

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)