Ontario Health Study
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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.

Section I: Research Personnel

1. Applicants:

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

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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.

Name	**Affiliation**	**Position**	**Email**

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:

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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.

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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:

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.

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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.

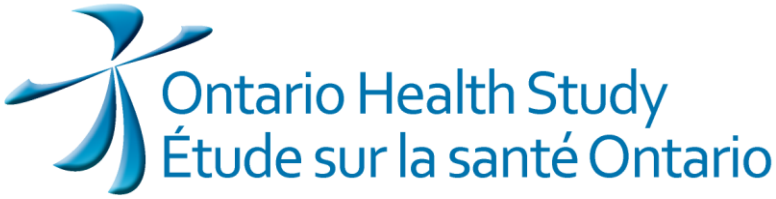
10. Funding:

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:



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:

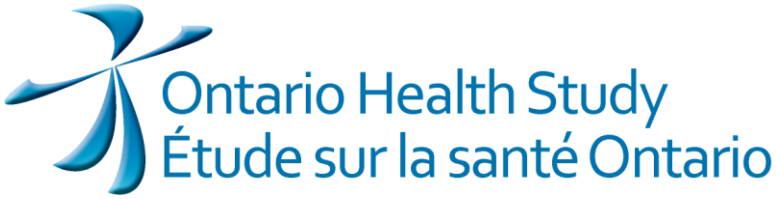
a) Are you requesting aggregate data or individual-level data?

- ☐ 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
  - ☐ Health Compared to 1 Year Ago
  - ☐ Last Medical Exam
  - ☐ Last Dental Visit
  - ☐ Pre-pregnancy Medical Exam
  - ☐ Pre-pregnancy Dental Visit
  - ☐ Stand without assistance
- ☐ Reproductive Health – Men Only
- ☐ Reproductive Health –Women Only (Not Pregnant)
  - ☐ Reproductive Health –Pregnant Women
  - ☐ Conception of Current Pregnancy
  - ☐ Mother's Health During Pregnancy
- ☐ Sleep Pattern
- ☐ Sunlight
- ☐ Food Consumption in a Typical Day
- ☐ Alcohol Use



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

<u>Physical Measures</u>

- ☐ Anthropometric measures
- ☐ Blood pressure and heart rate
- ☐ Grip strength
- ☐ Bio-impedance
- ☐ Spirometry
- ☐ No physical measures data needed

<u>Biosamples Data</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.

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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.

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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:

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

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

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:

☐ **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.

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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 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.

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Section III: Data Security

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.

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:

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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.