# CPCSSN SECURE RESEARCH ENVIRONMENT AND DATA USE AGREEMENT

**This Data Use Agreement outlines the non-negotiable terms of use for requested access datasets maintained in CPCSSN (as defined below) data repositories housed at and administered by Queen's University at Kingston.**

**Introduction**

The Canadian Primary Care Sentinels Surveillance Network (CPCSSN) has created data repositories that are housed at and administered through Queen's University at Kingston. These repositories allow for securely storing and sharing controlled-access human data submitted to CPCSSN, by member networks from across Canada.

The nature of the data held by CPCSSN requires that data must be shared in a manner consistent with the research participants' informed consent, research ethics board approvals and the confidentiality of the data and the privacy of participants must be protected.

Access to CPCSSN data will be provided to Principal Investigators who, along with their institutions ("Requesting Institution"), have certified their agreement with the expectations and terms of access detailed below.
CPCSSN expects that, through the Data Access Request (DAR) process, Approved Users of CPCSSN datasets recognize any restrictions on data use established through this Data Use Agreement.

The Agreement is made in accordance with made in compliance with section 44(5) of the *Personal Health Information Protection Act, 2004, S.O. 2004, c. 3 ("PHIPA")* and is effective as at the DAR approval date, as specified in the notification of approval of the Approved Study sent to the PI.

**Terms of Access**
1. **Definitions**

   i.     "**Approved Study**" means the study described in the DAR for which the Data is to be used.

   ii.    "**Approved User**" means a user identified in the DAR and approved by CPCSSN to access the Data for the purpose and for the period stated in an approved DAR.  The Principal Investigator may be an Approved User and all other Approved Users must be operating under the supervision of the PI at the Requesting Institution.

   iii.   "**Confidential Information**" means all information disclosed directly or indirectly to the Requesting Institution and/or Approved Users in connection with this Agreement that is confidential by its nature or in the circumstances in which it is received, regardless of whether it is identified as confidential or not, and whether recorded or not, and however fixed, stored, expressed or embodied, including, but not limited to: information related to CPCSSN, the Data, Personal Health Information of any individual

and information that CPCSSN is obliged not to disclose under provincial or federal legislation; but, with the exception of Personal Health Information, Confidential Information shall not include information that: (i) is or becomes generally available to the public without fault or breach by Requesting Institution or Approved Users, but only after that information becomes generally available to the public; (ii) Requesting Institution or Approved Users can demonstrate to have been rightfully obtained, without any obligation of confidence of any kind, from a third party who had the right to transfer or disclose it free of any obligation of confidence; (iii) Requesting Institution or Approved Users can demonstrate to have been rightfully known prior to this Agreement and in its possession free of any obligation of confidence, when disclosed; or (iv) is independently developed by Requesting Institution or Approved Users without the use of Confidential Information.

iv. "**Data**" means the health data requested in the DAR and approved by CPCSSN for access by Approved Users.

v. **"Personal Health Information"** has the same definition as in section 4 of PHIPA, as may be amended from time to time;

vi. "**Principal Investigator**" or "**PI**" means the researcher, who is a permanent employee of or holds a research academic appointment at the Requesting Institution and is designated as such by the Requesting Institution, and who submits the DAR to CPCSSN. The PI is responsible for the administration and oversight of the Approved Study.

vii. "**Requesting Institution**" means the home institution or organization of the Approved User that applies to CPCSSN for access to the Data.

2. **Research Use**

   i. The Requesting Institution agrees that if access is approved, (a) the PI named in the DAR and (b) those named in the DAR as researchers on the study requiring access to the Data, will become Approved Users of the Data.

   ii. Use of the Data will occur solely in connection with the Approved Study described in the DAR

   iii. If the Approved Users plan to collaborate with investigators outside the Requesting Institution, where such investigators will need to access the Data, the investigators at each external institution must submit an independent DAR using the same study title and study description as the Approved Study.

   iv. New uses of the Data outside those described in the approved DAR will require submission of a new DAR; modifications to the Approved Study will require submission of an amendment to this application (e.g., adding or deleting users, adding datasets to an Approved Study).

   v. Access to the Data is granted for a period of **stated in the approved DAR**, with the option to renew access at the end of that period.

**3. Requesting Institution and Approved Users Obligation**

    i.    The Requesting Institution certifies that the PI is in good standing (i.e., no known sanctions) with the institution, relevant funding agencies, and regulatory agencies and is eligible to conduct independent research (i.e., is not a postdoctoral fellow, student, or trainee).

    ii.    The Requesting Institution and any Approved Users may use the Data only in accordance with the parameters described on the approved DAR for the appropriate research use in the Approved Study, as well as any limitations on such use, of the Data, as described in the DAR, and as required by law.

**4. Compliance with Laws and Non-Identification**

    i.    Approved Users will use the Data in compliance with

        a) all applicable laws and regulations (**"Applicable Law"**), including but not limited to *PHIPA;*

        b) the applicable institutional policies and guidelines; and,

        c) the applicable Research Ethics Board clearances.

    ii.    Approved Users shall not use the Data either alone or in concert with any other information, to identify or contact individual participants from whom Data was collected. Approved Users shall not use the Data to generate information that could allow the identities of research participants to be readily ascertained.

**5. Confidentiality**

    i.    Subject to and in accordance with the terms of this Agreement, Requesting Institution and Approved Users shall safeguard Confidential Information received from CPCSSN and, shall only disclose Confidential Information of other Approved Users, and then only with ensuring that appropriate confidentiality agreements or confidentiality arrangements are in place.

    ii.    If any Personal Health Information is made available under this Agreement, Requesting Institution and Approved Users, shall not:

        a) Disclose or provide such Personal Health Information to any person who is not an Approved User, unless such disclosure or use is made with the consent of the individual to whom the information pertains.

    iii.    This Article shall survive

        a) indefinitely in respect of Personal Health Information provided by CPCSSN;

b) for all other Confidential Information, ten (10) years following the expiration or termination of this Agreement

6. **Non-Transferability**

    i. The Requesting Institution and Approved Users agree to retain control of access to the Data and further agree not to distribute such access to any entity or individual not identified in the submitted DAR.

    ii. The Requesting Institution and Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this Agreement and the appropriate research use of Data obtained through the DAR by research staff associated with the Approved Study, subject to applicable laws and regulations. Requesting Institution and Approved Users agree that Data obtained through the attached DAR, in whole or in part, may not be sold to any individual at any point in time for any purpose.

    iii. The PI agrees that if they change institutions during the access period, their access to the Data under this Agreement will terminate and any subsequent use at their new institution must be approved by CPCSSN under a separate DAR.

7. **Data Security and Unauthorized Data Release**

    i. The Requesting Institution and PI agree to notify CPCSSN of any unauthorized Data sharing, breaches of data security, or inadvertent Data releases that may compromise Data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of CPCSSN notification, the Requesting Institution agrees to submit to CPCSSN a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action. The Requesting Institution agrees to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to CPCSSN requests may result in further compliance measures affecting the Requesting Institution.

    ii. Requesting Institution, Approved Users and their associates agree to support CPCSSN investigations arising from any breaches reported in accordance with section 7(i) above and provide information, within the limits of applicable laws and regulations. In addition, Requesting Institution and Approved Users agree to work with CPCSSN to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.

8. **Data Use Violations**

i. The Requesting Institution and Approved Users acknowledge that CPCSSN may terminate the approved DAR and this Agreement and immediately revoke or suspend access to the Data at any time if CPCSSN, acting reasonably, finds that the Requesting Institution or its Approved Users are no longer in compliance with the terms described in this Agreement.

ii. Requesting Institution and Approved Users acknowledge that in using the Data, Approved Users shall not make copies of the Data, whether manually or through the use of electronic or optical means.

iii. Requesting Institution and Approved Users acknowledge that the Data is stored at and access through Queen's University, Centre for Advanced Computing (CAC). As a result, in accessing the CPCSSN Data, Approved Users must comply with the CAC's Acceptable Use Policy. Failure to comply with the CAC Acceptable use policy may result in further compliance measure affecting the Requesting Institution.

## 9. Intellectual Property

i. CPCSSN retains ownership of the Data and all intellectual property rights therein.

ii. Requesting Institution and/or Approved Users, in accordance with Requesting Institution's policies, retain all rights title and interest in and to any results generated from the use of the Data in the Approved Study.

## 10. Dissemination of Research Findings

i. It is CPCSSN's intent to promote the dissemination of research findings from use of the Data, subject to the terms of this Agreement, as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings.

ii. Approved Users will be free to publish or otherwise disseminate research findings arising from use of the Data, subject to the following:

    a) Approved Users shall remove all CPCSSN Confidential Information from the dissemination prior to disclosure.

    b) Approved Users shall include in all disseminations an acknowledgment indicating that the Data was made available by CPCSSN.

    c) Approved Users shall include in all disseminations a disclaimer indicating that the findings and opinions expressed in this document do not necessarily reflect those of Queen's University at Kingston or the Canadian Primary Care Sentinel Surveillance Network.

## 11. Non-Endorsement, Indemnification

i. The Requesting Institution and Approved Users acknowledge that although all reasonable efforts have been taken of the Data, the Data provided by CPCSSN is provided "AS IS" and without any warranty express or implied, including any warranty of merchantability or fitness for a particular purpose or that the use of the Data will not infringe or violate any patent, copyright, trademark or proprietary right of any third party.

ii. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this Agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this Agreement and the use of the results of the Approved Study.

**12. General**

i. *Audit* – CPCSSN shall have the right, from time to time and with reasonable notice, to audit Requesting Institution's compliance with the terms of this Agreement, including Approved Users' compliance with those terms. Requesting Institution and Approved Users shall cooperate with CPCSSN with respect to any such audits.

ii. *Governing Law and Jurisdiction* - This Agreement and the right, obligations and relations of the parties are governed by and construed in accordance with the laws of the Province of Ontario, and the federal laws of Canada applicable therein. All disputes arising from this Agreement will be instituted in the courts and/or tribunals in the Province of Ontario, and each party irrevocably submits to the exclusive jurisdiction of such courts and/or tribunals in any action or proceeding.

**Agreed by**:

Signature: _____

Name: _____

Title: _____

Date: _____

**Acknowledged by**:

Signature: _____

Name: _____

Title: _____Principal Investigator_____

Date: _____