

SickKids REB ICES Guidance Document

What is ICES?

The Institute for Clinical Evaluative Sciences (ICES) is a not-for-profit research institute encompassing a community of research, data and clinical experts, and an accessible collection of Ontario's health-related data. ICES conducts studies that evaluate health care delivery and outcomes. By linking data from many sources, ICES researchers can obtain a comprehensive view of population health and health care delivery (<https://www.ices.on.ca/>).

ICES authority to collect and use data

ICES is a prescribed entity under section 45 of Ontario's Personal Health Information Protection Act. Section 45 is the provision that enables ICES to conduct analysis related to the management, evaluation and monitoring of the health system. Section 45 authorizes health information custodians – like physicians, hospitals and long-term care homes – to disclose personal health information to a prescribed entity, like ICES, without consent for such purposes.

Conducting research with ICES

When SickKids researchers conduct studies within ICES they do so under the auspices, and as “agents”, of ICES. As such, their studies are legally exempt from REB approval so long as the studies use only personal health information and include specific and substantive objectives to conduct analysis related to the management, evaluation and monitoring of the health system.

However, in some cases REB approval may be legally required. This is the case if a study's objectives fall outside PHIPA section 45 parameters or use ICES data holdings governed by different laws or by data sharing agreements that specifically require REB approval.

All studies carried out within ICES are subject to a privacy impact assessment and approval from ICES' Privacy & Legal Office prior to launch. The privacy impact assessment is the mechanism that ICES uses to confirm the legal authority for use of the data. If a study requires REB approval, ICES will identify and communicate this requirement. The SickKids researcher is then responsible for obtaining approval of the SickKids REB in accordance with its guidelines.

SickKids REB approval is EXEMPT (not required) when:

- Data is being used under PHIPA section 45, for the purpose of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services. Studies conducted wholly under PHIPA section 45 (as determined by ICES PIA review).
- No SickKids patient data (or other non-ICES data) will be collected and/or combined with ICES data

SickKids REB approval is REQUIRED when:

- The objectives of the ICES project (a) do not include an explicit and substantive intent to conduct analysis with respect to evaluating, planning for or monitoring the health system and (b) meet the definition of “research” under PHIPA: “a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research”

- The ICES project uses ICES data governed by a data sharing agreement that obliges ICES to obtain REB approval; or
- The ICES project involves collection of data through surveys or observation or intervention studies that involve individuals directly, or collection of human biological materials.

TIP: If it has been determined that your ICES study requires REB approval, please include a copy of your ICES PIA and list of variables that will be collected from ICES with your eREB application. Indicate in the eREB application that ICES has determined that REB approval is required in section 1 of the eREB application. The REB may also request additional information as part of the ethics review.

How do I obtain a SickKids REB Exemption?

In order to obtain a SickKids REB Exemption for your ICES project, you must email a request and include a copy of your ICES Approved PIA to David Kenney, Manager Research Ethics and Regulatory Compliance: david.kenney@sickkids.ca.

If your PIA has not received ICES approval, an REB exemption will not be granted.

NOTE: If you currently have an ICES study that should be exempt from SickKids REB review, you may close this study with the SickKids REB. You will need to provide the REB with documentation that the study meets the exemption criteria