all applicable CTO Steam English approved documents must be uploaded into the 'Translation' tab of the study's CRRF.

- Once the translated documents are provided to the Investigator, an amendment must be submitted through CTO Stream enclosing the translated documents and certificate of translation for approval.

- The CTO Stream amendment approval letter for the translated documents must be uploaded into the 'Translation' tab of the study's CRRF in IRIS within 2 months of initial REB approval.
  - This means investigators have a total of 2 months to obtain the translated documents and received CTO Stream amendment approval in order to complete the translation tab in the CRRF.

Process for Translation in Amendments:

- Once the Investigator receives the Provincial and/or Centre amendment approval letter in CTO Stream, the REB approved English documents must be submitted immediately for translation.
  - If your translation service provider is OHRI Coordinated Translation, then all applicable CTO Steam English approved documents must be submitted to REBAdministration@ohri.ca for processing as the registration form in the CRRF does not currently have a post-form for translation services.

- Once the translated documents are provided to the Investigator, an Amendment must be submitted through CTO Stream enclosing the translated documents and certificates of translation for approval.

- The CTO Stream Amendment approval letter for the translated documents must be emailed to REBAdministration@ohri.ca within 2 months of Amendment approval.
  - This means investigators have a total of 2 months to obtain the translated documents and received CTO Stream amendment approval in order to complete the translation tab in the CRRF.

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SRERS Administration
The Ottawa 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.

At The Ottawa Hospital, Institutional Approval (IA) via the Clinical Research Registration Form (CRRF) in IRIS is required prior to study start. The CRRF must be completed immediately after submission of the Provincial Initial Application (if TOH/OHRI is leading or coordinating the project), or Centre Initial Application (if TOH/OHRI is participating in the project only).

CTO Stream Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

This access is automatically granted when the Centre Initial Application is created. **When The Ottawa Hospital is the Provincial Applicant site. the research team should immediately create the CIA for the Ottawa Hospital (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.

Email: amlarose@ohri.ca Role: Institutional Representative	Email: pphillips@ohri.ca Role: Institution Representative	Email: lquevillon@ohri.ca Role: Institutional Admin
Email: jewagner@toh.ca Role: Institutional Admin	Email: isalter@ohri.ca Role: Institutional Admin	Email: lturriff@toh.ca Role: Institutional Admin
Email: stmyers@ohri.ca Role: Institutional Admin		

Primary Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title:	Ms.
First Name:	Amy
Surname:	Larose
Organization:	Ottawa Hospital Research Institute
Address:	Civic Campus, 725 Parkdale Ave, Civic Box 675 Loeb
Building City:	Ottawa
Province/State:	ON
Postcode/Zip:	K1Y 4E9
Telephone:	613-798-5555 ext. 15072
Fax:	N/A
Email:	amlarose@ohri.ca

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The Secondary Institution Representative field should be left blank.

Absence Coverage – Institutional Representative Signature
Should Ms. Larose be away from the office, the Institutional Representative signature request can be sent to Ms. Penny Phillips (pphillips@ohri.ca).