Frequently Asked Questions

General

Q: What is ICES and how does it collect data?

A: ICES is a not-for-profit research and analytics institute. Its mission is translating data into trusted evidence that makes policy and healthcare better and people healthier.

ICES has a data repository of over 100 data holdings made up of record-level, coded, and linkable data from various sources, mainly from healthcare providers, hospitals, and other health-related organizations, but also from non-health sources, such as provincial and federal governments. Currently, ICES' data repository includes health data records for as many as 13 million people.

ICES also collects data for specific projects, called "project-specific data" or "PSD." PSD are not included in ICES' data repository and, with limited exceptions, are available only for the individual project for which the data are collected.

All collections of data by ICES are subject to rigorous privacy and security controls, such as Privacy Impact Assessments (PIAs) and Data Sharing Agreements (DSAs), as well as the secure transfer, storage and destruction of data at the end of its lifecycle.

Further information about ICES and its processes are available at ices.on.ca.

Research Ethics Board processes and requirements

Q: Why do some ICES projects require approval from a Research Ethics Board (REB) but others don't?

A: Whether a project requires REB review can depend on several factors. A common determinant is the overarching purpose of the project, namely whether the purpose is more accurately (a) research or (b) for analysis or the compilation of statistical information for purposes of Evaluation, Planning for, or the management or Monitoring of the health system, including the delivery of services (commonly referred to as "EPM" projects at ICES).

All projects whose purpose is research require REB approval, but many EPM projects do not. The reason for this distinction relates to ICES' designation as a "prescribed entity." This is a designation ICES holds under two laws of Ontario, the *Personal Health Information Protection Act* (PHIPA) and the *Coroners Act*.

Under PHIPA, a prescribed entity designation allows organizations like ICES to collect and use personal health information (PHI) without consent or REB approval from a category of organizations referred to in PHIPA as health information custodians or "HICs." HICs include

physicians, hospitals, pharmacies, retirement homes, mental health facilities, the Ministry of Health, and other healthcare-related entities.

Similarly, under the *Coroners Act* a prescribed entity can collect and use personal information from the Office of the Chief Coroner for purposes related to data analysis or the compilation of statistical information related to the health or safety of the public or any segment of the public.

If an ICES project is conducted for an EPM purpose and the data used for the project is collected and used under PHIPA and/or the *Coroners Act*, REB approval is not required because the project is not classified as research in the applicable privacy legislation.

Note, however, there may be additional factors necessitating REB approval for a project. These factors are discussed below in the next question.

Q: How do I know if my project requires REB approval?

A: Again, this may depend on several factors. Below is a non-exhaustive list of scenarios where an ICES project could require REB approval:

- If the overarching purpose of the ICES project doesn't align with the purposes for which ICES can collect and use PHI as a prescribed entity, i.e., the purpose is research that doesn't relate to EPM, (described in detail in the previous question).
- If the project is collecting external data (PSD) and the source of the data is a researcher. Note that this could include cases where the source of the data is a HIC or other healthcare-related organization that collected the PHI for a research purpose.
- If the source of the data is a type of organization not contemplated in PHIPA or the *Coroners Act*. This can apply to both PSD and existing data in ICES' data repository. For example, a non-health government body disclosing non-health data to ICES would likely need to rely on legislation other than PHIPA to authorize the disclosure. Many laws have limited avenues for disclosing personal information, in which case a disclosure for a research purpose might be relied on even if ICES' purpose of using the information aligns more with an EPM purpose. In other words, the disclosure to ICES may be 'research by default'.
- If ICES must disclose a limited amount of personal health information to an external third party, such as a HIC, so the third party can then identify which patients in its records meet criteria for inclusion in an ICES project. This scenario requires REB approval because it involves a disclosure of personal health information by ICES to a third party. Disclosure authorities for prescribed entities under PHIPA are limited and, like the example above, a disclosure for research is the only applicable avenue for ICES to disclose in this scenario.

There may be other scenarios not described above for which REB approval is required. The requirement and extent of REB review varies by a researcher's host institution, even for EPM projects that do not require REB review under PHIPA or the *Coroners Act*. Some institutions do not require REB review; some require a finalized ICES Project PIA to provide exemption to REB

review; some require an expedited review; and some require a full REB application with full review. For example, graduate student projects often require REB review as a matter of routine, regardless of legislative requirements or exemptions.

As such, a meeting at a project's initiation stage that includes relevant members of a project team and ICES subject-matter experts can be a helpful way to have a better understanding of whether a project requires REB approval prior to the submission of a Project PIA.

Q: If my project requires REB approval, what should my REB application say if I want to bring data into ICES?

A: The Regulation to PHIPA specifies required elements for a research plan that must be submitted to a REB for approval (see here for section 16 of the legislation, which provides the required content). One such requirement is that research plans must set out all persons who will have access to the information, why access is necessary, what their roles are in relation to the research, and what their related qualifications are. In order for a research project to bring in data to ICES, then, a research plan should explicitly set out that the project involves disclosure of personal health information to ICES. Note that even in cases where data have been desensitized, such as the swapping out of direct personal identifiers (DPIs) for a unique study ID code not known to the user, the resulting data may still meet the PHIPA definition of PHI. For this reason, your research plan should not make any claims about de-identification or anonymization while the research is in progress.

In addition to the above, the following elements should feature in your research plan:

- What are the data being disclosed to ICES? Do the data involve DPIs, such as an individual's name, health card number or address? If you aren't sure of every variable to be disclosed, you can provide more generalized categories of data, such as chart data relevant to the scope of the research.
- How did the data come to be in your possession? Was the information collected directly from research participants or was the information collected indirectly, say from existing medical records at a researcher's host institution?
- Why do the data need to be disclosed to ICES? For example, if the purpose of bringing in external data is for ICES to link it with other health data in ICES' custody, this should be expressly stated.

Q: Do I need to get REB approval before submitting my Project PIA?

A: No. If required, REB approval can be submitted at any point during the PIA review process. Note, however, that PIAs submitted with required documentation typically have a faster turnaround time for completion.

Q: My REB requires finalized documents before granting a REB exemption—who should review the request for exemption first, my institution or ICES?

A: There is no specified order in which a review of documents should occur. ICES is likely better suited to provide context as to why REB approval is not required for a given ICES project, but not for any exemptions for purposes outside of ICES.

Consent

Q: Does my ICES project require individual consent?

A: As explained above, ICES projects conducted for an EPM purpose typically do not require the consent of individual Ontarians. Such projects can include REB-approved research where express or implied consent of participants is obtained but can also include REB-approved research that involves the linking together of historical records of PHI where such linkages were not envisaged at the original point of collection. In the latter scenario, a REB can approve the linking of historical records where consent is impracticable or impossible to obtain, either because participant contact information is outdated, or because participants may be deceased.

ICES may review a project's consent form for a research project where REB approval may have been granted in part based on participant consent. In these such cases, it is still the case that ICES does not require consent, but it may review information about the consent as part of the PIA review process to ensure compliance with PHIPA and other applicable legislation.

Q: What information should a consent form include?

A: The elements of consent set out in PHIPA are:

- The consent should be the consent of the individual;
- The consent should be knowledgeable, meaning it's reasonable to believe the individual understands the purpose of the collection, use or disclosure of the personal health information to which they are consenting, and are also aware that they may give or withhold consent;
- The consent must relate to the information; and
- The consent must not be obtained through deception or coercion.

It's important to note that while PHIPA provides several circumstances under which consent may be implied rather than expressly provided, an individual's consent must be explicit for any disclosure of PHI to a non-HIC. Since ICES is not a HIC, any research project involving patient consent and onward disclosure of that information to ICES should ensure that consent is explicitly provided.

Moreover, different privacy laws in Ontario specify different elements of consent. Given that an ICES project could involve consent of individuals for non-health data, the following are additional best practice guidelines that may be included in your consent form:

- The specific information for which consent is being provided;
- To whom the information is being disclosed and for what purpose(s);
- The date on which consent is provided; and
- The organization to which consent is given.

Q: Can someone who consented to participate in research later withdraw their consent? Can a withdrawal of consent include a withdrawal of data?

A: PHIPA does allow for the withdrawal of consent if an individual provides written notice to the organization in possession of their data, but the withdrawal does not have a retroactive effect. This means, for example, if an individual provided consent to the disclosure of their PHI by a HIC to a researcher and then later withdrew their consent, such withdrawal would not obligate the HIC to retrieve the information already disclosed to the researcher. It would mean only that the HIC would be required to stop any ongoing disclosures once the withdrawal of consent is received.

Moreover, the withdrawal of one's data from a project as a result of withdrawing consent can be practically difficult. At ICES, an individual's data as part of a project typically exists only in coded form, and removing the individual's data would require ICES to first re-identify the individual to then withdraw the data. With many projects, such re-identification may not be practicable.

Transferring data to ICES

Q: How are data transferred to ICES for a project? Are ICES' methods of transfer secure?

A: Any data disclosed to ICES, whether as part of ICES' data repository or for a single project, must be done so through secure channels. Typically, data is sent to ICES through the Axway Secure File Transfer Protocol. As part of the IPC's review of prescribed entities, ICES must clearly demonstrate that its methods for the transfer of PHI are secure. See the IPC Manual here for its section on the secure transfer of records of PHI with which ICES is required to comply.

Retention of data at ICES

Q: How long are data kept at ICES? Are the data stored securely?

A: ICES' retention of data depends on a few different factors, such as the purpose of the data and its level of identifiability.

For example, data collected by ICES that form part of its data repository are retained indefinitely, because they are consistently used in ICES projects and third-party research projects. Conversely,

PSD are generally retained only for the duration of the project for which the PSD was collected, which is set out in both the REB-approved research plan (if applicable) and the corresponding DSA. An exception to this rule can occur if the PSD is requested to be used for multiple ICES projects by the same Principal Investigator, or for multiple projects by different investigators where the purpose(s) of the projects are similar to the purpose of the original project. As with single-use purposes where REB review and approval is required, permission to use PSD for multiple projects or by multiple investigators also must be approved by a REB and included in the DSA; however, the specified retention period for the PSD may be for a longer period if the data are envisioned to be used outside of a single project. A REB could also specify a retention period even where such a period is not set out in a PIA.

A retention period also takes into consideration the level of identifiability. For example, linking data with ICES' data repository requires ICES to initially collect fully identifiable data. After the data have been linked, however, any data with DPIs are destroyed. The level of data provided to project teams conducting research or analytics is desensitized data that do not include DPIs and is retained by the project team only for the duration of the project.

As part of the IPC's review of prescribed entities, ICES must clearly demonstrate that data are securely retained only as long as needed to satisfy the purpose for which it was collected, and that retention is in accordance with ICES' Records Retention Schedule. See the IPC Manual here for its section on the secure retention of records of PHI with which ICES is required to comply.

Return or destruction of data by ICES

Q: What does ICES do with data it no longer needs?

A: When data are no longer required or reach the retention period set out in ICES' Records Retention Schedule, ICES is required to either securely return the data to the organization that originally provided it, or securely destroy the data, whether on physical or electronic formats. ICES has different methods for secure destruction depending on the format, all of which are set out in its policy and procedure for the secure destruction of PHI. These documents and procedures also form part of the IPC's review of ICES as a prescribed entity. See the IPC Manual here for its section on the secure transfer of records of PHI with which ICES is required to comply.

Data Linking

Q: How are data linked at ICES?

A: When individual-level data are first collected by ICES, all DPIs are removed and replaced with an ICES Key Number (IKN). The IKN is derived from an individual's Ontario Health Insurance Plan (OHIP) number, which ICES receives as part of the OHIP Registered Persons Database. It is a unique code not known to the user and is persistent across ICES' data repository, thereby allowing DPIs to be removed from data while still enabling linking across datasets.

Where an individual's OHIP number is not known, Record Linkage techniques allow ICES to use other DPIs about an individual, such as full name, date of birth, sex, postal code, etc. to enable linking across datasets.

For non-individual data, such as information about healthcare facilities or geographic areas, ICES collects facility- and area-level identifiers to enable linking.

Q: Is it possible that someone could be indirectly identified by linking multiple sources of data at ICES?

A: While the addition of new information through data linking could conceivably increase the likelihood of an individuals' identifiability, ICES' policies and procedures expressly prohibit re-identification of individuals, except in limited cases where authorized under PHIPA for specific purposes. Moreover, any ICES project team wishing to publicize its findings (e.g., in a presentation or academic journal) must first conduct a re-identification risk assessment to clear any summary-level data contained in the proposed publication, which ensures that any residual re-identification risk is low. This is typically done by suppressing any person-level counts with a value of 1-5. This helps reduce the risk of reidentification to a level where it is not reasonably foreseeable that the information could be used, either by itself or in conjunction with other information, to identify an individual.