Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

ONTARIO HEALTH STUDY (OHS)

DATA AND BIOSAMPLE ACCESS POLICY

June, 2017

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

TABLE OF CONTENTS

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Ontario Health Study
Étude sur la santé Ontario

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

1. Purpose

The data and biosamples collected as part of the Ontario Health Study (OHS) are a valuable resource available to researchers to pursue investigator-initiated research. Scientific knowledge is a common good and should be shared within an appropriate framework. Data-sharing is increasingly regarded as an ethical and scientific imperative for the advancement of knowledge. OHS recognizes the importance that its data and biosamples be published in peer-reviewed journals in a timely manner and be presented at scientific meetings and conferences. The purpose of this document and appendices is to establish the principles, policies and procedures by which access to OHS Data and OHS Biosamples is sought and granted.

Collaboration amongst researchers is strongly encouraged to maximize access to and use of OHS Data and OHS Biosamples. Access to OHS Data and OHS Biosamples is time-limited and for approved analyses only. Proposals will be accepted for access to questionnaire, physical measures and community level data, environmental samples, and biorepository materials. Only de-identified data and biosamples will be provided to investigators. A Data Access Committee will review and evaluate data access requests, and oversee access to OHS Data and OHS Biosamples. During the review process, consideration will be given to the scientific merit of the research project, the potential impact on Research Participants, and appropriate use of limited resources (e.g., OHS Biosamples). To encourage a broad range of research, exclusive access to any data or biosamples will not be permitted. Further, researchers will not receive exclusive access to an analysis or question of interest. This *Data and Biosample Access Policy* has been developed and implemented in order to: encourage fair, timely and transparent access to data and biosamples for high-quality research; enable informed and efficient collaboration; and ensure that access is facilitated in a scientific and ethical manner.

2. Scope

This *Policy* details the various procedures and requirements for accessing OHS Data and OHS Biosamples. OHS is committed to sharing with the national and international scientific communities, to the principles of transparent and facilitated access to OHS Data and OHS Biosamples by *Bona Fide* Researchers, and to rapid data release. These data include, but are not limited to, responses to self- and interviewer-administered questionnaires, physical measures and data derived from biosamples.

OHS will not discriminate between access applications on the grounds of whether the Applicants are based in Canada or in other countries, or whether they are based in public or private institutions conducting scientific health-related not-for-profit research. All *Bona Fide*

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Researchers are invited to submit a *Preliminary Access Application Form* (see Appendix 1) prior to grant submission followed by a *Data and Biosample Access Application Form* (see Appendix 2) when funding has been secured.

Access to OHS Data and OHS Biosamples will be granted for the time period specified in the *Data and Biosample Access Agreement.* After this time, Applicants will be allowed to re-apply using the *Data and Biosample Access Renewal Form* (see Appendix 3). OHS Data and OHS Biosamples will only be released to Approved Users. There will be no exclusive access granted to any one party.

The OHS is part of a pan-Canadian initiative known as the Canadian Partnership for Tomorrow Project (CPTP). The CPTP includes prospective longitudinal cohort studies in five regions across Canada (Ontario Health Study, BC Generations Project, Alberta Tomorrow Project, CARTaGENE (Quebec), and Atlantic Partnership for Tomorrow's Health). All partner cohorts have been established and have built the infrastructure to recruit and re-contact CPTP participants and collect, safeguard and store their information, measurement data and biosamples. By design CPTP is harmonized with other national studies in Canada and large cohort studies being conducted elsewhere in the world. Applicants interested in accessing data and samples from two or more CPTP regional studies are encouraged to visit the CPTP researcher portal (https://portal.partnershipfortomorrow.ca/) for access information.

3. Definitions

Access Registry: public registry (i.e., online on a public website) providing basic information on Approved Research Projects that were granted access to OHS's Data and OHS's Biosamples. Information provided includes, but is not limited to: name(s) of the Investigator(s) involved; their status and credentials; the Institution with whom they are affiliated; and a lay summary of their Approved Research Project.

Aggregate Data: summed and/or categorized de-identified data that have been analyzed and placed in a format that precludes further analysis (for example, in tables or graphs) to prevent the chance of revealing an individual's identity, (individual records cannot be reconstructed). A minimum cell size of 4 is required to release Aggregate Data to decrease the likelihood of indirectly identifying individuals. While personal health information may be used to create Aggregate Data by specifically designated personnel at OHS, once created, Aggregate Data do not include personal health information.

Applicant: a researcher conducting health-related research who is applying for OHS Data and/or OHS Biosamples from the OHS. All Applicants must be affiliated with an institution.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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*.

Approved Research Project: means the research project outlined in the *Data and Biosample Access Application Form* that has been approved by the DAC.

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

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

Authorized Institutional Representative: an individual who will act as the representative of the Approved Institution in the *Data and Biosample Access Agreement.* The Authorized Institutional Representative is determined by the institution, but must be in a position to legally bind the institution.

***Bona Fide* Researcher:** a qualified researcher from a research or clinical institution.

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

Data and Biosample Access Agreement: a signed agreement between the Approved User(s), their Institution(s) and the Ontario Institute for Cancer Research (in respect of the OHS) substantially in the form set out in Appendix 4. It outlines the terms and conditions of access to OHS's Data and OHS`s Biosamples and must be signed before these data can be transferred. The Agreement legally binds its signatories.

Data and Biosample Access Policy: this document that outlines OHS's general principles and guidelines on access to its data and biosamples. It is an integral part of the *Data and Biosample Access Agreement*.

Data and Biosample Access Renewal Form: a document completed by an Approved User after the expiration of the one-year term associated with the use of OHS Data and OHS Biosamples. This *Data and Biosample Access Renewal Form* allows the Approved User to apply for an additional one-year term and to highlight any changes since the last application or renewal.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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

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*.

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.

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*.

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

Ontario Institute for Cancer Research (OICR): an independent, not-for-profit corporation funded by the government of Ontario. OICR is dedicated to research in prevention, early detection, diagnosis and treatment of cancer. OICR is the host institution for the OHS. See www.oicr.on.ca.

Preliminary Access Application Form (PAA): an application for interested users of OHS Data and/or OHS Biosamples who are in the grant application phase and seek a support letter. PAAs are reviewed for feasibility and impact assessment. An access budget will also be provided.

Research Participants: individuals who have consented to participate in OHS and have contributed data and/or biosamples to the OHS.

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*.

Unanticipated Events: 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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

4. Access to OHS Data and OHS Biosamples

The data and biosamples collected or generated by OHS will be made available to public and private institutions that conduct scientific research. OHS will not permit access to individual-level data or biosamples by commercial industry groups, however this does not preclude collaboration between OHS and industry. OHS will complete analyses requested by commercial industry groups and provide an aggregate-level report only. Requests to access individual-level OHS Data or OHS Biosamples for non-research related uses, including by law enforcement bodies or governmental agencies, will be resisted within the limits of the law. Exclusive access to OHS Data will not be granted to any party. Multiple data access requests for overlapping initiatives may be approved by the Data Access Committee (DAC) when the request does not include the analyses of biosamples. The DAC will notify the Applicant that a similar access request was received to promote collaboration between researchers. The DAC may offer suggestions for combining similar proposals, and will prioritize access applications if multiple overlapping requests for biosamples are received. Approved Users will be given access to OHS Data and/or OHS Biosamples for the period specified in the *Data and Biosample Access Agreement* with the possibility for subsequent renewals.

The data and/or biosamples may not be used for any purpose other than for the approved research project outlined in the *Data and Biosample Access Application Form*. The Approved User must inform the OHS DAC of any changes to the research project or status for continued approval. This is to be done through the reporting mechanism described in Section 7. Approved changes may require an amendment to the *Data and Biosample Access Agreement.*

5. Privacy of Participants

The OHS will uphold the rights of its Research Participants by respecting their consent and by protecting their privacy and the confidentiality of their data and biosamples. Approved Users accessing OHS Data and OHS Biosamples will also assume these obligations (see *Data and Biosample Access Agreement* – Appendix 4).

The Approved User shall agree to store, manage and use OHS Data and OHS Biosamples in strict confidentiality. In doing so, all reasonable efforts to maintain the security and confidentiality of the accessed data and/or biosamples, including any copies thereof, are to be employed. The Approved User may not disclose, transmit or transfer any data or biosamples to unauthorized individuals. The Approved User shall retain control of the transferred data and biosamples at all times, as delineated in the *Data and Biosample Access Agreement*.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

When requesting access to OHS Data and/or OHS Biosamples, Applicants must confirm that reasonable security measures are in place, and shall detail their plan to secure data and biosamples received from OHS (see Appendix 2).

Only coded data and biosamples will be provided to the Approved User by OHS. The Approved User must not attempt to re-identify any Research Participants by any means. If the Approved User involuntarily identifies a Research Participant, this constitutes a privacy breach and the OHS must be notified immediately (see Appendix 6).

6. Data Access Documents

The following section outlines the documentation that must be processed by the Applicant in accordance with Section 7 below, in order for a proposed research project to become an Approved Research Project.

a. Preliminary Access Application Form

Applicants seeking a letter of support for grant or ethics submissions are directed to submit a *Preliminary Access Application Form* (see Appendix 1). This will initiate a feasibility and impact assessment review of the research proposal and provide a budget estimate and support letter.

b. Data and Biosample Access Application Form

In order to receive access to OHS Data and/or OHS Biosamples, an Applicant must complete the *Data and Biosample Access Application Form* (see Appendix 2). This application will be sent to the DAC for review and evaluation along with the submission of the required documents:

- Research protocol (having received ethics approval)
- Proof of scientific peer-review of research protocol (if applicable)
- Approval by a Research Ethics Board (REB)
- 2-Page CV of the principal Applicant

This application will be reviewed by the DAC.

c. Data and Biosample Access Renewal Form

The *Data and Biosample Access Renewal Form* (see Appendix 3) is to be used by Approved Users who have successfully applied for access to OHS Data and/or OHS Biosamples and who wish access to these data and/or biosamples beyond the initial approval period. The *Data and*

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Biosample Access Renewal Form must be submitted at least one month prior to the end date identified in the *Data and Biosample Access Agreement*.

d. Data and Biosample Access Agreement

Approved Users and the Authorized Institutional Representative will be required to sign and comply with the *Data and Biosample Access Agreement* (see Appendix 4 for more details).

e. Final Project Report

Once an Approved Research Project has ended, Approved Users must submit a *Final Project Report* (see Appendix 5) to the DAC. This Report requires a summary of the research findings as well as comments and suggestions to improve OHS's access procedures.

f. Unanticipated Event/Significant Change Report

An *Unanticipated Event/Significant Change Report* (see Appendix 6) must be completed and submitted to the DAC if Unanticipated Events and/or Significant Changes occur during an Approved Research Project that may have an impact on the OHS Data, OHS Biosamples, Derived Data, and/or that may impact the ability of the Approved User to achieve the research goals.

Examples of Unanticipated Events and/or Significant Changes include, but are not limited to, the following:

- Impossibility to complete the Approved Research Project (e.g. loss of funding; lapse of the REB's approval; loss or change of scientific direction);
- Changes to the information provided by the Approved User in the *Data and Biosample Access Application Form*;
- Compromised data or material security, integrity or confidentiality, or a breach of ethics; or
- Any other changes that render full compliance with this *Data and Biosample Access Policy* or the signed *Data and Biosample Access Agreement* impossible.

g. Destruction of CPTP Research Data and/or Biosamples Form

Upon request by the DAC and as stipulated in the *Data and Biosample Access Agreement*, the Approved User must submit a *Certificate of Destruction* (see Appendix 7) to the DAC. This Certificate will certify that the transferred OHS Data and/or OHS Biosamples and all copies thereof have been destroyed.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

7. Review of Applications

a. General Procedure

Investigators who wish to develop a proposal for access to the OHS resource are strongly encouraged to contact the OHS if they have questions. If the Applicant chooses to proceed with requesting a letter of support for grant or ethics submissions, the Applicant will complete and submit a *Preliminary Access Application Form* to the OHS. If the Applicant is successful, the OHS will forward the Applicant a letter of confirmation of feasibility including: (a) acknowledgement of receipt of request; (b) confirmation that the OHS has sufficient data and/or biosamples to meet the request; (c) confirmation that data and/or biosamples may be available to the Applicant pending submission of the *Data and Biosample Access Application Form* and approval from the DAC; and (d) an estimate of the cost to access the requested data and/or biosamples.

An application to access OHS Data and/or OHS Biosamples should be submitted once funding, if required, has been approved, and the Applicant has received approval from their local REB, or its equivalent. Applications will be checked for completeness, feasibility, and impact assessment by the OHS. All completed *Data and Biosample Access Application Forms* evidencing requisite feasibility will be reviewed by the DAC. External bodies may be consulted at the discretion of the DAC to evaluate the proposal.

If the research proposal is approved, the OHS will notify the Applicant of the DAC approval and forward a signed copy of the Data and Biosample Access Agreement to the now Approved User(s). The Approved User(s) and the Authorized Institutional Representative(s) will be required to sign the *Data and Biosample Access Agreement*. Once the relevant agreements have been signed by all parties, and the access fee has been paid, the OHS Data Centre and OHS Biorepository will be notified, as needed. The Approved User(s) will then have access to the approved data and/or biosamples for the time specified in the *Data and Biosample Access Agreement.* To continue to access OHS Data and/or OHS Biosamples beyond the date specified in the *Data and Biosample Access Agreement*, the Approved User must complete a *Data and Biosample Access Renewal Form*.

Investigators will have exclusive access to any Derived Data during analysis for the agreed period of time specified in the *Data and Biosample Access Agreement*. Once this time period has elapsed, the additional data obtained and/or Derived Data will become part of the OHS Database, even if the results have not yet been published. These data will be made available to other Applicants.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

b. Requests for Access to Biological Samples

Some Research Participants have provided biological specimens such as blood and/or urine. These biosamples constitute a highly valuable but finite resource. Applicants are strongly encouraged to identify analysis methods that use the smallest amount of biosamples for the biomarker of interest. Applicants must indicate if the desired analyses can be completed using more than one sample type (e.g., serum or plasma) to allow the selection of the most abundant type available.

Priority for studies requesting biological or environmental samples will be given to studies that are novel and exhibit scientific excellence as determined by the DAC. In order to efficiently manage and maximize use of the biosamples, however, the following criteria will also be considered:

- Does not make use of biosamples from those Research Participants with the fewest biosamples;
- Use thawed biosamples whenever possible;
- Use the smallest sample volume possible; and
- Can be integrated with other studies to conserve biosamples or minimize freeze-thaw cycles.

In order to conserve biosamples and/or minimize the number of freeze-thaw cycles, the OHS may choose to coordinate the dissemination of biosamples for several approved studies. This may result in a delay of the provision of biosamples following approval of a *Data and Biosample Access Application Form*. This will be discussed with the Applicant at the time of study approval before the *Data and Biosample Access Agreement* is signed.

c. Requests for Linked Data

Applicants requesting to link OHS Data and/or OHS Biosamples with information in administrative or medical databases will require compliance with and approval of the entities in control of the other databases. Please contact the OHS for additional information and direction.

d. Criteria for Review

All completed *Data and Biosample Access Application Forms* will be assessed by the DAC. The DAC applies the following criteria in making the final decision on the access request:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

- The Applicant is a *Bona Fide* Researcher (i.e., evidence that the researcher has relevant experience and qualifications);
- The research study is in conformity with the informed consent(s) signed by the Research Participants;
- The DAC has received confirmation of administrative completeness and availability of OHS Data and/or OHS Biosamples;
- The DAC assessment has established that the *Data and Biosample Access Application Form* meets the following requirements:
    - Clarity, novelty and scientific excellence of the proposed research plan;
    - Experience and qualifications of the Applicant and co-investigators;
    - The adequacy of the Applicants' and the host institutions' processes regarding privacy, information security, and confidentiality;
    - Compatibility of the research study with the vision and ultimate goal of OHS, and its funders;
    - Potential impact on future uses of the OHS Data and/or OHS Biosamples repositories;
    - Potential to enrich the OHS Data and/or OHS Biosample repositories; and
    - Whether the Applicant has adequate financial and human resources (collaborators and staff) to effectively complete the proposed study.

All criteria must be met.

e. Data Access Committee

The DAC will act in an oversight and monitoring capacity. The DAC will review *Data and Biosample Access Application Forms* regularly and make decisions to approve, reject or request additional information for a data access request.

f. Resubmission Process

If the application is incomplete or more details are requested, the Applicant will be allowed to resubmit his/her *Data and Biosample Access Application Form* with the necessary information/documentation/approvals. If the Applicant is refused, the Applicant can resubmit a new *Data and Biosample Access Application Form* addressing the comments relayed by the DAC.

In the case of a refusal or incompleteness, the Applicant will be so notified by the DAC. Any refusal will be accompanied by reasons for the refusal and resubmission will be permitted. If the DAC proposes changes or has questions, the Applicant will be notified by the OHS. The rationale for requested changes will be provided and resubmission will be permitted.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

The OHS Executive Committee will receive reports of accepted/refused research, and provide advice to the DAC in the case of a dispute. The decision of the OHS Executive Committee is final.

8. Confidentiality of Research Projects Submitted

All information on research projects submitted to OHS will be kept confidential except as otherwise indicated in this Policy. Once access to OHS Data and/or OHS Biosamples is granted, the following information will be added to a publicly available registry created by OHS:

- Title of the Approved Research Project;
- Name(s) of the Investigator(s) involved, their status and credentials;
- Name(s) of the Institution(s) involved; and
- A lay summary of the scientific abstract submitted by the Applicant.

At the completion of the project, a lay summary of the results submitted by the Approved User will also be added to OHS's publicly accessible registry.

9. Publication Policy

Approved Users of OHS Data and/or OHS Biosamples are strongly encouraged to publish their research results so as to benefit both the scientific community and the general population.

All co-authors on publications arising from analyses of OHS Data and/or OHS Biosamples must satisfy the criteria established by the International Committee of medical Journal Editors (http://www.icmje.org/).

All publications and abstracts, including electronic submissions that use data and/or biosamples from OHS, should be submitted to the OHS at the same time they are submitted for publication to the journal or to a conference. The OHS will review the submission to ensure no individuals or communities are identified and that the analyses included are within the scope of the approved *Data and Biosample Access Application Form*.

Authors must acknowledge the contribution of OHS in their publications or presentations where data or biosamples from OHS were used. All publications and presentations must contain the following sentence:

> *"The data and/or biosamples used for this research were made available by the Ontario Health Study. We thank the participants in the Ontario Health Study."*

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Upon publication, a copy of the publication (or a web-link in the case of online publications) must be sent to the OHS.

10. Posting Derived Data

OHS recognizes the scientific importance of improving the depth and breadth of its database. In order to achieve this goal, Approved Users accessing OHS are required to submit Derived Data and associated documents to the OHS after a period of time negotiated between the Approved Users and the DAC. Derived Data will be made available by OHS to other Approved Users that have successfully applied for access to OHS's data and biosamples through the established procedure. This will allow future investigators to access enriched data and enable them to build upon previous research.

The need to protect intellectual property (e.g., patents) or pre-publication results may result in corresponding constraints on public disclosure of Derived Data. In such a situation, and where the provided timeframe is not sufficient, the Approved User may apply to the DAC for an extension.

11. Intellectual Property

The objective of the OHS is to maximize public benefit from data and biosamples collected by the OHS and its collaborators. Accordingly, OHS Data and OHS Biosamples will remain as accessible as possible. Therefore, Approved Users and Approved Institutions agree not to make intellectual property claims on OHS's primary data, but may choose to obtain intellectual property rights on subsequent innovations and downstream discoveries arising from such data.

Approved Users are strongly encouraged to follow the *Guidelines for the Licensing of Genetic Inventions* (http://www.oecd.org/dataoecd/39/38/36198812.pdf) adopted by the Organization for Economic Co-Operation and Development (OECD). Approved Users are expected to implement licensing policies that do not impede further research; see also the U.S. National Institutes of Health's document on *Best Practices for the Licensing of Genomic Inventions* (http://www.ott.nih.gov/policy/genomic_invention.html).

12. Archiving or Destruction of Data

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

After the Approved Research Project is completed and the results are submitted for publication and/or the data have been used for the purpose for which use was approved, the Approved User will be permitted to archive any transferred data for peer review and audit purposes for a maximum of 5 years. A plan for archiving or destruction of data and/or biosamples must be submitted to the DAC and this will be specified in the *Data and Biosample Access Agreement*, if applicable, or both.

13. Compliance

The Approved User and the Approved Institution shall comply with the *Data and Biosample Access Policy* (as amended from time to time), the *Data and Biosample Access Agreement* and any renewals thereof, any requirements set out by the OHS DAC and/or the OHS Executive Committee (see Section 7), as well as any applicable requirements of the Ontario Institute for Cancer Research (OICR) and all applicable laws and regulations in regard to the subject matter of this *Data and Biosample Access Policy*.

The Approved User shall report any deviation from full compliance with the *Data and Biosample Access Policy* and *Data and Biosample Access Agreement* using the *Unanticipated Event/Significant Change Report* (Appendix 6).

In case of failure to comply with the provisions of this *Data and Biosample Access Policy*, the *Data and Biosample Access Agreement*, the OICR in respect of the OHS shall take such measures in its discretion as it deems necessary to deal with such non-compliance, up to and including termination of the *Data and Biosample Access Agreement* and legal action against the Approved User and Approved Institution, including a claim to recover damages.

14. Financial Conditions

OHS will provide OHS Data and/or Biosamples to Approved Users on a cost-recovery basis. An estimated cost can be provided after review of the *Preliminary Access Application Form*. The final amount will be determined by the DAC and will be specified in the *Data and Biosample Access Agreement*.

15. Public Relations

All press releases on research based on analyses of OHS Data and/or OHS Biosamples should be approved by the OHS prior to release. OHS/OICR Communications also may decide to

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

pursue public relations opportunities about noteworthy findings/manuscripts and will expect lead authors to agree to these opportunities and to make themselves available for related media events. OHS may also ask lead authors to prepare a summary of manuscripts incorporating analyses of OHS Data and/or OHS Biosamples to include in reports to stakeholders and future funding applications for core support of OHS.

16. Amendments to this Policy

This *Data and Biosample Access Policy* will be reviewed at least every two years, or more frequently as needed. Amendments must be approved by the OHS Executive Committee. In case of amendments to this *Data and Biosample Access Policy*, a new version will be provided to all researchers who have inquired about access to OHS Data and/or OHS Biosamples.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 1: Ontario Health Study – Preliminary Access Application Form

DATE:	
PROPOSAL TITLE:	

1. Please provide the following information:

Principal Applicant's Name	
Principal Applicant's Educational Qualifications (PhD, MD, etc.)	
Principal Applicant's Position(s) (Rank, Faculty, Department, Institution)	
Institutional Mailing Address	
Telephone Number	
Institutional Email address	
Principal Contact (name, email and phone number)	

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

2. Project Information

Scientific abstract (maximum of 300 words)	
Project duration	**Proposed start date:** **Proposed end date:**
Anticipated outcome of project (e.g., manuscript, generation of pilot data in support of larger project)	
Intended Granting Agency, if funding being sought	
Grant submission date, if applicable	

3. Holdings Requested

Holding Type:	**Requested (Yes/No)**
Data – individual level	
Data – Aggregate	
Biosamples	
Data linkage	

Ontario Health Study
Étude sur la santé Ontario

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

4. Study Design

Number of participants requested	
Participant age range	
Participant sex	
Other inclusion/exclusion criteria (e.g., ethnicity, prescription medication, geographic location, prior disease)	
Additional parameters required	

5. Biosamples

☐ No biosamples required

Biosample Type	**Units**	**# of PTs**	**# of Tests**	**# of Bio-markers**	**Total Required Assay Volume or Amount**	**Total Required Dead Volume or Amount**	**Total Volume or Amount Requested**
SST: serum	µL						
EDTA: plasma	µL						
EDTA: red blood cells	µL						
Urine	µL						
ACD: whole blood in DMSO	µL						
DNA*	µg						

(*DNA may be extracted from blood or saliva)

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

☐ Biosample pre-analytical restriction(s) required

Describe and justify the need for biosample pre-analytical restrictions:

Where will the biosamples be analyzed?

☐ Applicant(s) laboratory

Provide evidence of the laboratory's analysis record, preliminary data and/or publications:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

☐ Commercial or Service Provider Laboratory

Analysis #1:
Laboratory Name:
Laboratory's website address: ☐ Unavailable
Is the laboratory accredited?
# of years proposed analysis has been performed at the lab:

Analysis #2:
Laboratory Name:
Laboratory's website address: ☐ unavailable
Is the laboratory accredited?
# of years proposed analysis has been performed at the lab:

6. Data Linkage

Will data from other sources be utilized to complete the proposed project? Please list all data linkages required to complete the proposed project, and where these data are held.

☐ Not applicable – OHS Data and/or OHS Biosamples will not be linked with data from other sources.

7. Other sources of data and/or biosamples

Have you applied for data and/or biosamples for this research project from another source?

☐ Yes ☐ No

If yes: Where?

What is the status of the request?

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

☐ Approved ☐ Pending ☐ Declined

8. Signature of Principal Investigator

I acknowledge that the details in this Preliminary Access Application are correct:

_____

Principal Investigator Date

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 2: Ontario Health Study – Data and Biosample Access Application Form

This application form is for requests for access to the data and/or biosamples of the Ontario Health Study (OHS). Applicants must complete this entire application form before access to data and/or biosamples will be approved. Research projects will be verified, among other things, for the qualifications of the Applicant to carry out the proposed research; whether the research project includes a scientifically and ethically appropriate research plan; proof of local ethics review; the adequateness of the Applicants' and their host institutions' processes regarding privacy and confidentiality and the availability of resources to effectively complete the study (collaborators and staff).

Upon approval of an access request by the applicants, access to data and/or biosamples will be granted for a one year period (starting from the date of approval) unless otherwise agreed to in the *Data and Biosample Access Agreement*. A *Data Renewal Application Form* must be completed to access/use data beyond that one-year period.

The names, institutions and lay summaries of the scientific abstracts of all applicants having been granted access to OHS Data will be added to its publicly accessible access registry.

NOTE: OHS does not hold the Ontario Cancer Registry database. This database can be linked to OHS through Cancer Care Ontario (CCO) or ICES. Researchers should approach CCO or ICES directly regarding cancer data access requests and associated access costs.

Section I: Research Personnel

1. Applicants:

Principal Applicant:	Name:	
	Institution:	
	Position:	
	Email:	
	Telephone:	
	Address:	
Co-applicants:	Name:	

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Institution:	
Email:	
Name:	
Institution:	
Email:	

Please submit additional pages if there are more than two co-applicants.

While only one *Data and Biosample Access Application Form* is required, any authorized personnel with access to OHS Data and/or OHS Biosamples that is affiliated with an institution other than that of the Principal Applicant is required to provide information on their Authorized Institutional Representatives, and have them sign a separate *Data and Biosample Access Agreement.*

Authorized Institutional Representative:
Please provide a valid institutional e-mail address and a full postal address of the host institution.

Name:	
Institution:	
Position:	
Email:	
Telephone:	
Address:	

Please submit additional pages if OHS Data and/or OHS Biosamples will be accessed at more than one Approved Institution.

Is the data being requested for a student thesis or project? Yes ☐ No ☐

2. Research Team:
Excluding those investigators listed above, please provide the names of all investigators, collaborators, students and research staff that will have access to the data in order to work on the research project. A valid institutional email address for each name along with their job title/function is also required.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Name	Affiliation	Position	Email

Names and contact details of Service Providers and Commercial Laboratories:

☐ This application involves a service provider or commercial laboratory that will require access to the requested data and/or biosamples.

Please provide the details of all service providers and commercial laboratories that will have access to the requested data and/or biosamples in order to work on the research project. All service providers and commercial laboratories will need to meet the terms and conditions of the *Access Agreement*.

Service Provider or Commercial Laboratory Name:
Mailing Address:

Contact Name:

Title:

Institutional E-mail Address:

Telephone Number:

Website address (if available):

Section II: Research Project

3. Project Title:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

4. Research Category/Type:
Check the items that best describe the type of research project that would be conducted using the OHS Data and/or OHS Biosamples (*more than one may apply*).

☐ Genetic wide association study ☐ Genome wide association study ☐ Environment association study ☐ Gene by gene and gene by environment interaction study ☐ Genotype-based comparative study ☐ Case-control study ☐ Descriptive study (e.g., health care utilisation) ☐ Data linkage ☐ Surveillance study (e.g., estimation of the prevalence or incidence)	☐ Risk score or index development ☐ Biomarker validation or discovery ☐ GIS-based or mapping study ☐ Fundamental research study (e.g., in vitro) ☐ Study using data from multiple cohorts (e.g., data pooling project) ☐ Prospective study ☐ Genealogical study ☐ Multicentre study or international study ☐ Other (*specify*):

5. Study Design

Total number of Research Participants requested:	
Inclusion criteria	
Exclusion criteria	
Stratification or grouping:	
Any additional parameters required	
For case-control studies:	
Matching criteria:	
Case-control ratio:	

6. Research Project (Scientific Abstract):
Please provide a clear scientific description of the research project and its specific hypotheses in no more than 500 words.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

7. Lay Summary of Project:

Please provide a short description of the project for the general public in no more than 250 words. Scientific jargon and acronyms should be avoided as much as possible. This description will be made available on the OHS website.

8. Anticipated Outcomes:

List all anticipated outcome(s) of project (e.g., academic publication, internal/organizational report, discovery research)

9. Ethics Approval:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Has this study been approved by a research ethics board or a comparable decisional committee that has been formally designated to approve and/or monitor research involving humans with the aim of protecting the rights and welfare of the research participants? Yes ☐ No ☐

If yes, please append a copy of the approval.

Additionally, please provide the following supporting documents specifically related to this access application:

☐ Research Ethics Board (REB) approved research protocol

☐ Decision letter from a Research Ethics Board (REB) or comparable decisional committee (English or French; an institutional approval number should also be provided if available)

If no, please specify arrangements for obtaining the appropriate approvals.

The Data Access Committee and OHS are not responsible for the ethics approval/monitoring of individual research projects and bear no responsibility for the Applicant's failure to comply with local/national ethical requirements.

10. Funding:

Has the project been or will it be peer reviewed? Yes ☐ No ☐

If yes, by what organization?

Has funding been approved? Yes ☐ No ☐ Not applicable ☐

Please attach a detailed budget for the project and the approximate date funding will be available. If "No" or "Not Applicable" was selected, please explain how the research project will be funded or why funding is not required:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

If applicable, what is the deadline for application to the funder*?

**Please note that OHS Data and OHS Biosamples cannot be reserved pending funding approval, even if the Data and Biosample Access Application is approved.*

11. Proposed Methods and Analysis:

a) Are you requesting aggregate data or individual-level data?

- ☐ Aggregate Data
- ☐ Individual-level Data

b) Health & Risk Factor Questionnaire

Select the set of variables that specifically support the research project that you have identified in Section II.

- ☐ Age, sex, country of birth
- ☐ Socio-demographic and economic characteristics (marital status, education, language, ethnicity, residence, working status, household income)
- ☐ Sexual Orientation and Gender Identity
- ☐ Your Health
  - ☐ Handedness
  - ☐ General Health Perception
  - ☐ Last Medical Exam
  - ☐ Last Dental Visit
- ☐ Reproductive Health – Men Only
- ☐ Reproductive Health –Women Only
- ☐ Sleep Pattern
- ☐ Sunlight
- ☐ Food Consumption in a Typical Day

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

☐ Alcohol Use
☐ Tobacco Use
    ☐ Other Types of Tobacco Smoke
☐ Physical Activity
☐ Cancer Screening
☐ Personal Medical History
☐ Emotional Health and Well-Being
☐ Joints and Pain
☐ Family Characteristics
☐ Ethnic Background – Family
☐ Family Health History
☐ Medications

<u>Physical Measures</u>
☐ Blood pressure and heart rate
☐ Grip strength
☐ Bio-impedance
☐ No physical measures data needed

<u>Lab Values</u>
☐ Interpretive variables (e.g., time of last meal)
☐ Glycated hemoglobin
☐ Complete blood count

c) Please describe the design and methodology of the proposed project, including the primary outcome measures and the methods that will be used to analyze the study data. This section should include justification for the sample size requested.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Is there potential for incidental research findings from the proposed analyses? Yes ☐ No ☐

If yes, please describe your plan to address any potential incidental research findings.

12. Laboratory Analyses:

☐ Not applicable – access to OHS Biosamples is not requested.

a) If the proposed project includes analyses of blood and/or urine samples, please list the samples types capable of completing the analysis (e.g., serum, plasma). Provide evidence that the biomarker/category of biomarkers in the proposed biosamples type measurement is stable and that a single time point analysis provides a reliable representation of the question being asked. If this information is available within your submitted research proposal you may reference the page(s) where the information can be found.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Please describe the required type and amount of biosamples needed to support the research project. Supplementary details on the biosamples requested can be added to the additional information field.

Requested	Biosample Type	Units	# participants	Total # of assays planned	# of biomarkers measurements	Total required assay volume/ amount	Total required dead volume/ amount	Total volume/ amount requested
☐	SST: Serum	µL						
☐	EDTA: Plasma	µL						
☐	EDTA: RBC	µL						
☐	Urine	µL						
☐	ACD: Whole blood in DMSO	µL						
☐	DNA*							

(*DNA may be extracted from blood or saliva)

☐ Biosample pre-analytical restriction(s) required
Describe and justify the need for biosample pre-analytical restrictions:

For this research proposal, have you applied for biosamples from another source? ☐ Yes ☐ No

If yes, where?
Status of the request: ☐ Approved ☐Pending ☐Declined

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

b) Describe the proposed methodology for biosamples analysis that will be performed for each requested biosamples. This should include what methodologies are available and the rationale for using the proposed assay. Include the reagent source. Provide evidence of the assay's performance and list 2 to 5 publications where this quality has been demonstrated. If the methodology information is available within your submitted research proposal you may reference the page(s) where the information can be found.

c) Please describe the impact of the freeze-thaw cycle on the biomarker(s) of interest if this information is available.

d) Where will the biosamples be analyzed?

☐ **Applicant(s) Laboratory** Provide evidence of the laboratory's assay usage record, preliminary data and/or publications:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

☐ **Commercial or Service Provider Laboratory**
Analysis #1:
Laboratory Name:
Is the Laboratory accredited?
# of years proposed analysis has been performed at the lab:

Analysis #1:
Laboratory Name:
Is the Laboratory accredited?
# of years proposed analysis has been performed at the lab:

13. Data Linkage:

Will data from other sources be utilized to complete the proposed project? Please list all data linkages required to complete the proposed project, and where these data are held.

☐ Not applicable – OHS Data and/or OHS Biosamples will not be linked with data from other sources.

14. Return of Data:
a) Please outline how any new data derived or measured (e.g., cholesterol level) will be returned to the Ontario Health Study. Data that must be returned include new variables issued from assay results (if applicable), and derived variables generated from existing variables using an

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

expression, including all intermediates of these derived variables. For example, a derived variable can be an index combining several variables (e.g., risk scores) or a numeric variable created by doing the sum of values stored in two or more numeric variables.

The Derived Data must be returned in the analytical format used to create your final working dataset such as SAS (.sas), SPSS (.sps), .CSV or the equivalent, along with the data dictionary or codebook. The Derived Data must include the original IDs supplied by the Ontario Health Study when the de-identified data were provided.

All biosample analysis data is to be accompanied by the corresponding methodology source, in the form of a statement defining what quality control steps were taken and whether they were met or not.

15. Proposed Time-lines:
Briefly outline the proposed timelines required to complete the project, including the projected start date, the number of months required to complete the project, and the expected date data will be returned to the OHS.

Section III: Data Security

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

16. Information Technology (IT) Security Assessment:

To avoid any privacy breaches, you must follow reasonable IT security practices and procedures. You must not disclose any OHS Data to third parties who have not agreed to OHS's privacy requirements. You must ensure that this is also the case for research staff and any external collaborators mentioned in Section I. To be eligible for access, all boxes from A to F must be checked.

A. ☐ My institution has an IT security policy.

B ☐ I will store OHS Data in secure physical computer systems. If OHS Data are stored on portable computers (whether laptops or other mobile devices), they must be encrypted to avoid any unauthorized disclosure in case the portable system is lost or stolen.

C. ☐ I will implement appropriate access security to ensure that only the authorized individuals mentioned in Section I of this *Data and Biosample Access Application Form* be allowed to access the OHS Data. This requires, for example, that if OHS Data are stored on a shared computer system or on a file server, that it be password or encryption-protected. If OHS Data are stored on a network-accessible computer, there should be measures in place to prevent access by computer hackers or contamination by viruses and spyware. Moreover, if the computer(s) that hold OHS Data are backed up, the backed up media must also be encrypted and stored in a secure location.

D. ☐ I understand that anyone (mentioned in Section I of this *Data and Biosample Access Application Form*) who will use OHS Data should be trained in the responsible use of OHS Data and be familiar with the terms and conditions of the *Data and Biosample Access Policy*, this *Data and Biosample Access Application Form*, and the *Data and Biosample Access Agreement*. I am responsible for ensuring research staff comply with these terms and conditions.

F. ☐ I understand that upon completion of my research project, I must destroy all local copies, including backups, of the OHS Data by the date specified in the *Data and Biosample Access Agreement*. I must also send a copy of my analysis code to OHS in case of potential needs to reproduce my variables or findings at a later date.

17. Biosamples Security Assessment:

☐ Not applicable – access to OHS Biosamples is not requested.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

To avoid any privacy breaches, you must follow reasonable biosamples security practices and procedures. You must ensure that this is also the case for research staff and any external service providers and commercial laboratories mentioned in Section I. To be eligible for access, all boxes from A to E must be checked.

A. ☐ My institution has a biosamples security policy.

B. ☐ The services provider(s) and/or commercial laboratory(ies), if applicable, each has a formal biosamples security policy.

C. ☐ I will implement appropriate access security so as to ensure that only the authorized individuals mentioned in Section I of this *Data and Biosample Access Application Form* are able to access the OHS Biosamples. This requires, for example, that OHS Biosamples be stored in a room with restricted access and, if not, in a locked freezer/refrigerator.

D. ☐ I understand that anyone (mentioned in Section I of this *Data and Biosample Access Application Form*) who will use OHS Biosamples should be trained in the responsible use of OHS Biosamples and be familiar with the terms and conditions of the *Data and Biosample Access Policy*, this *Data and Biosample Access Application Form* and the *Data and Biosample Access Agreement*. I am responsible for ensuring research staff comply with these terms and conditions.

E. ☐ I understand that upon completion of my research project, I may be asked to either destroy or return OHS Biosamples, as per OHS's request.

18. Publication

A. ☐ I 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."*

SIGNATURE:

Principal Applicant:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Name _____ Position _____

Signature _____ Date _____

Authorized Institutional Representative of the host institution:

Name _____ Position _____

Signature _____ Date _____

Checklist of Required Documents

Please attach the following required OHS access documentation before submitting your application.

- ☐ Research Ethics Board (REB) approved research protocol
- ☐ Decision letter from a Research Ethics Board (REB) or comparable decisional committee (English or French; an institutional approval number should also be provided, if available)
- ☐ Proof of scientific peer-review, if available
- ☐ Proof of funding granted, if available
- ☐ 2-Page CV of Principal Applicant

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

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 3: Ontario Health Study – Data and Biosample Access Renewal Form

This *Data and Biosample Access Renewal Form* should be completed and signed by an Approved User who has successfully applied for access to OHS Data, has used them for research purposes for the time specified in the *Data and Biosample Access Agreement*, and who's *Agreement* will expire shortly. This *Data and Biosample Access Renewal Form* provides the Approved User with the possibility of confirming that the information contained in each section of the original *Data and Biosample Access Application Form* (if it is the Approved User's first renewal) or the previous *Data and Biosample Access Renewal Form* (if the Approved User has previously renewed his/her application) has remained unchanged. In case of changes to the research project or to the information provided in previous access applications to OHS, the *Data and Biosample Access Renewal Form* will allow the Approved User to specify them. This *Data and Biosample Access Renewal Form* does not replace or supersede these previous agreements.

The date of signature by the Data Access Committee of the original *Data and Biosample Access Agreement* or, if applicable, the previous *Data and Biosample Access Renewal Form*, will determine the year-end date when this form should be completed.

File number (provided in your original approval letter): _____

Original title and lay summary of the main research project:

1. Name of Principal Applicant including affiliation and contact details.
Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

If yes, complete this section, while reflecting the new changes.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address: Open ID:

2. Name of the Authorized Institutional Representative, including affiliation and contact details.

Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

If yes, complete this section, while reflecting the new changes.

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address:

3. Title of Project

Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

If yes, complete this section, while reflecting the new changes.

4. Names of authorized personnel

Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Yes ☐ No ☐

If yes, complete this section reflecting the new changes. A valid institutional email address for each name along with their job title/function is required.

All new authorized personnel should be given a copy of the *Data and Biosample Access Application Form* and receive proper training and briefing on the security and confidentiality issues and be familiarized with the *Data and Biosample Access Agreement* in effect. It is your responsibility to see that they follow the terms of the *Data and Biosample Access Agreement*.

Name: Title: Position: Affiliation: Institutional E-mail Address:

5. Research Project

a) Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

If yes, complete this section, by informing us of any major change concerning your research project, including changes in the informed consent process and documents and/or research ethics review.

b) What is the current status of the project? Provide a brief summary of study progress and results.

6. Lay summary of the research project

Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

If yes, complete this section, while reflecting the new changes.

7. Information Technology Security

Has the information provided in your last approved *Data and Biosample Access Application/Renewal* for this section changed?

Yes ☐ No ☐

If yes, complete this section, while reflecting the new changes.

I declare that the information presented above is true and up to date.

I recognize that I am still bound by the terms and conditions of the *Data and Biosample Access Agreement* that I signed on _____.

Principal Applicant:

Name _____ Position _____

Signature _____ Date _____

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Authorized Institutional Representative of the host institution:

Name _____ Position _____

Signature _____ Date _____

Please fax or e-mail a PDF of the signed *Data and Biosample Access Renewal Form* to 416-977-6573 or access@ontariohealthstudy.ca.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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*

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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;

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

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

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 5: Ontario Health Study – Final Project Report

This *Final Project Report* should be completed and signed by an Approved User who has successfully applied for access to OHS Data, has used them for research purposes for the time specified in the *Data and Biosample Access Agreement*. This *Final Project Report* provides the User with the opportunity to provide a summary of the research findings as well as comments and suggestions for improving OHS's access procedure.

File number (provided in your original approval letter): _____

Original title and summary of the main research project:

1. Name of Principal Applicant including affiliation and contact details.

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address:

2. Name of the Authorized Institutional Representative, including affiliation and contact details.

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address:

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

3. Title of Project

4. Summary of the research project

Please provide a summary of the results of the research project. This summary should be written for an academic audience and will not be published. Please also attach any publications (including published abstracts) arising from this work.

5. Lay summary of the research project

Please provide a summary of the results of the research project. This summary should be written for a lay audience and will be published on OHS's publicly available accessible registry.

6. Improving access procedures

The OHS is committed to sharing its data with the national and international scientific communities. Please provide feedback and suggestions for improving OHS Data and Biosample Access procedures.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Principal Applicant:

Name _____ Position _____

Signature _____ Date _____

Authorized Institutional Representative of the host institution:

Name _____ Position _____

Signature _____ Date _____

Please e-mail a PDF of the signed *Final Project Report* to access@ontariohealthstudy.ca.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 6: Ontario Health Study – Unanticipated Event/Significant Change Report

This *Unanticipated Event/Significant Change Report* must be submitted to the Data Access Committee for the occurrence of Unanticipated Events and/or Significant Changes 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.

Notification of compromised data or material security, integrity or confidentiality, or a breach of ethics must be reported at the first reasonable opportunity by telephone to OHS DAC, followed by this written notice report within 48 hours of the event.

File number (provided in your original approval letter): _____

Original title and summary of the main research project:

1. Name of applicant including affiliation and contact details.

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address:

2. Name of the authorized institutional representative, including affiliation and contact details.

Name: Title: Position: Affiliation: Institutional E-mail Address: Mailing Address:

3. Title of Project

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

4. Description of the Unanticipated Event/Significant Change

a) Date of the event: _____

b) ☐ Requesting additional variables for the same participants for a previously approved *Data and Biosample Access Application.*

c) Description of the unanticipated event/significant change.

d) Has the Research Ethics Board or a comparable decisional committee been notified?

e) What action (if any) has been taken, or will be taken, by the Approved User?

Principal Applicant:

Name _____ Position _____

Signature _____ Date _____

Authorized Institutional Representative of the host institution:

Name _____ Position _____

Signature _____ Date _____

Please e-mail a PDF of the signed *Unanticipated Event/Significant Change Report* to access@ontariohealthstudy.ca.

Ontario Health Study
661 University Ave, Suite 510
Toronto, ON M5G 0A3
access@ontariohealthstudy.ca
www.ontariohealthstudy.ca

Appendix 7: Ontario Health Study - Certificate of Destruction

File number (provided in your original approval letter): _____

Project title: _____

This is to certify that all copies of the data file transferred on (*insert date*) have been destroyed and can no longer be accessed.

Principal Applicant:

Name _____ Position _____

Signature _____ Date _____

Authorized Institutional Representative of the host institution:

Name _____ Position _____

Signature _____ Date _____

Once completed, please send an original signed copy to:
Ontario Health Study, Data Access Committee
MaRS Centre
661 University Avenue, Suite 510
Toronto, Ontario
Canada M5G 0A3