Memorandum of Understanding ("MOU") dated December 17, 2020 between Her Majesty the Queen in Right of Ontario, as Represented by the Minister of Health (the **"Ministry"**) and the Institute for Clinical Evaluative Sciences (**"ICES"**) (each a **"Party"** and collectively **"Parties"**).

1.0 INTRODUCTION

- 1. The Minister, together with the Ministry, is a Health Information Custodian under the *Personal Health Information Protection Act, 2004* ("PHIPA").
- 2. The Ministry is the executive sponsor of the Ontario Health Data Platform ("OHDP"), a collaborative initiative that aims to accelerate research and analytics within Ontario to help the province better manage and respond to the COVID- 19 pandemic. A key component of this project is a high-performance computing environment for the linkage of large health data sets (hereafter referred to as "OHDP-Q"). As executive sponsor, the Ministry is the Health Information Custodian accountable for the collection, use and disclosure of the personal health information ("PHI") maintained in the OHDP-Q, including PHI collected pursuant to the PHIPA Regulation.
- 3. ICES is an independent not-for-profit corporation and registered charity that for more than 25 years has conducted complex data preparation, linkage and analysis for scientists to conduct research and analytics.
- 4. Under PHIPA, ICES is also designated as a Prescribed Entity to enable Health Information Custodians to disclose PHI for the evaluation, planning, and monitoring of the health system. The designation sets parameters and limits ICES in its ability to onward disclose PHI to third parties.
- 5. As part of the COVID19 provincial response and to enable ICES as a Prescribed Entity to disclose PHI to the Minister, s. 18 of O. Reg. 329/04 (General) under PHIPA was amended.
- 6. S. 18(11) of O. Reg. 329/04 (General) under PHIPA provides that despite subsection 45 (6) of the Act and subject to subsection (12), the ICES and Ontario Health shall, upon request of the Minister, disclose PHI to the Minister where the Minister has determined that such disclosure is necessary for the purposes of,

(a) researching, analyzing, investigating, preventing, responding to or alleviating COVID-19 or its effects; or

(b) evaluating or monitoring the impact of COVID-19 on the management of, the allocation of resources to or planning for all or part of the health system.

7. Where the Minister requests that ICES disclose such PHI, ICES must comply with the request as required by subsection 18(11) of the PHIPA Regulation; however subsection 18(12) of the PHIPA Regulation exempts ICES from the requirement to disclose PHI to the Ministry if the disclosure is otherwise prohibited by law or by the terms of an agreement to which ICES is a party.

2.0 PURPOSE

The purpose of this MOU is to:

- (a) clarify the accountabilities for each of the Minister and ICES;
- (b) specify the process to be followed by the Ministry and ICES when the Minister has requested ICES to disclose such PHI under the PHIPA Regulation;
- (c) document the PHI requested by the Minister and disclosed by ICES to the Minister under the PHIPA Regulation; and
- (d) confirm the manner in which this MOU will be updated and publicly posted.

3.0 DEFINITIONS

"PHIPA" means the Personal Health Information Protection Act, 2004.

"PHIPA Regulation" means s.18(11) and (12) of O. Reg. 329/04 (General) under PHIPA.

"Request Letter" means a letter from the Minister in which the Minister requests that ICES disclose PHI to the Minister pursuant to the PHIPA Regulation.

The Terms "Disclose", "Health Information Custodian", "IPC", "Minister", "Personal Health Information" or "PHI", "Prescribed Entity", "Research" shall have their respective meanings as under PHIPA or the PHIPA Regulation.

4.0 ACCOUNTABILITIES FOR THE MINISTER AS HEALTH INFORMATON CUSTODIAN

- 1. The Ministry is the Health Information Custodian accountable for the collection, use and disclosure of PHI in relation to the OHDP-Q, which includes any PHI collected by the Ministry from ICES that must be disclosed by ICES to the Minister pursuant to the PHIPA Regulation.
- 2. Further, the Ministry acknowledges the reputational harm that would be caused to ICES should the necessary due diligence not be employed by the Ministry when collecting and using such PHI disclosed by ICES.

5.0 TRANSPARENCY FOR REQUEST PROCESS BY MINISTER

- 1. Before the Minister makes a request to ICES under the PHIPA Regulation, the Ministry will consult with ICES on the request. The Ministry will consider and endeavor to address any concerns or risks raised by ICES, including concerns or risks related to use of PHI from ICES.
- If ICES is aware of circumstances, including concerns or risks that may result in the PHI being insufficiently protected by the Minister, ICES will bring the matter to the attention of the Minister. There is nothing in this MOU which prohibits ICES from bringing such concerns to the Information and Privacy Commissioner of Ontario ("IPC").
- 3. To enable a transparent request process, the following schedules are to be appended with the MOU:

| Consultation process for proposed requests for PHI in the custody and control of ICES. Schedule 'A' would not include PHI that ICES has not already collected for its own purposes under PHIPA. | Schedule 'A ' |
|---|-----------------------|
| Request Letter(s) from the Minister to ICES requesting the disclosure of PHI (as the letter(s) become available); | Schedule ' B ' |
| Descriptions of the PHI requested by the Minister and disclosed by ICES (as the schedule(s) become available and updated from time to time). | Schedule ' C ' |

4. The Parties will keep the Schedules to the MOU up to date in order to ensure that the public is informed in a timely manner of the PHI that is being disclosed by ICES to the Ministry under the PHIPA Regulation.

5. The Ministry will also post any policies, including supporting documentation in relation to the collection, use, disclosure, retention, and destruction, in relation to the PHI collected under the PHIPA Regulation.

6. The MOU and any amendments will be posted at:

For MOH: <u>https://computeontario.ca/covid-19-health/privacy-security/</u>

For ICES: ICES website at [www.ices.on.ca]

and the Parties will co-ordinate the timing of the posting.

6.0 AMENDMENTS TO THE MOU

1. The Parties will at a minimum review the MOU every six months or earlier upon joint agreement, to determine if amendments are required. Any amendments to the MOU will be set out in writing, including in respect of any schedules. Either Party may make a written request to review the MOU upon providing 30 days' notice in writing to the other Party.

7.0 TERM

This MOU will remain in effect until July 30, 2022, the date the PHIPA Regulation is set to expire, or upon a 60-day written notice from one Party to the other, whichever comes first.

IN WITNESS WHEREOF the Parties have executed this Memorandum of Understanding.

Institute for Clinical Evaluative Sciences

Allace Aul

By: _____ Name: Michael Schull Title: CEO, ICES Date: December 17, 2020

By:

HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO as represented by the MINISTER OF HEALTH (the "Ministry")

SHar

Name: Greg Hein Title: Assistant Deputy Minister, Digital Health Division Date: Dec 17, 2020

SCHEDULE 'A' – CONSULTATION PROCESS FOR PROPOSED REQUESTS FOR PHI

1. CONTACTS

The Ministry and ICES shall each identify an individual to be the contact person for their respective organizations to collaborate on a proposed request under subsection 18(11) of O. Reg. 329/04 (General) under PHIPA.

2. PROCESS

Once the Ministry has determined that PHI held by ICES is necessary for the purposes set out in the PHIPA Regulation, the Parties agree to work collaboratively to undertake the following steps. For:

- 1. Advance Notice. The Ministry will advise ICES of the proposed request with a mutually agreeable time frame for PHI.
- Transfer Planning. The Ministry and ICES, as will jointly develop a PHI transfer plan for the PHI
 requested pursuant to the PHIPA Regulation. The data transfer plan will include (at a minimum but
 not exclusively) a precise description of each PHI package to be transferred and a diagram /summary
 of the proposed data flow.
- 3. Advance Consultation. ICES will identify any issues or concerns related to preserving the privacy of individuals or vulnerable communities, and/or in respect of data governance, (for example, related to Indigenous, Métis, Inuit and First Nations data; related to any of the enumerated grounds under Ontario's Human Rights Code, RSO 1990, c. H.19 (i.e. race, ethnicity-based or other community concerns), records subject to consent directives; or personal identifiers in free text), cybersecurity and technological safeguards, or any other concerns in connection with the proposed file transfer, retention, destruction, collection, use and disclosure.
- 4. **Remediation.** The Ministry and ICES will work to address any concerns or risks raised in the manner set out in Section 5.0 of this MOU. If a process for remediation is developed by the Parties, it will form part of this Schedule 'A.'
- 5. **Third Party Notice.** ICES will identify to the Ministry, any third -party providers of data. ICES, as required, will notify those third-party data providers, who initially disclosed the PHI to ICES, about the Ministry's intent to collect, use and disclose the PHI pursuant to the PHIPA Regulation.
- 6. **Transparency.** The Ministry, in consultation with ICES, will prepare a new or amended Schedule '**C**' to the MOU, with a description of the PHI to be disclosed, and will document that PHI in a letter to be issued to ICES by the Minister.
- Execution. The Minister will request via a Request Letter (in the form provided in Schedule 'B') that ICES disclose the PHI to the Ministry, and ICES will respond in turn and provide confirmation once the requested PHI has been prepared and is ready for secure disclosure and transfer to the Ministry.

8. Once the Request Letter has been issued by the Minister, that letter will form Schedule 'B', which together with Schedule "C" shall be incorporated into the MOU and posted in accordance with Section 5.0 of this MOU.