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Linking your study data with the large healthcare databases held at ICES guidance document

This guidance document will provide you with information about the Institute for Clinical Evaluative Sciences (ICES), determining which scenario is most appropriate for your intended data use, and boiler-plate language necessary for drafting your Patient Letters of Consent and Data Sharing Agreements.

What is ICES?

The Institute for Clinical Evaluative Sciences is a not-for-profit research institute whose mandate is to enable health system evaluation and research. ICES conducts studies that evaluate health care delivery and outcomes. ICES researchers access a vast and secure array of Ontario’s health-related data, including population-based health surveys, desensitized patient records, as well as clinical and administrative databases. For additional information regarding ICES, please see our public website: www.ices.on.ca.

ICES authority to collect and use data

ICES is a prescribed entity for the purposes of section 45 of Ontario's Personal Health Information Protection Act. This means that health information custodians — like physicians, hospitals or long-term care homes — are permitted to disclose personal health information about their patients to ICES without patient consent. This information is used for statistical analysis in order to evaluate and monitor aspects of the health system. ICES may also collect, use and disclose personal health information for purposes described as research under PHIPA subject to certain conditions, including approval of a research ethics board. At ICES Western all investigator initiated studies that intend to transfer data to ICES for the purposes of linking with ICES’ data holdings must be submitted for review and approval by the Western University Health Sciences REB.

ICES Data

The ICES Data Repository consists of record-level, coded and linkable health data sets. It encompasses much of the publicly funded administrative health services records for the Ontario population eligible for universal health coverage since 1986 and is capable of integrating research-specific data, registries and surveys. Currently, the repository includes health service records for as many as 13 million people. For more information about ICES data, go to www.ices.on.ca/Data-and-Privacy/ICES-data.

How could ICES data enhance your study?

Linkage with ICES data can enable long-term passive follow-up of your participants at a significantly lower cost than direct patient follow-up in a study. The ICES data repository captures the majority of patient health encounters in Ontario, also minimizing loss to follow-up.

ICES data can be used to:

- estimate patient level costs on the health care system
- compare study participants to other populations or control groups
- provide enriched patient information (e.g. past medical history, health care use, immigration status)

- provide estimates of how representative the study population is to other patients in Ontario
- examine elderly patient medication use

What is needed for linkage with ICES data?

- 1) Most data collected by ICES are record level with direct personal identifiers — usually **health card number (version code not required) and/or last name, first name, date of birth and gender**. These personal identifiers are necessary for the accurate assignment of a unique, confidential ICES number — or "code". Each person in Ontario is assigned his/her own ICES number. This ICES number (IKN) is the key to successful linkage across data sets.
- 2) You have identified the most appropriate scenario for the intended linkage of your study data to ICES from the following options:
 - a. The data collected from your study participants will be used at ICES for a **single project related to this study**.
 - b. The data collected from your study participants will be used at ICES for a **series of projects related to this study**.
 - c. The data collected from your study will be used at ICES to **enable the conduct of future related research by the research team or other approved researchers**.
- 3) You have obtained patient consent to collect and store these linkage variables, and other study data as applicable, and transfer them to ICES. Please see below for sample wording to be included in the Patient Letter of Consent according to each of the 3 scenarios.
- 4) You store the key identifiers securely

Sample wording for Patient Letter of Consent for each of the 3 scenarios

Scenario A – single ICES study:

In addition to our main study we invite you to participate in our ICES sub-study. You can still participate in the main study without participating in the sub-study.

To do this we would like to gather more information about your medical care from the Institute for Clinical Evaluative Sciences (ICES). ICES is an independent research facility in Toronto, ON that studies the impact of health care and diseases in Ontario. ICES is a “prescribed entity” under Ontario privacy law. This special designation allows ICES to collect and use personal health information, including information about the use of physician services, hospitalizations, and prescriptions for patients residing in this province, for evaluation and monitoring of Ontario’s health system and other research. As a prescribed entity ICES is required by law to have its policies and procedures related to the data security and privacy protection reviewed and approved by the Information and Privacy Commissioner of Ontario every three years. At ICES, data used for research and analysis are coded and kept in a secure environment, to maintain individuals’ privacy.

If you agree to participate in the ICES sub-study, ICES will provide access to data about your long-term use of the health care system. To do this, your OHIP number, full name, date of birth

and gender [and any other study data to be transferred] will be collected and transferred to ICES in a secure, encrypted manner.

Scenario B – series of ICES studies

In addition to our main study we invite you to participate in our series of ICES sub-studies related to this project. You can still participate in the main study without participating in the sub-studies.

To do this we would like to gather more information about your medical care from the Institute for Clinical Evaluative Sciences (ICES). ICES is an independent research facility in Toronto, ON that studies the impact of health care and diseases in Ontario. ICES is a “prescribed entity” under Ontario privacy law. This special designation allows ICES to collect and use personal health information, including information about the use of physician services, hospitalizations, and prescriptions for patients residing in this province for evaluation and monitoring of Ontario’s health system and other research. As a prescribed entity ICES is required by law to have its policies and procedures related to data security and privacy protection reviewed and approved by the Information and Privacy Commissioner of Ontario every three years. At ICES, data used for research and analysis are coded and kept in a secure environment, to maintain individuals’ privacy.

If you agree to participate in the series of ICES sub-studies, ICES will provide access to data about your long-term use of the health care system. To do this, your OHIP number, full name, date of birth and gender [and any other study data to be transferred] will be collected and transferred to ICES in a secure, encrypted manner.

Scenario C – use in future related research

In addition to our main study we are asking for your permission to use your study data for future related research conducted at the Institute for Clinical Evaluative Sciences (ICES). You can decline this request and still participate in the main study.

ICES is an independent research facility in Toronto, ON that studies the impact of health care and diseases in Ontario. ICES is a “prescribed entity” under Ontario privacy law. This special designation allows ICES to collect and use personal health information, including information about the use of physician services, hospitalizations, and prescriptions for patients residing in this province for evaluation and monitoring of Ontario’s health system and other research. As a prescribed entity ICES is required by law to have its policies and procedures related to data security and privacy protection reviewed and approved by the Information and Privacy Commissioner of Ontario every three years. At ICES, data used for research and analysis are coded and kept in a secure environment, to maintain individuals’ privacy.

At ICES, your study data will be used to enable researchers within ICES to conduct projects subject to the approval of a research ethics board and ICES’ Privacy and Compliance Office. The study data may also be made available to authorized researchers who are external to ICES through ICES’ Data and Analytic Services (ICES DAS) division. Access to data through ICES DAS is subject to approval by a research ethics board and ICES’ Privacy and Compliance Office. If you agree to allow ICES to use your study data to enable future related research, your OHIP number, full name, date of birth and gender [and any other study data to be transferred] will be

collected and transferred to ICES in a secure, encrypted manner. This information is needed to link your study data to health databases held at ICES, and will enable researchers to better understand your use of the health care system over time.

How can researchers access ICES data?

Researchers who are unaffiliated with ICES may access ICES data (a) by collaborating with an ICES scientist on an ICES project or (b) for research conducted through ICES' Data and Analytic Services.

(a) Collaborating with an ICES scientist on an ICES project

A researcher who is unaffiliated with ICES may conduct a project within ICES provided he/she collaborates with an ICES scientist. Although the researcher may assume the role of Principal Investigator, the ICES scientist will participate fully in the project and is the responsible project team member within ICES. The ICES scientist is expected to attend all project meetings, co-direct the analysis, and ensure that all ICES policies and procedures are followed. For example, study data cannot be transferred to ICES until a project privacy impact assessment and data sharing agreement has been approved by ICES.

(b) ICES' Data & Analytic Services

As part of the Ontario SPOR SUPPORT Unit (OSSU), ICES' Data & Analytic Services provides researchers, students and knowledge users who are unaffiliated with ICES with access to ICES data and analytic services: www.ices.on.ca/DAS

ICES DAS provides the following services:

- Access to research-ready, linked health administrative datasets and analytic tools through a secure virtual desktop infrastructure over the internet, subject to prior approval of a research ethics board
- Support and advice on health administrative dataset creation
- Data analysis and reports

Costs of services will depend on the type and complexity of the request.

For more information about ICES or opportunities to collaborate with a [local ICES Scientist](#) please contact ICES Western by [email](#) or at 519-685-8500 ext. 56045.