661 University Avenue, Suite
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Tower Toronto, Ontario
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www.ctontario.ca

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 Stream.

Missions and Values

St. Joseph's Healthcare Hamilton (SJHH) is a Catholic health care provider and a member organization of the St. Joseph's Health System (SJHS) along with Research St. Joseph's – Hamilton (RSJH). RSJH is the Research Institute with the mandate to advance research across the SJHS by carrying out scientific research and experimental development.

Privacy Considerations

ClinicalConnect

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

Requesting External Medical Records

If applicable, the following paragraph should be added to the confidentiality section of the informed consent form:

> "If you are admitted to another hospital for any reason or die from natural or other causes while participating in this study, your medical records will be requested in order to collect information relevant to your study participation. By signing this consent form, you are allowing such access."

Pre-Screening Medical Records

Research personnel may pre-screen medical records of potential participants without consent, under the condition that this proposed process/plan is outlined in the REB application and approved.

Permission to Contact (PTC) Process

At SJHH, PTC is required before approaching patients about research participation. PTC must be obtained by:

- A member of the patient's circle of care; or,
- An authorized agent of the Health Information Custodian (HIC).

PTC is typically obtained:

- During patient registration; or,
- By a member of the patient's circle of care or an authorized agent of SJHH

RSJH and its staff are considered agents of St. Joseph's Healthcare Hamilton (SJHH) for the purposes of coordinating, participating and conducting SJHH's research on behalf of SJHH. The PTC plan must be described in the REB application and approved.

SJHH may appoint other agents to work with RSJH on research such as SJHH staff, clinicians or personnel (including faculty, learners, staff) of McMaster University.

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 section(s) that outline reproductive risk(s):

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"The effects that *insert name of investigational 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)

2. For studies that are to have a study record created/built in Dovetale (as per Policy 055-RSJ-H Acceptable Use of Information and Information Technology), the following language must be used in the centre informed consent form:

   "Your participation in this study will be recorded in your electronic health record (EHR), also called a medical record, at St. Joseph's Healthcare Hamilton. If you participate, some of the information about you that is collected for this study, including the results of tests described in this consent form, will be stored in your EHR and accessible to others working at this hospital (like your current and future health care provider(s)). This hospital may share patient information stored in its EHR with other hospitals and healthcare providers in Ontario. In addition, any person or company to whom you give access to your medical record may have access to this information. The study team can tell you what information about you will be stored electronically, and what may be shared outside of this hospital."

3. RSJH institutional branding is required to be applied to the informed consent form utilized at SJHH/SJHS sites. Please see the SJHS website regarding the use of institutional branding for more information (https://sjhs.ca/visualidentity/).

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SRERS Administration
Research St. Joseph's - Hamilton

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Corporate/Clinical Resource Utilization
Research St. Joseph's – Hamilton (RSJH) researchers seeking REB approval through CTO must ensure that the Research Institute and SJHH/SJHS corporate and/or clinical departments/resources impacted by the research project 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, RSJH 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 RSJH and McMaster University, and the research will be conducted (e.g., participants recruited and/or intervention administered) at a SJHS site, the researcher's organization and the institutional representatives must be those associated with RSJH

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.

Stream Collaborators:
The following collaborators must be given a role on all Clinical Trial Initial Applications (CTIA), Observational Study Initial Applications, and Participating Site Initial Application (PSIA):

Email: aweerden@stjoes.ca
Role Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **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 CTIA/OSIA prior to submission.

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

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Title: Mr.
First Name: Adam
Surname: Weerdenburg
Organization: Research St. Joseph's – Hamilton
Address: 50 Charlton Avenue East
City: Hamilton
Province/State: ON
Postcode/Zip: L8N 4A6
Telephone: 905.522.1155 x35280
Fax: None
Email: aweerden@stjoes.ca

The Secondary Institution Representative field should be left blank.

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.

Institutional Sites

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

Charlton Campus
50 Charlton Avenue East
Hamilton, ON
L8N 4A6

West 5th Campus
100 West 5th Street
Hamilton, ON
L8N 3K7

King Campus
2757 King Street East
Hamilton, ON
L8G 5E4

Access Research Program

St. Joseph's Healthcare Hamilton (SJHH) 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 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