CCIS Ontario's Critical Care Information System

# Data Stewardship COVID-19 Research Review Sub-Committee

**Purpose:**

The Critical Care Information System (CCIS) Data Stewardship COVID-19 Research Review Sub-Committee will provide oversight for expedited review and approval of COVID-19 Research Study Plans, including personal health information (PHI) from the CCIS Prescribed Registry consistent with prescribed requirements under the *Personal Health Information Protection Act, 2004* (PHIPA).

**Membership:**

Isabel Hayward, Executive Director, CritiCall Ontario (Co-Chair)
Dr. Bernard Lawless, Provincial Lead, Critical Care Services Ontario (CCSO) (Co-Chair)
Mary Gavel, Privacy Lead, CritiCall Ontario
Jackie Schleifer Taylor, Chief Clinical Officer LHSC, President, Children's Hospital, LHSC
Dr. John Drover, Department of Critical Care Medicine, Kingston General Hospital

**CCIS Data Stewardship COVID-19 Research Review Sub-Committee Expedited Review Process:**

1. Completed CCIS COVID-19 Research Data Request Forms will be received by the CritiCall Ontario Privacy Lead through email at privacy@criticall.org

2. **Within two (two) business days of receipt** of a CCIS COVID-19 Research Request Form, the CritiCall Ontario Privacy Lead will perform a preliminary review of the COVID-19 Data Request Form, Research Study Plan and Research Ethics Board approval, to confirm requirements under Section 44 of PHIPA have been met and the following information is documented on the COVID-19 Research Request Form:

   Required Documentation:

   1. Name of requesting Organization.
   2. Name and contact information of Principal Investigator and their Role/Title within Organization.
   3. Name of any Co-Investigator(s) and their Role(s)/Title(s) within Organization.
   4. Type of Organization requesting the data.
   5. Title of the COVID-19 Research Study.
   6. Description of the COVID-19 Research Study.
   7. Do the Investigator(s) plan on contacting patients?
   8. Is there Research Ethics Board (REB) approval?
   9. Name of REB and Name and contact information of Chair of REB.
   10. Will the COVID-19 Research Study be peer reviewed?

11. List of data elements including PHI requested or a list of the de-identified or aggregate data elements requested.
12. List of all Investigators that will have access to the PHI, their title and affiliation with the study.
13. Safeguards that will be applied to the PHI (including physical, technical and administrative).
14. If the PHI or de-identified or aggregate data will be linked to other data? PHI from other sources?

**Within one (1) business day after the confirmation by the CritiCall Ontario Privacy Lead** (or delegate) the COVID-19 Research Request Form, Research Study Plan and REB Approval Letter will be circulated electronically to the CCIS Data Stewardship COVID-19 Research Sub-Committee. **Within two (2) business days, members will review** and provide feedback and/or approval through electronic vote to the CritiCall Ontario Privacy Lead (or delegate).

3. The CCIS Data Stewardship COVID-19 Research Sub-Committee will use the following criteria, consistent with PHIPA, for their review:

    1. Can the research be satisfied with the release of aggregate or de-identified data?
    2. Is the PHI requested, the minimum data set in order to meet the needs of the Research Study Plan?
    3. Is the data requested consistent with the data identified in the submitted Research Study Plan?
    4. Is the disclosure aligned with the CCSO and CritiCall Ontario's mandates for the CCIS?
    5. Has enough detail been provided in the written Research Study Plan to allow for a decision to be made, or are additional details required.

4. If additional information is required before a decision can be made by, **the CritiCall Ontario Privacy Lead or a member of the CCIS Data Stewardship COVID-19 Research Sub-Committee will contact the Principal Investigator, within one (1) business day** and request that the additional information be forwarded to the CritiCall Ontario Privacy Lead at privacy@criticall.org

5. **Within one (1) business day following receipt of the additional information by the CritiCall Ontario Privacy Lead**, the CritiCall Ontario Privacy Lead will circulate the information electronically to members of the CCIS Data Stewardship COVID-19 Research Sub-Committee. Members **will respond with their decision with two (2) business days of the electronic circulation**.

6. **Within two (2) business days of a Decision by the CCIS Data Stewardship COVID-19 Research Sub-Committee**, the CritiCall Ontario Privacy Lead will ensure that a letter is sent to the Principal Investigator to advise of the decision.

7. If the Research has been approved, the letter will list any conditions that must be satisfied prior to the disclosure, including execution of a CCIS Research Data Sharing Agreement (DSA) consistent with s. 44 (5) of PHIPA. The CCIS DSA will be included with the letter if the Research Study has been approved.

8. The CritiCall Ontario Privacy Lead will be the primary contact for addressing and confirming that all conditions and restrictions are met and receiving the signed Research DSA from the Principal Investigator.

9. The CritiCall Ontario Privacy Lead will follow up with the Principal Investigator **within two (2) business days** following receipt of the signed Research DSA to confirm the process and any conditions or restrictions for the secure means of transmission of the PHI from the CCIS.

10. The CritiCall Ontario Privacy Lead will ensure that the use of the PHI through the CCIS for prospective COVID-19 Research Study Plans is monitored, and report minimum monthly to the CCIS Data Stewardship COVID-19 Research Sub-Committee Co-Chairs, for confirmation of continued secure transmission of data from the CCIS.