

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

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 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)

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 Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms:

Email: gmartin@stjoes.ca

Role: Institutional Representative

Email: aweerden@stjoes.ca

Role Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Research St. Joseph's - Hamilton is the Provincial Applicant site the research team should immediately create the CIA for the participating St. Joe's site(s) (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.

Institution Representative in application forms

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

Title: Dr.

First Name: Gail

Surname: Martin
Organization: Research St. Joseph's – Hamilton
Address: 50 Charlton Avenue East
City: Hamilton
Province/State: ON
Postcode/Zip: L8N 4A6
Telephone: 905.522.1155 x34916
Fax: None
Email: gmartin@stjoes.ca

The Secondary Institution Representative field should be left blank.

Absence Coverage – Institutional Representative Signature

Should Dr. Martin be away from the office, the Institutional Representative signature request can be sent to Mr. Adam Weerdenburg (aweerden@stjoes.ca).