

Documented Institutional Ethics Requirements Research St. Joseph's - Hamilton

IMPORTANT: Projects that are solely to establish the creation of a database/biobank/registry must not be submitted through CTO Stream.

Missions and Values

St. Joseph's Healthcare Hamilton is a Catholic health care provider.

Privacy Considerations

Clinical Connect 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 clinical connect to see patient data, they cannot access Clinical Connect for research related data.

Informed Consent Form Requirements

1. The wording in the local informed consent form must be consistent with Catholic values. Specifically, if there are potential or known reproductive risks associated with the research, the following text must be used as the template for the site-specific 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)

General Contact Information

Should participants have questions or concerns regarding their rights as a research participant, they can contact either the CTO Board of Record or the SJHH Patient Relations department (PatientRelations@stjoes.ca, tel: 905-522-1155, ext. 34952). If there are general questions about research and/or clinical trials, patients may contact researchinstitute@stjoes.ca.

Permission to Contact

St. Joseph's Healthcare Hamilton is committed to providing its patients with equitable opportunities to be aware of and participate in clinical research studies. Through this commitment, SJHH has established the Access Research program in collaboration with The Research Institute of St. Joe's Hamilton (RSJH). This program allows researchers at SJHH to request basic patient contact information in order to reach out to those who may be eligible for participation in a research study. For more information, please visit <https://research.stjoes.ca/research-innovation-services/access-research>

Institutional Requirement for Databases/Registries/Biobanks

SJHH and RSJH require researchers to obtain ethical approval of all research studies, including databases, registries

and biobanks. SJHH/RSJH will accept ethics approval granted through the CTO Stream using the single REB of Record model.

[Research sites under St. Joseph's Healthcare Hamilton's auspices](#)

St. Joseph's Healthcare Hamilton encompasses three (3) campuses located across the City of Hamilton:

1. Charlton Campus:
 - 50 Charlton Avenue East Hamilton, ON L8N 4A6
2. West 5th Campus:
 - 100 West 5th Street Hamilton, ON L8N 3K7
3. King Campus:
 - 2757 King Street East Hamilton, ON L8G 5E4

SRERS Administration

Research St. Joseph's - Hamilton

Hospital Resource Utilization

Similar to the HiREB application Research St. Joseph's – Hamilton researchers seeking REB approval through CTO must ensure that the Research Institute and hospital departments/resources impacted by the study are aware and approve. An approval form has been developed and is available from Research Admin. Please contact Adam Weerdenburg aweerden@stjoes.ca.

Cross-Appointed Researchers

For researchers sharing cross-appointments at more than one institution (e.g., Hamilton Health Sciences Corporation, Research St. Joseph's – Hamilton and/or McMaster University), you must use the credentials for the institution where the research is being conducted.

For example, if the researcher is cross-appointed between Research St. Joseph's – Hamilton and McMaster University, and the research will be conducted (e.g., participants recruited and/or intervention administered) at a St. Joe's site, the researcher's organization and the institutional representatives must be those associated with The Research Institute at St. Joe's - Hamilton.

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must also ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Clinical Trial Initial Applications/Observational Study Initial Application forms and Participating Site Initial Application forms.

Email: aweerden@stjoes.ca

Role Institutional Representative

This access is automatically granted when the Participating Site Initial Application (PSIA). **When Research St. Joseph's - Hamilton is the Lead Applicant site the research team should immediately create the PSIA for the participating St. Joe's site(s) (right after creating the new study).** This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the Clinical Trial Initial Applications/Observational Study Initial prior to submission.

Institution Representative in application forms

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

Title:	Mr.
First Name:	Adam
Surname:	Weerdenburg
Organization:	Research St. Joseph's – Hamilton
Address:	50 Charlton Avenue East



661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

City: Hamilton
Province/State: ON
Postcode/Zip: L8N 4A6
Telephone: 905.522.1155 x35280
Fax: None
Email: aweerden@stjosham.on.ca

The Secondary Institution Representative field should be left blank.