

Documented Institutional Ethics Requirements

Kingston Health Sciences Centre (KHSC) – Kingston General Hospital (KGH) Site and Hotel Dieu Hospital (HDH) Site

Kingston General Hospital (KGH) and Hotel Dieu Hospital (HDH) Site Requirements

COVID-19 – Informed Consent Form Requirements (Not applicable to studies review by OCREB)

For in person study visits only: Consent forms need to be amended to include acknowledgement of the remote possibility that a participant could come into contact with someone with COVID-19 during their research pathway and to allow for contact tracing. It is the Principal Investigator’s responsibility to ensure the following statement is added to the “How will participant information be kept confidential?” section of the consent form:

“There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes”.

Access to Personal Health Information for Recruitment to Research - Kingston Health Sciences Centre (KGH and HDH sites)

KHSC policy with respect to personal health information includes implied consent for both chart review research and for contact for participation in research. Patients must “opt out” of either use of their personal health information. Patients may withdraw their consent at any time to share their personal health information for research. Withdrawal of consent is not retroactive and must be provided in writing using our “Withdrawal of Consent” form. When this occurs, withdrawal is flagged within individual medical records.

This information is available on the KHSC public-facing website under “Privacy and Access to Information” and in our “Privacy Commitment to Patients” brochure at various locations in the hospital. Consequently, credentialed research staff may screen or review medical records for the purposes of a chart review or to contact patients who may be eligible for a research project.

Kingston Health Sciences Centre (KHSC) – Hotel Dieu Hospital (HDH) Site Requirements

Missions and Values

KHSC (HDH site) is a Catholic health care provider.

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 Kingston Health Sciences Centre (KHSC)

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.

Hospital Based Researchers

For hospital-based research occurring at both Queen's University affiliated hospitals (KHSC and Providence Care) with a single Principal Investigator, the Principal Investigator must specify their primary institution in the "Centre" tab of the Centre Initial Application, and the secondary institution in the response to question 2.5 (click "Yes" and then enter the additional affiliated hospital name in the sub-questions).

When research is occurring at both Queen's University affiliated hospitals, the Kingston research team must also ensure that collaborators (as outlined in the CTO Stream section of each applicable SRERS Administration form) from each affiliated hospital are manually added to the Centre Initial Application.

For more information on hospital-based research please refer to:

<https://www.queensu.ca/traq/awards/supportive-documents>.

TRAQ

A TRAQ DSS FORM must be completed for all Research projects.

If your research is taking place within one or both of the Queen's University affiliated hospitals (KHSC and/or Providence Care) please be sure to include the Hospital Departmental Impact & Information Form with your TRAQ submission. All hospital departments impacted by your research must be checked off on the "Approvals" tab.

For more information, please consult "Hospital Based Research - Tips for Completing the TRAQ DSS FORM", "Hospital Departmental Impact & Information Form Tips", and "Hospital-Based Research Frequently Asked Questions (FAQ)" available at <https://www.queensu.ca/traq/awards/supportive-documents>.

CTO Stream

Collaborators

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Dr. Steven Smith

Email: sps1@queensu.ca

Role: Institutional Representative

Jennifer Couture

Email: jennifer.couture@queensu.ca

Role: Institutional Representative

Lisa McAvoy

Email: lisa.mcavoy@kingstonhsc.ca

Role: Institutional Admin

Lisa Kozycz

Email: lisa.kozycz@kingstonhsc.ca

Role: Institutional Admin

This access is automatically granted when the Centre Initial Application is created. **When KHSC is the Provincial Applicant site the research team should immediately create the CIA for KHSC (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: Steven
Second Name: Smith
Organization: Kingston General Health Research Institute
Address: Connell 4, Room 2-4-033
76 Stuart Street
City: Kingston
Province/State: ON
Postcode/Zip: K7L 2V7
Telephone: (613) 549-6666 ext. 4287
Fax: N/A
Email: sps1@queensu.ca

The Secondary Institution Representative field must be indicated as follows:

Title: Ms.
First Name: Jennifer
Second Name: Couture
Organization: Queen`s University
Address: University Research Services, Fleming Hall-Jemmett Wing
City: Kingston
Province/State: ON
Postcode/Zip: K7L 3N6
Telephone: (613) 533-6000 ext. 78223
Email: jennifer.couture@queensu.ca