



**THIS AGREEMENT** is made between You and ICES as of the date last signed below (the “**Effective Date**”).

**RECITALS:**

A. ICES is a not-for-profit corporation and a Prescribed Entity, which holds data from Ontario's health system and other sources for the purposes of health system analysis and research;

B. As part of the Ontario SPOR SUPPORT Unit, ICES Data & Analytic Services infrastructure and processes have been established to make ICES Data and expertise available to a broad array of Ontario and Canadian researchers and health system stakeholders, and in furtherance of its mission ICES has initiated the offering of analytic services to private sector organizations;

C. You have requested from ICES, and ICES has agreed to provide to You, analytic services in accordance with the terms and conditions of this Agreement;

**THEREFORE**, in consideration of the above and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by each Party, the Parties agree as follows:

**1. Definitions**

- (a) “**Act**” means the *Personal Health Information Protection Act* (Ontario), as amended from time to time, including all regulations and any successor legislation.
- (b) “**Agreement**” means this agreement as it may from time to time be amended, restated, replaced or supplemented.
- (c) “**Analytic Material**” means information and materials of any kind, provided by ICES by any means, including verbally, to support the Research or interpretation of ICES Data or Research Output.
- (d) “**Authorized Research**” means research that is described in a research plan that meets the requirements of section 44(2) of the Act and approved in a written decision of a Research Ethics Board made under section 44(4) of the Act, or in the case of research approved outside Ontario, research that meets the requirements of section 44(10) of the Act.
- (e) “**Authorized Researcher**” means an individual who is identified in the Research Plan.
- (f) “**Dataset**” means any dataset created by ICES for the Research.
- (g) “**Dataset Creation Plan/DCP**” means the plan for creation of the Dataset by ICES for the purposes of the Research.
- (h) “**De-identified**” means data that has been adjusted so that it could not, in any reasonably foreseeable circumstances, be used, either alone or in combination with other information, to identify a person.
- (i) “**Draft Deliverable**” means a draft version of the Final Deliverable or any constituent content or part of the Final Deliverable.
- (j) “**Fees**” means the fees payable by You for the Services to be provided by ICES pursuant to this Agreement, as set forth in the ICES Services Quote at [Appendix 1](#) to this Agreement or as otherwise agreed by the parties in writing.

- (k) **"Final Deliverable"** means a document prepared by ICES and provided to You that includes the methodology, Research Output, interpretation, and limitations of the Research, and is approved by ICES for release to You for the purposes of this Agreement.
- (l) **"ICES"** means the Institute for Clinical Evaluative Sciences.
- (m) **"ICES Data"** means data that is in ICES' custody and control.
- (n) **"ICES Documentation"** means written information prepared by ICES related to ICES Data, Research Output or the Services, excluding Analytic Material.
- (o) **"ICES Services Quote"** means the document that is attached as Appendix 1, developed by ICES in consultation with You to estimate the Fees.
- (p) **"Party"** means ICES and You, which are each a Party and collectively the Parties.
- (q) **"Prescribed Entity"** means an organization prescribed under section 18(1) of Ontario Regulation 329/04 under the Act, which meets the statutory requirements of section 45(3) of the Act, and includes ICES as a named entity.
- (r) **"Principal Researcher"** means Your employee or agent, whom You designate to have primary responsibility for the Research and identify as such on the Research Plan.
- (s) **"Publication"** means any report in any medium that arises from the Research, including, without limitation, journal articles, reviews, book, posters and presentations, whether written or oral.
- (t) **"Research"** means the research referred to by the research title recorded at the top of this Agreement.
- (u) **"Research Ethics Board"** has the meaning as set out under the Act.
- (v) **"Research Output"** means summary data, such as tables and figures, that is derived from the Dataset for the purposes of the Research.
- (w) **"Research Plan"** means a document in the form that is attached as Appendix 3 that describes, and is submitted as part of any Research Ethics Board application for, the Research.
- (x) **"Services"** means the services to be provided by ICES, which are identified in the ICES Services Quote and section 2 of this Agreement.
- (y) **"Your Data"** means data, which may include personal health information within the meaning of section 4 of the Act, You wish to transfer to ICES for incorporation into the Dataset.

## 1.1

### Appendices

The following appendices are incorporated by reference into and form part of this Agreement:

Appendix 1	ICES Services Quote
Appendix 2	Research Ethics Board Requirements
Appendix 3	Research Plan
Appendix 4	Your Data

## 2. Services

You request and ICES agrees to deliver to You the following Services. ICES agrees to:

- (a) Assist You with completion of the Research Plan;
- (b) Prepare the Dataset Creation Plan, based on decisions made by You combined with ICES' knowledge of available data;
- (c) If the Research involves incorporation of Your Data into the Dataset, work with You to complete, and then transfer Your Data to ICES in accordance with, Appendix 4;
- (d) Create the Dataset in accordance with the Dataset Creation Plan;
- (e) Analyze the Dataset to address the research objectives for the Research; and
- (f) Prepare the Final Deliverable.

## 3. The Research & Research Ethics Board Requirements

You acknowledge and agree that:

- (a) You are responsible for obtaining any approvals, including amendments, and renewals that are required in order for the Research to be, and remain at all times during the provision of the Services, Authorized Research. Information to facilitate such approvals is set out in Appendix 2;
- (b) You must include, and demonstrate to ICES inclusion of, a completed Research Plan with Your submission to the Research Ethics Board for approval of the Research;
- (c) You must identify ICES as an Authorized Researcher, and your agent for the purposes of the Research, in the Research Plan;
- (d) You, and not ICES, are responsible for the choice of analytical, statistical and research methods in all cases, including the Research design, and for the conduct and scientific integrity of the Research;
- (e) You must provide to ICES evidence of Research Ethics Board approval and notify ICES promptly if at any time (i) the Research ceases to be Authorized Research or (ii) You cease to be in compliance with associated Research Ethics Board approvals; and
- (f) ICES will not be able to receive, or incorporate Your Data into the Dataset, unless this is explicitly reflected in the Research Plan that has been approved by a Research Ethics Board.

## 4. Conflict of Interest

You warrant, represent and covenant that:

- (a) You have read and understood ICES' publicly available Mission, Vision & Values statement,<sup>\*</sup> and Your conduct of the Research, including without limitation any use of Research Output or Analytic Material or Publications, will not result in any actual, perceived or potential conflict with such statement or conflict of interest generally; and

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\* Available online: <http://www.ices.on.ca/About-ICES/Mission-vision-and-values>.

- (b) You will not engage or attempt to engage any employee or independent contractor of ICES as an Authorized Researcher.

**5. Services & Data To Be Provided “As Is”**

- (a) ICES will supply only the Services and will not provide any other service to You unless the supply of such service has been requested by You and agreed to in writing by ICES in advance through an amendment to this Agreement.
- (b) You acknowledge and agree that:
  - (i) ICES Data is collected from third parties and therefore ICES cannot control, and is not responsible and shall have no liability for its accuracy, quality or completeness;
  - (ii) You are using the Services (including without limitation Analytic Material) at your own risk and on the understanding that all Services will be provided to You on an “as is” basis; and
  - (iii) ICES makes no representation, warranty or covenant that any of the Services (including Analytic Material) are accurate, complete or up-to-date or fit for your intended purpose.

**6. Fees & Payment**

- (a) You acknowledge and agree to pay the Fees set out in the ICES Services Quote, which shall be invoiced to You by ICES as set out in the ICES Service Quote. Payment of such Fees shall not constitute acceptance by You of the Services nor acknowledgement of Your satisfaction with such Services.
- (b) You agree to promptly pay all the Fees invoiced to You by ICES and owing pursuant to section 6(a) above, within sixty (60) days of Your receipt of the invoice. Late payment of any invoiced amount will bear interest at a rate of twelve percent (12%) per annum and may result in an immediate suspension of the Services, and/or termination of this Agreement.

**7. Limitation on Use, Protection, Ownership and Control of the Dataset**

- (a) You will immediately report to ICES any failure to comply with this Agreement and co-operate with ICES to investigate and remediate any non-compliance.
- (b) You acknowledge and agree that neither You nor any of Your employees or agents, except for ICES, will at any time be granted access to the Dataset.
- (c) You acknowledge and agree that, notwithstanding incorporation of any of Your Data into the Dataset, the Dataset will be, and shall at all times remain, ICES Data.
- (d) Nothing in this Agreement or otherwise will (i) convey to You or any of Your employees or agents, including the Principal Researcher, any title or ownership in the Dataset, Analytic Material (subject to subsection (e) below) or ICES Documentation, including without limitation, any intellectual property or proprietary information in respect thereof, or (ii) limit or restrict ICES or any third party from independently performing the Research or research that is similar to the Research. Subject to the compliance with section 8(a), ICES hereby grants You and Your Researchers a licence to use the Final Deliverable including, without limitation, for the preparation and delivery of Publications. As between You and ICES, it is expressly acknowledged and agreed that You shall own all copyright in the Publications, and that ICES shall have no rights or interests in the Publications or services or products delivered by You to Your clients.
- (e) Where the Services include delivery of Analytic Material, ICES hereby grants to You, subject to the terms and conditions of this Agreement, including section 4(a), a non-exclusive licence to use and copy such Analytic Material for purposes reasonably related to the Research.
- (f) You agree to promptly destroy all Draft Deliverables upon receipt of the Final Deliverable, and to use the Final Deliverable solely for the purposes approved by the Research Ethics Board and for no other purpose.

## 8. Publications & Confidentiality

- (a) You agree to provide copies of Publications to ICES upon request.
- (b) To enable publication of Publications, ICES will maintain a copy of each Dataset for 10 years from the Effective Date.
- (c) You agree to include the following in any Publication and provide an advance copy to ICES so that it can confirm Your compliance:
  - (i) On the first page, or in the case of journal articles, in the appropriate section:

*This study made use of de-identified data from the ICES Data Repository, which is managed by the Institute for Clinical Evaluative Sciences with support from its funders and partners: Canada's Strategy for Patient-Oriented Research (SPOR), the Ontario SPOR Support Unit, the Canadian Institutes of Health Research and the Government of Ontario. The opinions, results and conclusions reported are those of the authors. No endorsement by ICES or any of its funders or partners is intended or should be inferred.*
  - (ii) In an appropriate location, any acknowledgments of ICES Data that are identified in the Final Deliverable.
- (d) Each Party shall keep confidential and shall not, without the prior written consent of the other Party or as expressly provided by the terms of this Agreement, disclose to any third party any information (whether in oral, written, graphic, machine readable or physical form) provided or made available to it by the other Party that is identified as, or by its nature is, confidential, including, but not limited to, the terms of this Agreement and any information relating to current or future business plans of the other party (collectively "**Confidential Information**"), except as expressly provided in this Agreement or otherwise agreed to by the Parties in writing. Each Party hereto agrees to treat the Confidential Information of the other as confidential using the same degree of care used by the receiving Party to protect the receiving Party's own confidential information, but in any event not less than a reasonable degree of care. The obligations with respect to confidentiality hereunder shall survive any expiration or termination of this Agreement.
- (e) Neither Party may be restricted from disclosing Confidential Information of the other Party to the extent required by law, rule or regulation or required by the demand of a court or government agency, provided, however, that in such event, the disclosing Party shall promptly notify the other Party in writing of any such intended disclosure sufficiently in advance to permit the other Party, at its option, to take legal or other action to protect its Confidential Information. Notwithstanding the foregoing, either party may disclose the terms of this Agreement to their respective financial and legal advisors.
- (f) Subsection 8(d) above does not apply to any information which is generally available to the public or is in or comes into a Party's possession without obligation of confidentiality.
- (g) Notwithstanding anything to the contrary contained in this Agreement:
  - (i) You acknowledge and agree that, at the time You confirm to ICES Research Ethics Board approval of the Research, ICES will post the following information to its public website: the title of the Research, the name of Your organization, and the research objectives. You further acknowledge and agree that ICES will add to the information on its website a copy of the Final Deliverable and Dataset Creation Plan one (1) year after deliver of the Final Deliverable to You or at the time of the first Publication, whichever comes first.
  - (ii) Governments and government funded agencies will have the opportunity to request the Final Deliverable and other details from ICES before they are posted on the ICES public website. ICES will notify You within five (5) business days of receiving the request if/when information is provided by ICES to a government or government-funded agency.

## 9. Representations, Warranties, Liabilities & Insurance

- (a) Each of the Parties represents and warrants that they have authority to enter into this Agreement and to grant the rights provided herein. Each Party represents and warrants to each other that it is not a party to any agreement or understanding and knows of no law or regulation that would prohibit it from entering into and performing this Agreement or that would conflict with this Agreement and it shall comply with all prevailing laws, rules, and regulations and obtain all necessary approvals, consents, and permits required by the applicable agencies of the government of the jurisdictions that apply to its activities or obligations under this Agreement.
- (b) The liability of ICES to You arising under this Agreement is limited to direct damages only, up to an amount equivalent to the Fees You have paid hereunder.
- (c) IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR SPECIAL, INDIRECT, CONSEQUENTIAL OR INCIDENTAL LOSSES OR DAMAGES OR LOST PROFITS, LOSS OF EXPECTED SAVINGS OR BUSINESS INTERRUPTION.
- (d) THE LIMITATIONS AND DISCLAIMER OF LIABILITY SET OUT IN SECTIONS 9(b) AND 9(c) ABOVE APPLY REGARDLESS OF WHETHER ARISING FROM BREACH OF CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, EVEN IF THE INDEMNIFYING PARTY IS ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, OR IF SUCH LOSS OR DAMAGE COULD HAVE BEEN REASONABLY FORESEEN.
- (e) You hereby agree to indemnify and hold harmless ICES from all costs, damages, fines, penalties, or other liabilities arising out of Your failure to comply with the terms and conditions of this Agreement. You will maintain in full force and effect general liability insurance with a minimum of \$2million coverage for any one occurrence in order to fund Your indemnity obligations under this Agreement. You will provide evidence of such insurance to ICES upon request from time to time.

## 10. Term & Termination

- (a) This Agreement shall commence on the Effective Date, and shall remain in force and effect until terminated in accordance with this Agreement.
- (b) Either Party may terminate this Agreement for convenience upon ninety days (90) days' written notice to the other.
- (c) Either Party is entitled to immediately terminate this Agreement for cause without further notice or penalty in the event that the other Party breaches any of the terms or conditions of this Agreement. The Agreement will be terminated automatically if the Research ceases to be Authorized Research or if You fail to report to ICES, or co-operate in the rectification of, any failure to maintain any of the protections identified in section 7.
- (d) In the event You terminate this Agreement for convenience or ICES terminates this Agreement for cause, You agree as a condition of termination to pay on an accelerated basis all Fees that would have been payable by You in connection with the full performance of this Agreement by ICES whether or not any of the Services have actually been provided as of the date of termination. In the event of early termination of this Agreement for any reason other than termination by You for convenience or termination by ICES for cause, and without prejudice to any other rights or remedies of the parties in such circumstance, You shall owe to ICES only the portion of the Fees corresponding to the portion of the Services that was properly performed by ICES up to the effective date of such termination. Where such termination occurs after the full payment of the Fees to ICES in accordance with section 6 hereof, ICES shall reimburse to You any portion of such Fees that would no longer be owed to ICES pursuant to this section 10(d).

## 11. General Terms & Conditions

- (a) Nothing in this Agreement constitutes the Parties as partners or joint venturers, and You shall not publish or release any advertisement, press release, public statement or other publication naming or referring to ICES or this Agreement without the prior written approval of ICES.

- (b) Neither Party may assign this Agreement or any rights or obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. This Agreement enures to the benefit of and is binding upon the Parties and their successors and assigns.
- (c) This Agreement shall be governed by and interpreted in accordance with the laws of the Province of Ontario, and the federal laws of Canada applicable in Ontario. Each Party submits to the exclusive jurisdiction of any Ontario courts sitting in Toronto in any proceeding arising out of or related to this Agreement and agrees that all claims in respect of any such proceeding shall be heard and determined in such Ontario courts.
- (d) Either Party shall be excused from any delay or failure in performance under this Agreement caused by reason of any occurrence or contingency beyond its reasonable control, provided in no event shall any event of financial impecuniosity by You be deemed to be an occurrence or contingency beyond Your reasonable control.
- (e) All notices under this Agreement shall be in writing and shall be delivered by personal delivery/courier, email, fax or registered mail to the other Party at its address indicated on the signature page. The notice shall be deemed to have been delivered on the day of personal delivery, on the day received by email or fax (as evidenced by a transmission confirmation), or on the fifth day following mailing.
- (f) Each of the Parties to this Agreement shall execute and deliver such other documents and do such other acts and things as may be necessary or desirable to carry out the terms, provisions and purposes of this Agreement.
- (g) The failure to enforce at any time the provisions of this Agreement or to require at any time performance by the other Parties of any of the provisions hereof shall in no way be construed to be a waiver of such provisions or to affect either the validity of this Agreement (or any part hereof), or the right of any of the Parties thereafter to enforce each and every provision in accordance with the terms of this Agreement.
- (h) If any provision of this Agreement or its application to any party or circumstance is restricted, prohibited or unenforceable, the provision shall be ineffective only to the extent of the restriction, prohibition or unenforceability without invalidating the remaining provisions of this Agreement.
- (i) This Agreement contains all of the agreements, representations and understanding of the Parties and supersedes and replaces any and all previous understandings, commitments or agreements, oral or written, related to the subject matter hereof. Any amendment to this Agreement must be in writing and signed by duly authorized officers of each Party.
- (j) Neither party shall perform any actions that are prohibited by local and other anti-corruption laws (collectively "Anti-Corruption Laws") that may be applicable to one or both parties to this Agreement. Without limiting the foregoing, neither Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate Anti-Corruption Laws.
- (k) This Agreement may be executed by the Parties in counterparts and the counterparts may be executed and delivered by electronic means, with all counterparts together constituting one agreement.
- (l) The Parties confirm that it is their wish that this Agreement, as well as any other documents relating to this Agreement, including notices, schedules and authorizations have been and shall be drawn up in the English language only. *Les signataires confirment leur volonté que la présente convention, de même que tous les documents s'y rattachant, y compris tout avis, annexe et autorisation, soient rédigés en anglais seulement.*

**IN WITNESS OF WHICH** the parties have duly executed this Agreement.

**INSTITUTE FOR CLINICAL  
EVALUATIVE SCIENCES**

**XXXXXX**

By: \_\_\_\_\_

Name: Michael Schull

Title: President and CEO

Date: \_\_\_\_\_

By: \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_

**Address for Notice:**

Contact: Ximena Camacho \_\_\_\_\_

Address: G106, 2075 Bayview Avenue \_\_\_\_\_

Toronto, ON, M4N 3M5 \_\_\_\_\_

Telephone: 416-480-4055 x 89333 \_\_\_\_\_

Facsimile: 416-480-6048 \_\_\_\_\_

Email: ximena.camacho@ices.on.ca \_\_\_\_\_

**Address for Notice:**

Contact: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Telephone: \_\_\_\_\_

Facsimile: \_\_\_\_\_

Email: \_\_\_\_\_

**APPENDIX 1**  
**ICES SERVICES QUOTE**

**APPENDIX 2**  
**RESEARCH ETHICS REQUIREMENTS**

I. Proof of Research Ethics Board approval is required to conduct the Research at ICES. . Any research ethics board that is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and meets the requirements of section 15 of Ontario Regulation 329/04 of the Act is acceptable. Those requirements are summarized as follows:

*Ontario Research Ethics Boards*

1. The research ethics board must have at least five members, which include:
  - a. One (1) with no affiliation with the person(s) who established that research ethics board
  - b. One (1) knowledgeable about research ethics
  - c. Two (2) with relevant scientific expertise, and
  - d. One (1) knowledgeable about privacy
2. There is no actual or perceived conflict of interest between the research ethics board's duties and any member's personal interest in the project

II. To facilitate approval of the Research by a Research Ethics Board, ICES recommends inclusion of the following statements in Your submission:

**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 has custody and control of a vast array of Ontario health information and other information ("ICES Data") that is collected and used by ICES in accordance with applicable law, research ethics approvals and contractual commitments.

**Legal authority**

As a prescribed entity under s. 18(1) of O.Reg. 329/04 of Ontario's *Personal Health Information Protection Act* (PHIPA), ICES is authorized to disclose ICES Data for research that is described in a research plan that meets the requirements of s. 44(2) of PHIPA and approved by a research ethics board, or in the case of research approved outside of Ontario, for research that meets the requirements of s. 44(10).

**Consent**

As a prescribed entity under PHIPA, ICES is authorized to collect personal health information from health organizations without consent for the purposes of evaluation and monitoring of Ontario's health system. ICES is prohibited, under its agreements with data providers, from contacting individuals whose information has been entrusted to ICES. This obligation restricts any opportunity to seek individuals' consent for use of their information for research.

**Data storage & retention**

ICES Data are held on ICES servers, located in a restricted area within ICES' locked and 24/7/365 video-monitored facility. ICES retains a copy of any ICES Data used for the research for 10 years.

**APPENDIX 3  
RESEARCH PLAN**

**About this Form:** As a prescribed entity under s. 1

**A. RESEARCH TITLE**

**B. RESEARCH SUMMARY & OBJECTIVES**

**Summary**

**Research objectives**

- 1.
- 2.
- 3.

**Research duration**      Estimated start date      Estimated end date **Date**

**C. PRINCIPAL RESEARCHER**

**Name**      **Qualifications**

**Affiliation**

**Address**

**E-mail**      **Phone number**

**Sponsoring organization**  
*(organization on whose behalf  
the research will be conducted)*

D. RESEARCH DATA		
<b>Data source</b>	The data identified at whose mandate is to custody of a vast arra the health system – c applicable law, resea The source of any da identified in that sect	
<b>Data linkages</b> (identify need and methodology)	The Research object data listed in section by ICES analysts in a dataset for analysis b confidential identifier	
<b>Analysis plan</b> (describe how the Research Data will be used)		
<b>Necessity for data</b>	All Research Data id <i>Dataset Specification</i> which cannot be acco	
<b>(a) ICES Data</b> <i>(Complete only for ICES Data intende</i>		
<b>ICES Data</b>	<b>Rationale for use</b>	<b>Other rationale</b>
Registered Persons Database (RPDB)	See list	
Canadian Institute for Health Information (CIHI) Discha Abstract Database (DAD)	See list	
Canadian Institute for Health Information (CIHI) Same-d Surgery (SDS)		
National Ambulatory Care Reporting System (NACRS)	See list	
Ontario Health Insurance Plan (OHIP)	See list	
Ontario Drug Benefit (ODB)	See list	
Asthma (ICES-Derived Cohort)	Health service utilization and cost	
Congestive Heart Failure (ICES-Derived Cohort)	Health service utilization and cost	
Chronic Obstructive Pulmonary Disease (ICES-Derived Cohort)	Health service utilization and cost	
Ontario Diabetes Database (ICES-Derived Cohort)	Health service utilization and cost	
Ontario Myocardial Infarction Database (ICES-Derived Cohort)	Health service utilization and cost	
Hypertension (ICES-Derived Cohort)	Health service utilization and cost	
Ontario Home Care Administrative System (OHCAS)	Health service utilization and cost	
Homecare Database (HCD)	Health service utilization and cost	
Other <i>(Please add rows and complete as required)</i>		
	See list	

<b>(b) REQUEST TO TRANSFER THIRD PART</b> <i>(Use this section to identify Third Party Data t Data. Where Research Ethics Board approva to ICES, the application approved by the Res to transfer the data to ICES.)</i>		<input type="checkbox"/> Not applicable
<b>Source</b>		
<b>Estimated # of records</b>		
<b>Description</b>		
<b>Type</b>	<input type="checkbox"/> Clinical data <input type="checkbox"/> Other personally identifiable information <i>(specify below)</i> :	
<b>Current use</b>	<input type="checkbox"/> Clinical/other primary use <input type="checkbox"/> Research	

E. PRIVACY PROTECTION & DATA SECU	
<b>Access &amp; use</b> (describe applicable safeguards)	Prior to access, identifiers, such identifier or "cod Research Data have access on
<b>Retention &amp; destruction</b> (describe applicable safeguards)	All Research Da within ICES' loc Research Data ICES systems.
<b>Consent</b> (justify why consent will not be obtained)	As a prescribed information from and monitoring with data provid entrusted to ICE individuals' con
<b>Confidentiality agreement</b>	ICES analysts, Data, are requir of employment.

F. RESEARCH MEMBERS <i>(List all individua identified below are agents of the Sponsorin</i>			
<b>1</b>	<b>Name</b>	TBD	<b>Access to Research Data required</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(specify reason below)</i>
	<b>Affiliation</b>		
	<b>Qualifications</b>		
	<b>Role</b>	ICES Analyst	
<b>2</b>	<b>Name</b>		<b>Access to Research Data required</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(specify reason below)</i>
	<b>Affiliation</b>		
	<b>Qualifications</b>		
	<b>Role</b>	Choose an item.	
<b>3</b>	<b>Name</b>		<b>Access to Research Data required</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(specify reason below)</i>
	<b>Affiliation</b>		
	<b>Qualifications</b>		
	<b>Role</b>	Choose an item.	
<b>4</b>	<b>Name</b>		<b>Access to Research Data required</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(specify reason below)</i>
	<b>Affiliation</b>		
	<b>Qualifications</b>		
	<b>Role</b>	Choose an item.	

G. RESEARCH ETHICS BOARD REVIEW & <i>(Use this section to identify all Research Ethics This includes applications and approvals requi section D(b) to ICES for linking with ICES Data accompanying protocols and applicable amend</i>	
Research Ethics Board <i>(List all institutions)</i>	Approval
1.	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> Application to be submitted
2.	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> Application to be submitted
3.	<input type="checkbox"/> Attached <input type="checkbox"/> Pending <input type="checkbox"/> Application to be submitted

H. RESEARCH FUNDING	
<b>Source name</b>	
<b>Source type</b>	<input type="checkbox"/> Government Funding Agency <input type="checkbox"/> Charity <input type="checkbox"/> Industry <input type="checkbox"/> Other <i>(specify):</i>

I. RISKS & BENEFITS	
<b>Anticipated public or scientific benefit</b> <i>(Maximum 150 words)</i>	
<b>Contextual sensitivities or foreseeable harms</b> <i>(Potential to stigmatize or harm any person or institution)</i>	<input type="checkbox"/> None identified <input type="checkbox"/> Yes <i>(Identify and suggest mitigation below)</i>

J. CONFLICT OF INTEREST DISCLOSURE <i>(A conflict of interest may arise when a Princip commercial or financial interests unduly, or app related to the Research. The Principal Researc participation in the Research would result in an</i>	
<b>Conflict of interest</b>	<input type="checkbox"/> None <input type="checkbox"/> Yes <i>(Identify and suggest management strategy below)</i>

K. KEY ASSUMPTIONS AND LIMITATIONS

## Dataset Specifications

**Schedule:** This Schedule is used to iden

Type of study	<input type="checkbox"/> Cohort	<input type="checkbox"/> Case-control
Matching required	<input type="checkbox"/> No	<input type="checkbox"/> Yes
<b>Index event</b>		
Description		
Age range	Min:      to Max:	<input type="checkbox"/> All non-missing
Sex	<input type="checkbox"/> Male	<input type="checkbox"/> Female <input type="checkbox"/> All non-missing
Required ICES Data		Date to Date Date to Date Date to Date Date to Date Date to Date Date to Date
Demographic data	<input type="checkbox"/> Income quintile	<input type="checkbox"/> Age at outcome <input type="checkbox"/> Age at death
Geographic data	<input type="checkbox"/> Rural/urban indicator	<input type="checkbox"/> LHIN <input type="checkbox"/> Sub-LHIN
Comorbidity data	<input type="checkbox"/> ACGs	<input type="checkbox"/> Charlson index <input type="checkbox"/> Other:
<b>Additional covariates</b>		
Description		
Required ICES Data		Date to Date Date to Date Date to Date Date to Date Date to Date Date to Date
<b>Outcome</b>		
Description		
Required ICES Data		Date to Date Date to Date Date to Date Date to Date Date to Date Date to Date
Resource Utilization Data	<input type="checkbox"/> Physician visits <input type="checkbox"/> Emergency department visits <input type="checkbox"/> Hospitalizations <input type="checkbox"/> Prescription Drug Use <input type="checkbox"/> Costs	
Required ICES Data:		

**APPENDIX 4**  
**YOUR DATA**

**1. Purpose**

- a. You wish to disclose Your Data to ICES for incorporation into Datasets prepared for You by ICES in accordance with the Dataset Creation Plan that will be established with You under this Agreement.
- b. You and ICES agree that no more data is being disclosed by You or collected by ICES than is necessary, and that de-identified or aggregate information will not suffice because identifying information is required to link Your Data with ICES Data.
- c. Your Data is described more specifically in Section 6 of this Appendix.

**2. Authority to Collect, Use & Disclose**

- a. Disclosure of Your Data to ICES by You is not inconsistent with any consent or agreements that govern Your authority to use and disclose Your Data.
- b. ICES' will collect, use and disclose Your Data only as permitted by the Act or required by law, and as consistent with ICES' policies and procedures as a Prescribed Entity.

**3. Preparation & Protection of Your Data by ICES**

- a. ICES will code Your Data by:
  - i. Replacing health card numbers and other identifying numbers with a unique ICES anonymous identifier (ICES Identifier); or
  - ii. Where identifying numbers are not provided, matching Your Data to information in other databases for the purposes of assigning the correct ICES Identifier; then
  - iii. Removing any remaining information that directly identifies an individual (Direct Personal Identifiers) (Coded Data).
- b. ICES will use the ICES Identifier to link the Coded Data to other coded information to create the Dataset.
- c. ICES will limit access to Your Data with Direct Personal Identifiers to ICES employees who have been designated to create Coded Data, store and retrieve data files from data safes, and destroy data with Direct Personal Identifiers, for those purposes.
- d. To permit identification and resolution of errors and data quality issues, ICES may retain a copy of Your Data with Direct Personal Identifiers for 180 calendar days after it has been transformed into Coded Data, after which ICES will destroy it by:
  - i. Permanently deleting copies on servers, hard drives and storage devices;
  - ii. Wiping or overwriting any laptop hard drives; and
  - iii. Shredding any physical media that contains it.
- e. Within five (5) business days of destroying the copy of Your Data with Direct Personal Identifiers, ICES will send you a signed certificate of destruction that confirms the data destroyed, the date, time, location and method of destruction used, and the name of the individual who performed the destruction.
- f. ICES will ensure that destruction carried out at (d) protects Your Data against unauthorized copying, modification, use or disclosure in accordance with industry standards and is therefore secure.
- g. Any ICES employee who handles Your Data will be required to be aware of, and agree to comply with, the terms of this Agreement.

- h. ICES will retain Your Data, including Coded Data, in a physically secure manner at all times until it is destroyed in accordance with this Agreement.
- i. If the copy of Your Data with Direct Personal Identifiers You disclose to ICES is, or is believed to have been, stolen, lost or accessed by unauthorized persons, ICES will take reasonable steps to contain the breach and promptly inform You using the contact information You record on this Agreement when you sign it.

**4. Method of Transfer**

- a. You will transfer Your Data to ICES as follows:

<b>Method</b>	
<b>Procedure</b>	
<b>ICES Contact</b>	
<b>Schedule</b>	

**5. Statement of Purpose**

<b>Purpose</b>	
<b>Research Title</b>	
<b>Principal Researcher</b>	
<b>Your Data</b>	
<b>Dataset Name</b>	
<b>Why Your Data is Necessary</b>	
<b>Estimated Timeframe for Use</b>	
<b>Variables</b>	<b>Collectio</b>