

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)