

Documented Institutional Ethics Requirements Lawson Research Institute – St. Joseph's Health Care London

Mission and Values

Research involving Lawson Research Institute sites under St. Joseph's Health Care London must comply with the research provisions of the Catholic Health Ethics Guide. Particular attention should be paid to sections on research involving gametes, embryos, foetuses, stem cells, reproductive cloning, and genetics.

Research Locations under Lawson's Auspices

The sites listed below are under Lawson's auspices. Any research being conducted at a location that is not on the list below, including Western University locations and Robarts Research Institute are considered off-site from Lawson Research Institute. Any off-site activities should be clearly noted in the ethics submission and the letter of information.

Sites under St. Joseph's Health Care London

Mount Hope Centre for Long Term Care
Parkwood Institute
Parkwood Institute - Mental Health Care Building
Southwest Centre for Forensic Mental Health Care (St. Thomas, Ont.)
St. Joseph's Family Medical and Dental Centre
St. Joseph's Hospital (SJHC)

Archiving:

1. Investigators conducting **non-regulated studies** must retain all study related documents and data for a period of 15 years.

Database/Registry/Biobank

1. Lawson Research Institute requires local ethics review to establish a new Database/Registry/Biobank

Informed Consent Form Requirements

- The Lawson Research Institute logo should be included for all research being conducted at one of our sites.
 Additional individual site logos that are acceptable to be included are: Any branding logo representing St.
 Joseph's Health Care London, and their affiliated sites listed above, as well as partner institutions such as
 London Health Sciences Centre: London Health Sciences Centre Research Institute; Western University;
 Schulich School of Medicine and Dentistry; and Robarts Research Institute.
- 2. Insert a space for the participant to initial the bottom of each page. (Not enforced by OCREB)
- 3. In the confidentiality section, add the following bullet to the list of organizations with direct access to (e.g., who can look at) participant records:
 - The Quality Assurance and Education Officers from the Hospital's Office of Research Services may audit this research study for quality assurance purposes
- 4. Include the following language for our institutional contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 61234.



5. Include the following conflict of interest language if applicable:

If you would like additional information about the funding for this study, or about the role of the doctor in charge of the study, please speak to the study staff or contact the Patient Relations Office at St. Joseph's at 519-646-6100 ext. 61234.

6. Reproductive risks - Research taking place at Lawson Research Institute sites under St. Joseph's Health Care London may not

allow use of specific birth controls. Suggested language:

"If you are a woman and can have children, you will need to have a pregnancy test before enrolling in the study to be sure that you are not pregnant. If you are pregnant, you cannot participate in this study. You must not become pregnant or father a baby while on this study [and for ## months afterward] because the drugs or procedures used in this study might be harmful to an unborn baby. Your study doctor should discuss methods with you to ensure that you do not become pregnant or father a baby during the study. Your study doctor will be able to inform you of methods that are safe to use while on this study. If you do become pregnant during the study or if you father a child during the study, you should immediately notify your study doctor." or substantially similar language.



SRERS Administration

Lawson Research Institute and London Health Sciences Centre Research Institute

Reminder: Institutional Research Administration Requirements

Information and a guidance document on the required Lawson Approval is available at https://intra.lawsonresearch.ca/preparing-research/regulations-procedures/research-approvals or by contacting researchapprovals@sjhc.london.on.ca (Lawson) or researchapprovals@lhsc.on.ca (LHSCRI).

Please see the Documented Institutional Ethics Requirements (DIER) form for Lawson (SJHC) and LHSCRI (LHSC) site-specific requirements to be incorporated into your Centre Initial Application. Questions on these requirements can be directed to the Institute's Research Quality and Education team at ResearchQualityandEducation@sjhc.london.on.ca or ResearchQualityandEducation@lhsc.on.ca.

Effective September 7, 2017 all Lawson research should first be registered with Lawson using the ReDA tool before submitting for Research Ethics Board (REB) approval. Please go to https://www.westernLawsonResearch.ca for the portal to ReDA. Information in ReDA will support all elements of the Lawson Approval and alerts Lawson to delegate ethical review and oversight to an REB of Record. Documentation on ReDA is available at https://intra.lawsonresearch.ca/ and support is available through contacting researchapprovals@sjhc.london.on.ca or researchapprovals@lhsc.on.ca.

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.

CTO Stream

Collaborators:

The following collaborators must be given a role on the initial study-wide application, called the Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) and the Participating Site Initial Application (PSIA):

Email: cindy.hartgers@lhsc.on.ca Email: janet.knechtel@lhsc.on.ca

Role: Institutional Representative Role: Institutional Admin

Email: katrina.haasen@lhsc.on.ca Email: leslie.boisvert@lhsc.on.ca Role: Institutional Representative Role: Institutional Admin

Email: becky.champion@lhsc.on.ca Email: sophie.wang@lhsc.on.ca Role: Institution Admin Role: Institution Admin

Email: kamary.coriolanodasilva@lhsc.on.ca Email: Alicia.Schiassi@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: jocelyn.edwards@lawsonresearch.com Email: Catherine.hann@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: johana.mccallum@lhsc.on.ca Email: diane.love@lhsc.on.ca Role: Institution Admin



Email: lawsonhealthandsafety@lhsc.on.ca Email: rupinder.mann@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: lawrence.burns@lhsc.on.ca Email: Jessica.Grant@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: lisa.rigg@lhsc.on.ca Email: sarah.periard@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: Justina.diazlegaspe@lhsc.on.ca Email: Ifeoluwa.Aderanti@lhsc.on.ca

Role: Institution Admin Role: Institution Admin

Email: uzodinma.emeka@lhsc.on.ca

Role: Institution Admin

This access is automatically granted when the Participating Site Initial Application is created. When Lawson Research Institute or London Health Sciences Centre Research Institute is the Lead Applicant site, the research team should immediately create the PSIA for the London site (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.

Primary Institution Representative in application forms

The Primary Institution Representative for Lawson Health Research Institute must be indicated as follows in the applications within CTO Stream:

Title: Ms.
First Name: Cindy
Surname: Hartgers

Organization: Lawson Health Research Institute Address: 750 Baseline Road Suite 300

City: London
Province/State: ON
Postcode/Zip: N6L 2R5

Telephone: 519-685-8500 ext. 74728

Fax: 519-432-7367

Email: cindy.hartgers@lhsc.on.ca

The Secondary Institution Representative field should be indicated as follows:

Title: Ms.
First Name: Katrina
Surname: Haasen

Organization: Lawson Health Research Institute Address: 750 Baseline Road Suite 300

City: London
Province/State: ON
Postcode/Zip: N6L 2R5

Telephone: 519-685-8500 ext. 77735

SRERS Administration



Fax: 519-432-7367

Email: katrina.haasen@lhsc.on.ca

Absence Coverage – Institutional Representative Signature

Should Ms. Hartgers be away from the office, the Institutional Representative signature request can be sent to Ms. Katrina Haasen (katrina.haasen@lhsc.on.ca).