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

Documented Institutional Ethics Requirements
University of Ottawa Heart Institute

Scope

These requirements apply to research being conducted at the University of Ottawa Heart Institute.

Privacy Policy

1. The University of Ottawa Heart Institute does not permit the release of true initials or full date of birth (e.g. year/month/day) for research purposes. These must be replaced with pseudo-initials and partial date of birth (month/year) on any data released from this institution.
2. ConnectingOntario, ClinicViewer, OLIS and 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.
3. The University of Ottawa Heart Institute does not permit the use of social media (i.e., Facebook, Twitter, etc.) to contact participants.
4. Research Personnel are permitted to pre-screen potential participant medical records. This plan must be described in the Research Ethics Board (REB) application and approved by the REB Board of Record.
5. Potential participants must provide permission to contact (PTC) prior to being contacted about research. Patients are approached about PTC by an agent of the Health Information Custodian (HIC) or someone within the Circle of Care. Generally, PTC is obtained at the time of registration by the registration clerks or by the patients themselves in MyChart. However, research staff are considered agents of the HIC and are authorized to obtain PTC. Research staff must complete institutional training and follow institutional guidelines. No script will be submitted to the REB for the PTC discussion as it is an institutional process.

French Translation Requirement for Centre Initial Applications

The Institutional Translation Policy remains in effect for all investigators submitting their studies in CTO. This policy applies to all UOHI patient-facing documents (e.g. recruitment materials, informed consent forms, questionnaires, wallet cards, etc.).

Clarification for when an exemption for translated patient documents applies:

- Short-term recruitment (i.e., recruitment will be completed within 3 months)
- Study does not involve the recruitment of participants from UOHI or the Ottawa Hospital (TOH)
- Purpose of the study is to create a validated survey/tool in English only
- Participants are Ottawa Hospital/University of Ottawa Heart Institute staff
- Study is recruiting participants from another study ONLY, of which all were English speaking.

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Process for Translation in Initial Applications

Once the investigator receives the Participating Site Initial Application approval letter, the approved English documents must be submitted immediately to the translator. The translated documents and the translation certificate must be submitted through CTO Stream as an amendment. Applicants will have 90 days after the initial REB approval to receive the Translated Document Amendment Approval Letter from CTO Stream.

Process for Translation in Amendments

When the investigator receives the amendment approval letter, any updated/new patient facing English documents must be translated into French. The translated documents and the translation certificate must be submitted through CTO Stream as an amendment. Applicants will have 90 days after the amendment approval to receive the Translated Document Amendment Approval Letter from CTO Stream.

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SRERS Administration
University of Ottawa Heart Institute

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 University of Ottawa Heart Institute (UOHI), Institutional Approval (IA) via the Clinical Research Registration Form (CRRF) is required prior to study start. The CRRF must be completed immediately after submission of the Clinical Trial Initial Application (if UOHI is leading or coordinating centre), or Participating Site Initial Application (if UOHI is participating site only).

CTO Stream

Collaborators:
The following collaborators must be given a role on all Clinical Trial Initial Application (CTIA) forms and Participating Site Initial Application (PSIA) forms.

This access is automatically granted when the Participating Site Initial Application is created. **When the University of Ottawa Heart Institute is the Clinical Trial Initial Applicant site the research team should immediately create the PSIA for the University of Ottawa Heart Institute (right after creating the CTIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PSIA prior to submission.

Email: SCrowe@ottawaheart.ca
Role: Institutional Representative

Email: LegalAffairs@ottawaheart.ca
Role: Institutional Admin

Email: JKnudson@ottawaheart.ca
Role: Institutional Representative

Email: TPowell@ottawaheart.ca
Role: Institutional Admin

Email: AlCarrier@ottawaheart.ca
Role: Institutional Representative

Institutional Representatives:

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

Title:	Ms.
First Name:	Suzanne
Surname:	Crowe
Organization:	University of Ottawa Heart Institute
Address:	40 Ruskin Street, room H1263
City:	Ottawa
Province/State:	ON
Postcode/Zip:	K1Y 4W7
Telephone:	613-696-7000 x 10656
Email:	SCrowe@ottawaheart.ca

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The Secondary Institutional Representative should be indicated as follows in the applications within CTO Stream:

Title:	Ms.
First Name:	Jennifer
Surname:	Knudson
Organization:	University of Ottawa Heart Institute
Address:	40 Ruskin Street, room H1261
City:	Ottawa
Province/State:	ON
Postcode/Zip:	K1Y 4W7
Telephone:	613-696-7000 x 18687
Email:	JKnudson@ottawaheart.ca

Absence Coverage – Institutional Representative Signature

Should Suzanne Crowe be away from the office, the Institutional Representative signature request can be sent to Jennifer Knudson (JKnudson@ottawaheart.ca).