Appendix 4: Ontario Health Study – Data and Biosample Access Agreement

Project title: _____

BACKGROUND:
This *Agreement* governs the terms of access to the coded data and biosamples generated by the Ontario Health Study ("OHS Data" and "OHS Biosamples" as defined below).

For the sake of clarity, the terms and conditions of access set out in this *Agreement* apply to the Approved User and to the Approved Institution (as defined below). Approved User and Approved Institution are referred to within this *Agreement* as "You" and "Your", and shall be construed accordingly.

The Approved User's request to access the OHS Data and OHS Biosamples was approved by the Data Access Committee which is governed by the *OHS Data and Biosample Access Policy.*

1. **DEFINITIONS**

1.1 Unless otherwise defined in the body of this *Agreement*, capitalized words have the following meanings:

a) **Applicable Laws:** in relation to a Party, any and all federal and provincial laws or regulations to which the Party is subject relating to its activities in connection with this *Agreement* as are in existence on the Effective Date or come into existence during the Term, as the same may be amended, re-enacted, consolidated and/or replaced, from time to time.

b) **Approved Institution**: the host institution with whom the Approved User is affiliated for the purpose of the research project outlined in the *Data and Biosample Access Application Form*.

c) **Approved User**: an Applicant who is granted access to OHS Data and/or OHS Biosamples by the Data Access Committee. This access must be renewed annually if the proposed project is not completed within a year.

d) **Associated Data:** information related to the standard operating procedures, equipment specifications, reagents used, storage conditions, and quality assurance details of OHS Data and OHS Biosamples collection, processing, and storage. This does not include OHS Data related to Research Participants or derived data.

e) **Business Day**: any day except Saturday, Sunday or any statutory holiday in the Province of Ontario.

f) **Data Access Committee (DAC):** a monitoring committee that will review and approve or deny access applications and provide overall oversight.

g) **Data and Biosample Access Application Form:** the form submitted to the OHS Data Access Committee by the Approved User to request access to the OHS Data and OHS Biosamples.

h) **Derived Data:** any and all data generated from or based upon the use of OHS Data and/or OHS Biosamples.

i) **Destroy**: with respect to the OHS Data, to take all necessary steps to: i) physically eliminate all print and other hard copies of it; ii) erase, scrub or otherwise remove all electronic, digital or other versions of it from every item of equipment and all media (including disks, tapes, computers, servers and related peripheral equipment such as disk arrays, tapes or disk backup units) that it has been installed, downloaded or otherwise put onto; and iii) otherwise obliterate it.

j) **Effective Date**: the date when all parties (i.e., the Ontario Institute for Cancer Research in respect of the OHS, the Approved User and Authorized Institutional Representative) have signed a *Data and Biosample Access Agreement*.

k) **Ontario Health Study (OHS)**: a not-for profit research platform promoting research in cancer and in other chronic diseases, within the national Canadian Partnership for Tomorrow Project. See www.ontariohealthstudy.ca.

l) **OHS Biosamples**: biological samples such as red blood cells, serum, plasma, DNA from buffy coat or saliva, and urine with Associated Data from a unique, but not directly identifiable, individual made available to Approved Users in accordance with the *Data and Biosample Access Application Form*.

m) **OHS Data**: coded data associated with a unique, but not directly identifiable, individual.

n) **Parties**: the OHS, the Approved User and the Approved Institution, collectively.

o) **Research**: the research to be conducted by the Approved User at the Approved Institution using the OHS Data and/or OHS Biosamples pursuant to the *Data and Biosample Access Application Form*, the protocol, and ethics review for which has been reviewed and approved by the Data Access Committee.

p) **Research Participants**: individuals who have contributed their data and/or biosamples to the OHS.

q) **Research Staff:** those individuals who are listed in the *Data and Biosample Access Application Form*, who are approved by the Data Access Committee to have access to the OHS Data and OHS Biosamples for the purpose of conducting the Research.

r) **Significant Changes:** changes that modify the accuracy and/or scope of the initial information provided by the Applicant in the *Data and Biosample Access Application Form.*

s) **Unanticipated Event:** an event that takes place during an approved research project, that may have an impact on the OHS Data, OHS Biosamples, Derived Data, and/or the ability of the Approved User to achieve his research goals. These include, but are not limited to, situations of compromised data or material security, integrity or confidentiality, or breaches of ethics.

t) **Term:** has the meaning given to it in section 7.1.

1.2 The division of this *Agreement* into sections and the insertion of headings are for convenience of reference only and are not to affect the construction or interpretation of this *Agreement*. Unless otherwise specified, words importing the singular include the plural and vice versa, and words importing one gender include all genders.

1.3 All rights and obligations of the Approved User shall be interpreted and construed to be joint and several rights and obligations of the Approved Institution. Any breach of the provisions of this *Agreement* by the Approved User shall be deemed a breach by the Approved Institution, and vice versa.

TERMS AND CONDITIONS

In signing this *Agreement*:

2. ACCESS TO, USE AND DISCLOSURE OF THE OHS DATA AND OHS BIOSAMPLES

2.1. You and Your Institution agree to use the OHS Data and/or OHS Biosamples in compliance with the OHS *Data and Biosample Access Policy*.

2.2. This *Agreement* becomes active upon the Effective Date. Access is limited to one year with a possibility of subsequent annual renewals; thus, You and Your Institution must submit a *Data Access Renewal Form* to the OHS when the year-end date is approaching.

2.3. You and Your Institution agree to use OHS Data and/or OHS Biosamples for the approved purpose and research project described in the *Data and Biosample Access Application Form* and as approved by your Research Ethics Board or comparable decisional committee in the document requested in Section 6 of the *Data and Biosample Access Policy*. Use of the OHS Data and/or OHS Biosamples for a new purpose or research project will require a new application and approval.

2.4. You and Your Institution shall reimburse OHS $(*insert value)* to cover costs incurred when preparing and sending OHS Data to you.

2.5. You and Your Institution shall reimburse OHS to cover costs incurred when preparing and shipping OHS Biosamples to you as outlined in the appended User Fee Schedule within 30 days of receiving the invoice.

2.6. You and Your Institution acknowledge and agree that the OHS Data and OHS Biosamples remain subject to Section 3 of this *Agreement* and the Approved User has only a royalty free, non-exclusive, non-assignable, non-transferable licence to use the OHS Data and OHS Biosamples solely and only to the extent required to conduct the Research in accordance with the terms and conditions of this *Agreement*. You and Your Institution shall not make any significant changes relating to the information provided in the *Data and Biosample Access Application Form*, without the prior written approval of the OHS, through the DAC.

2.7. You and Your Institution must report to the DAC any Significant Changes and/or Unanticipated Events related to your research project as outlined in Section 6 of the *Data and Biosample Access Policy*.

2.8. You and Your Institution accept that it may be necessary for the OHS or its appointed agent to alter the terms of this *Agreement* from time to time in order to address new concerns. In this event, the OHS or its appointed agent will contact You and Your Institution to inform you of any changes.

2.9. You and Your Institution agree to submit a *Final Project Report* as outlined in Section 6 of the *Data and Biosample Access Policy* on completion of the agreed purpose.

2.10. **Safe Guards To Protect OHS Data And OHS Biosamples**

a) You and Your Institution shall comply with the *Data and Biosample Access Policy* and the terms and conditions contained in the *Data and Biosample Access Application Form*.

b) You and Your Institution agree not to transfer or disclose the OHS Data and/or OHS Biosamples, in whole or in part, to anyone not listed in the *Data and Biosample Access Application Form* for any purpose without the prior written approval of the OHS DAC.

c) You and Your Institution shall provide a copy of this *Agreement* and explain its content to all Research Staff members. The Approved User shall ensure that all Research Staff members comply with the provisions of this *Agreement*. The Approved User shall take appropriate disciplinary action against any Research Staff member who breaches the terms of this *Agreement,* and shall deny such individual any further access to the OHS Data and OHS Biosamples.

d) You and Your Institution shall remain responsible for the acts of the Research Staff. Any breach of the provisions of this *Agreement* by the Research Staff shall be deemed a breach by the Approved User.

e) You and Your Institution agree to preserve, at all times, the confidentiality of the information, OHS Data and/or OHS Biosamples. In particular, you undertake not to use, or attempt to use, the OHS Data and/or OHS Biosamples to compromise or otherwise infringe the confidentiality of information on Research Participants and their right to privacy. You and Your Institution agree to follow the plans and procedures outlined in Section 4 of the *Data and Biosample Access Application Form*.

f) You and Your Institution agree to protect the confidentiality of Research Participants in any research papers or publications that you prepare by taking all reasonable care to limit the possibility of identification. A minimum cell size of 4 is required when publishing OHS Data.

g) You and Your Institution agree that in case of involuntarily identification of a Research Participant, this information will be destroyed and you will notify the OHS. You and Your Institution will not collect, use, or disclose any identifying information or attempt to contact a Research Participant.

h) You and Your Institution agree not to link or combine the OHS Data and/or OHS Biosamples provided under this *Agreement* to other information in a way that could re-identify the Research Participants, even if access to that data has been formally granted to You and Your Institution(s), or is freely available without restriction.

i) You and Your Institution shall maintain appropriate administrative, physical and technological safeguards to limit the risk of theft, loss, unauthorized access, copying, modification, use, disclosure or disposal of the OHS Data and OHS Biosamples consistent with prudent practice, using at least the same means that it uses, or would reasonably be expected to use, to protect its own confidential and proprietary information.

j) You and Your Institution's practices shall include security software and encryption protocols, firewalls, locks and other access controls, staff training and education. You and Your Institution shall ensure that the OHS Data is only downloaded onto secure servers and not onto any personal devices. You and Your Institution shall not intentionally insert, into any part or component of the OHS Data, any virus, time lock, clock, back door, disabling device or other code, routine or instruction which tends to destroy, corrupt or disable software, data or systems or allow unauthorized access thereto. The Approved User shall not store or use OHS Data in any facility outside of the Approved Institution.

k) You and Your Institution understand that the OHS will only prepare and ship project biosamples after a small trial shipment of test cases has been sent to You and Your Institution to test the delivery mechanism and the quality of analyses on OHS Biosamples. Confirmation of the successful receipt and assay performance in this preliminary test is necessary before the OHS will release project specific biosamples to You and Your Institution.

l) You and Your Institution shall comply with all Applicable Laws in the storage, handling, use, return and disposal of the OHS Biosamples.

m) You and Your Institution agree to promptly report in writing (email acceptable) the quality of, or problems encountered with OHS Biosamples.

n) You and Your Institution acknowledge hazards associated with handling biosamples from human participants given that biosamples may carry viruses, latent viral genomes, and other infectious agents. By accepting delivery of these biosamples, full responsibility is assumed for their safe and appropriate

handling, storage, and disposal by trained personnel under suitable laboratory conditions.

o) You and Your Institution agree not to use OHS Biosamples in connection with human experimentation of any kind.

p) If the OHS has concerns about You and Your Institution's compliance with the terms and conditions of this *Agreement*, the OHS shall provide the Approved User with written notice of such concerns and its reasons for them. You and Your Institution shall, within five Business Days' of receipt of the notice, investigate the matter and provide the OHS with a report stating the cause of the deficiency, if any, and the steps taken to prevent a recurrence, if required.

3. INTELLECTUAL PROPERTY AND PUBLICATION

3.1. You and Your Institution agree to recognize the contribution of OHS, including a proper acknowledgement in all reports, presentations and publications resulting from your use of the OHS Data and/or OHS Biosamples. The following statement shall be included:

"The data and/or biosamples used for this research were made available by the Ontario Health Study with the support of the Governments of Ontario and Canada. We thank the participants in the Ontario Health Study."

3.2. You and Your Institution agree to abide by the terms outlined in the OHS *Publication Policy* available in the OHS *Data and Biosample Access Policy*.

3.3. You and Your Institution recognize that nothing in this *Agreement* shall operate to transfer to you any intellectual property rights on OHS's Data and/or OHS Biosamples. However, you have the right to develop intellectual property rights on subsequent innovations and downstream discoveries arising from such data or biosamples. In doing so, You and Your Institution agree to implement licensing policies that will not obstruct further research and to follow the U.S. National Institutes of Health's *Best Practices for the Licensing of Genomic Inventions* and the OECD *Guidelines for the Licensing of the Genetic Inventions*. You and Your Institution recognize that the OHS does not assume any rights to intellectual property derived from the use of OHS Data and/or OHS Biosamples.

4. RETENTION, RETURN AND DESTRUCTION OF OHS DATA AND OHS BIOSAMPLES

4.1. You and Your Institution shall retain the OHS Data and OHS Biosamples only for so long as necessary to complete the Research in accordance with the *Data and Biosample*

Access Application Form, unless required to retain the OHS Data and OHS Biosamples longer for archival peer review or audit purposes in conformity with legal requirements.

4.2. Upon expiration, early termination of this *Agreement*, or the reasonable request of OHS, the Approved User shall:

a) Cease accessing and using the OHS Data and OHS Biosamples;

b) Destroy copies of the OHS Data downloaded onto its computers and servers, or otherwise in its possession or control, in accordance with the OHS's directions as to timing of destruction and method of secure destruction of records, unless obliged to retain the OHS Data for archival purposes in conformity with audits, peer review or legal requirements, upon: a) the reasonable request of OHS; b) on expiration of this *Agreement*; c) in the event that You or Your Institution are in breach of any of the conditions of this *Agreement*; or d) in the event of a withdrawal of a Research Participant. When requested by the DAC, you shall certify that the transferred data and all copies thereof were Destroyed.

c) Use all reasonable endeavours to ensure that OHS Biosamples – including aliquots and derivatives – in your possession or under your control shall be returned or destroyed, as directed by the DAC, unless obligated to retain the OHS Biosamples for archival purposes in conformity with audits or legal requirements. When requested by the DAC, you shall certify that the transferred material and all copies thereof were Destroyed.

d) You and Your Institution agree to return Derived Data that arose from analyses of OHS Data back to OHS within one year of completing the analyses.

5. DATA BREACHES

5.1. If You and Your Institution becomes aware that there has been a breach or suspected breach of this *Agreement*, or that a person has or is suspected as having obtained unauthorized access to the OHS Data or OHS Biosamples other than as contemplated in this *Agreement*, or that the OHS Data or OHS Biosamples have been stolen or lost, You and Your Institution shall, at the first reasonable opportunity notify the OHS DAC by telephone, followed by a written notice report, within 48 hours, using the Unanticipated Event/Significant Change Report form. You and Your Institution shall take the steps that are reasonable in the circumstances to contain the breach and prevent reoccurrence and shall notify the OHS in writing of the steps taken.

5.2. The OHS reserves the right to use legal action against You and Your Institution for any damages caused by the breach of this *Agreement.*

6. **GENERAL**

6.1. You and Your Institution agree not to transfer or disclose the OHS Data and/or OHS Biosamples, in whole or in part, or any identifiable material derived from the OHS Data and/or OHS Biosamples, to anyone not listed in the *Data and Biosample Access Application Form*, except as necessary for safety monitoring, audits or programme management. Should You or Your Institution wish to share the OHS Data or OHS Biosamples with an external collaborator, this third party must complete a separate *Data and Biosample Access Application Form* and follow the normal access procedures at OHS.

6.2. **Governing Law.** This *Agreement* shall be construed, interpreted and governed by the laws of Canada and the province of Ontario and the Parties attorn to the jurisdiction of the Ontario courts.

6.3. **Amendment.** This *Agreement* may be amended, modified or supplemented only by written agreement signed by each Party.

6.4. **Assignment.** No Party may assign its rights or obligations under this *Agreement* without the prior written consent of the other Parties, not to be unreasonably withheld, except that a Party may, without consent, assign its rights under this *Agreement* to a successor entity, or an acquirer of all or substantially all of its assets. This *Agreement* enures to the benefit of and binds the Parties and their respective successors and permitted assigns.

6.5. **Survival.** Any provision of this *Agreement* that contemplates performance or observance subsequent to termination or expiration of this *Agreement* shall survive termination or expiration of this *Agreement* and continue in full force and effect.

7. **TERM AND TERMINATION**

7.1. **Term.** This *Agreement* shall be effective for a period of one (1) year from the Effective Date ("Term"). This *Agreement* may be extended by mutual agreement of the Parties or terminated in accordance with the provisions of this *Agreement*.

7.2. **Termination for Convenience.** This *Agreement* may be terminated upon the mutual written agreement of the Parties.

7.3. **Termination without Cause by Notice.** Any Party may terminate this *Agreement* without cause upon the provision of 30 days' prior written notice.

7.4. **Automatic Termination.** This *Agreement* shall automatically and immediately terminate if a Party becomes bankrupt or insolvent, ceases to carry on business, or is subject to an order made or a resolution passed for the winding up of its operation or if the OHS ceases to be funded or is terminated for any other reason.

7.5. **Termination for Breach by Notice.** Any Party may terminate this *Agreement*: (1) if another Party fails to carry out a material duty or obligation under this *Agreement* and such default has not been remedied to the satisfaction of the non-defaulting Party within 10 Business Days' written notice to the defaulting Party detailing the nature of the default; or (2) in the event of a conflict between the terms of this *Agreement* and Applicable Laws.

7.6. **Suspension of Access.** Notwithstanding any other provisions in this Section 7, the OHS, acting in its sole discretion, may immediately suspend the Approved User's access to the OHS Data and/or OHS Biosamples if it believes that there is: (a) a breach of any material term of this *Agreement*; or (b) an extreme circumstance that would warrant such action including a compromise of the integrity or security of the OHS Data and/or OHS Biosamples. The OHS shall notify, through the OHS Access Committee, the Approved User in writing of such suspension including when the suspension is to take effect.

8. NO WARRANTY/LIMITATION OF LIABILITY/INDEMNIFICATION

8.1. You and Your Institution accept that the OHS:

a) bears no legal responsibility for the accuracy or comprehensiveness of the OHS Data and/or OHS Biosamples and OHS makes no representations and extends no warranties of any kind, either express or implied of merchantability or fitness for a particular purpose, or that the use of the OHS Data and/or OHS Biosamples will not infringe any patent, copyright, or trademark, or other rights or any other express or implied warranties;

b) accepts no liability for indirect, consequential, or incidental, damages or losses arising from acceptance or use of the OHS Data, or OHS Biosamples or their by-products, or from the unavailability of, or break in the access to the OHS Biosamples for whatever reason and shall not be liable for any lost profits or other economic loss; and

8.2. You and Your Institution agree to indemnify, hold harmless and defend OHS, its members, officers, employees, contractors, subcontractors, students and agents against any and all third party claims, suits, proceedings, costs, or expenses resulting

from any negligence or from any injury (including death), damage, or loss or the alleged infringement of any copyright, patent, trademark, trade secret or other intellectual property or proprietary right arising out of You or Your Institution use of the OHS Data and/or OHS Biosamples or any products or services derived therefrom.

This *Agreement* is agreed to as described between the Parties as of the Effective Date and is hereby signed by the duly authorized signatories with the power to bind the Parties.

I have read and agree to abide by the terms and conditions outlined in the *Data and Biosample Access Agreement*.

☐ Yes ☐ No

Principal Applicant:

Name _____ Position _____

Signature _____ Date _____

Authorized Institutional Representative of the host institution:
(He/she should be the same person mentioned in the *Data Access Application Form*):

Name _____ Position _____

Signature _____ Date _____

Ontario Health Study
Étude sur la santé Ontario

USER FEE SCHEDULE AND DESCRIPTION OF MATERIALS:

This *Agreement* governs the use the following OHS Biosamples:

Type (i.e., red blood cells, serum, plasma, DNA from buffy coat or saliva, or urine)	Quantity (i.e., volume and number of aliquots provided)	Description (i.e., further notes and biosamples identification number)	Fee

The cost to ship OHS Biosamples will be charged to You and Your Institution on a cost-recovery basis.

Please e-mail a PDF of the signed *Data and Biosample Access Agreement* to access@ontariohealthstudy.ca