

Department	Reference Number		Organizational Scope	ICES Site	IPC Scope
PLO	012-01-01		ICES Network	ICES Network	All Acts
Original Date (YYYY-MM-DD)	Current Version (YYYY-MM-DD)		Review Frequency	Next Review (Month YYYY)	Supersedes (if applicable)
2022-09-30	2025-07-30		Annual	July 2026	PO.012-NPR.01
Procedure Owner (Title)		Director, PLO			
Required Reviewers (Titles)		Managing Legal Counsel, Manager Legal Services			

Please refer to the glossary for terms and definitions.

Provisions highlighted in grey are not yet in effect and are subject to review and approval by the Information and Privacy Commissioner.

1.0 ROLES AND RESPONSIBLITIES

- 1.1 Privacy Subject Matter Expert ("SME")
 - 1.1.1 Provides requests (via recommendations contained in completed Privacy Impact Assessments ("PIAs") for DSAs to the Legal SME.

1.2 Legal SME

- 1.2.1 Drafts and facilitaties legal review of DSAs, in accordance with the *Contract Review Procedure* and this procedure.
- 1.2.2 Ensures that any DSA addresses the requirements set out in the *Data Sharing Agreement Standard*.

1.3 ICES Requestor

- 1.3.1 Submits a draft PIA to a Privacy Analyst and including any applicable detailed request to transfer/download/import/collect data -, and
- 1.3.2 Upon request, supports the Legal SME with external review of DSAs, as needed.
- 1.4 ICES personnel who are stakeholders in the intended activities to be governed by a DSA, as necessary, are responsible for reviewing and providing feedback about non-standard terms and/or revisions to standard terms and providing feedback to the Legal SME to support appropriate drafting.
- 1.5 ICES designated signatories are designated as such via the *Signing Authority Policy* and are responsible for reviewing draft DSAs upon request and signing DSAs where appropriate.
- 1.6 The Managing Legal Counsel, Manager Legal Services is responsible for supporting the Legal SME with drafting and facilitating legal review of DSAs, throughout the development and negotiation process.



1.7 ICES Designated Signatories are responsible for reviewing and signing DSAs in a manner consistent with ICES' Signing Authority Policy.

2.0 DETAILS

- 2.1 Purpose of this procedure
 - 2.1.1 The purpose of this Procedure is to set out the procedure that ICES must follow when entering into a Data Sharing Agreement ("DSA") prior to ICES collecting Personal Health Information ("PHI") or disclosing PHI for purposes other than Third Party Research.
- 2.2 <u>Collecting data for ICES Data Holdings (General Use Data ("GUD") holdings and Controlled Use</u>

 <u>Data ("CUD") holdings)</u>
 - 2.2.1 A Privacy Analyst provides a completed copy of a PIA containing a recommendation to prepare a DSA, amending an existing DSA or Data Sharing Request Form (as applicable) to datapartnershipsanddevelopment@ices.on.ca and datasharing@ices.on.ca.
 - 2.2.2 Using the applicable contract template, and following any other instructions identified in the completed PIA, the Legal SME prepares the requested contract and sends a copy to the ICES Requestor for review.
 - 2.2.3 After the ICES Requestor confirms the content of the draft agreement, the Legal SME facilitates further development, review, negotiation and signing in accordance with the *Contract Policy*, the *Contract Review Procedure*, and the *Signing Authority Policy*.
 - 2.2.4 After the requested DSA is fully signed, the Legal SME uploads a signed copy into the Contract Management Software ("CMS"), and ensures the applicable information is logged, including:
 - (a) Data Provider;
 - (b) Effective date;
 - (c) Purpose identified in Appendix A of the DSA;
 - (d) Nature of the Personal Health Information ("PHI") and/or Personal Information ("PI"); and
 - (e) ICES Time Resource and Information Management ("TRIM") system number
 - 2.2.5 The Legal SME sends a copy of the fully executed DSA to the ICES Requestor, datapartnershipsanddevelopment@ices.on.ca, DataDQIMDept@ices.on.ca, and compliance@ices.on.ca
 - 2.2.6 The ICES Requestor logs the new ICES Data Holding in the ICES Data Inventory, and shares a copy of the logged information with compliance@ices.on.ca for verification.
 - 2.2.7 Only after the Data Quality and Information Management ("DQIM") department receives the signed DSA may it proceed to collect/download the data governed under the terms of the DSA, and when it does so, DQIM personnel logs it in the CMS;
 - (a) the collection date; and
 - (b) the data destruction date; and
 - (c) any other information identified as required in the Secure Collection, Disclosure and Transfer of PHI/PI Procedure.



- 2.2.8 DQIM personnel downloads/collects the data in accordance with the transfer processes defined in the DSA.
- 2.2.9 DQIM personnel schedules a time to generate meta-data from the newly posted ICES Data Holding and reflects this in the Data Dictionary, then notifies datapartnershipsanddevelopment@ices.on.ca.
- 2.2.10 After DQIM personnel confirms the Data Dictionary is successfully updated, Strategic Partnerships provides a summary of the Data Holding Obligations ("DHO") to compliance@ices.on.ca, and compliance@ices.on.ca adds information about the new ICES Data Holding to the DHO page of the ICES Data Dictionary.
- 2.3 Collecting Project Specific Data ("PSD") for ICES Projects
 - 2.3.1 The Privacy Analyst who reviews the ICES Project Privacy Impact Assessment ("Project PIA") communicates completion of the review and assessment following the steps set out in the *Privacy Impact Assessment Review and Analysis for ICES Projects Procedure*, which include providing a PDF copy of the approved Project PIA to the Legal SME.
 - 2.3.2 The Legal SME establishes the requested agreement, by following the instructions in the Project PIA, and then submits the draft to the Managing Legal Counsel, Manager Legal Services, ICES signatory(ies), and the Data Provider for review, in accordance with the Contract Review Procedure.
 - 2.3.3 As soon as possible after receiving a fully-signed copy of the recommended agreement, the Legal SME uploads the signed agreement into the CMS, and ensures all applicable information is logged, including
 - (a) Data Provider;
 - (b) Effective Date;
 - (c) Purpose from Appendix A of the DSA;
 - (d) Nature of the PHI/PI; and
 - (e) TRIM number
 - 2.3.4 The Legal SME provides notification and a signed copy of the agreement by email to each member of the Project Team, DQIMDept@ices.on.ca, psd@ices.on.ca, compliance@ices.on.ca, and the applicable ICES Research Program's general Inbox, along with instructions for transferring data.
 - 2.3.5 Only after DQIM personnel receives the signed agreement and verifies ICES has the authority to collect the data pursuant to the agreement may it proceed to collect the data.
 - 2.3.6 After the data has been collected (becoming ICES Data), DQIM personnel logs in the CMS:
 - (a) The collection date; and
 - (b) The data destruction date; and
 - (c) Any other information identified as required in the Secure Collection, Disclosure, and Transfer of PHI/PI Procedure.
 - 2.3.7 Where the contract identifies more data variables than actually were disclosed to ICES, an amendment to the PIA may not be required. In these circumstances. DQIM personnel notifies the appropriate Research Program Manager ("RPM"), who makes a decision with the



Project Team to either request a replacement file or leave as is. DQIM personnel also records a description of the discrepancy in the CMS.

2.4 Collecting data for Third Party Research Projects ("TPR Projects")

- 2.4.1 Third Party Researchers ("TPRs") must prepare a study proposal and submit their proposals electronically to the Program Leader of the Primary Care and Health Systems ("PCHS") program for preliminary review. The Program Leader (PCHS) determines eligibility and feasibility of the study, and appropriate use of the data requested.
- 2.4.2 If approved, TPRs can submit the approval from the Program Leader (PCHS), the Data & Analytic Services ("DAS") request form and study proposal to the Research Program Coordinator ("RPC") for DAS.
- 2.4.3 The RPC (DAS) requests initial adjudication from the Project Manager ("PM") (for DAS), who assesses whether the proposed research is feasible.
- 2.4.4 If approved, the RPC (DAS) is responsible for scheduling a consultation, including the TPR, Staff Scientist (for DAS), and PM (DAS).
- 2.4.5 The Privacy and Legal Office ("PLO"), DQIM department, and Strategic Partnerships may be consulted to determine feasibility and cost of the importation of the applicable data.
- 2.4.6 The RPC (DAS) or PM (DAS) and Staff Scientist (DAS) jointly prepare a Confirmation of Feasibility ("COF"), which includes a letter of support, written research plan, and preliminary quote for services, and provides it to the TPR for submission to a valid Research Ethics Board ("REB").
- 2.4.7 The TPR is required to provide the COF to a REB as supporting documentation for the application. After REB approval is obtained, the TPR provides the approval letter, application, and supporting documentation to the RPC (DAS) for review, serving as proof that conditions outlined in the COF were met. Evidence of submission is required by the PLO to ensure the REB has reviewed the submission in its completed form.
- 2.4.8 The PLO reviews the submitted documents and communicates to the RPC (DAS) if conditions are satisfied for approval, and/or if REB amendment is required.
- 2.4.9 If necessary, the RPC (DAS) arranges a follow-up consultation between the TPR and the Staff Scientist (DAS) to discuss revisions to the research scope or funding, in order to develop a preliminary Dataset Creation Plan ("DCP"). The Staff Scientist (DAS) advises the PM (ICES) and RPC (DAS) of any changes to the budget.
- 2.4.10 Upon development of the preliminary DCP, the RPC (DAS) drafts the applicable agreement and provides it to the TPR. The agreement includes the data sharing conditions, the contractual obligations, including terms and conditions of the agreement, and agreed upon research.
- 2.4.11 The TPR must also sign an "Authorized Researcher Confidentiality Agreement".
- 2.4.12 An unmodified agreement provided by ICES to the TPR is considered fully-signed when the TPR (and, if applicable, their institution) provides signed copies of the agreement and "Authorized Researcher Confidentiality Agreement". If any revisions to the agreement are requested before signing, these must be forwarded to datasharing@ices.on.ca for review, and if approved then the signatories must be added, and the agreement must be countersigned by ICES in accordance with the Signing Authority Policy.



- 2.4.13 After the agreement is fully signed, the RPC (DAS) sends a copy of the quote and the signed agreement to Finance@ices.on.ca for ICES' TRIM system number assignment, and a copy of the agreement to DQIMDept@ices.on.ca.
- 2.4.14 DQIM personnel contact the TPR and provides instructions for the transfer of the data governed by the agreement. DQIM personnel collect the data from the individual specifically identified in the agreement and only after the DQIM department receives a copy of the fully signed agreement.

3.0 RELATED DOCUMENTATION

- 3.1 Policies
 - 3.1.1 Signing Authority Policy
 - 3.1.2 Contract Policy
- 3.2 Standards
 - 3.2.1 Data Sharing Agreement Standard
- 3.3 Procedures
 - 3.3.1 Contract Review Procedure
 - 3.3.2 Secure Collection, Disclosure, and Transfer of PHI/PI Procedure
 - 3.3.3 Privacy Impact Assessment Review and Analysis for ICES Projects Procedure
- 3.4 Tools
 - 3.4.1 Authorized Researcher Confidentiality Agreement
- 3.5 Guidelines

4.0 CHANGE TABLE

Change Date (YYYY-MM-DD)	Change Notes
2025-07-30	 Reviewed to ensure compliance with the IPC Manual Reviewed as part of ongoing review activities of ICES' Policy Suite