Ontario Health Study
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ONTARIO HEALTH STUDY (OHS)

ACCESS POLICY

March 2026

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1. Introduction and Purpose

The Ontario Health Study (OHS) is a research platform that supports research on cancer and chronic disease through a longitudinal cohort study (see https://www.ontariohealthstudy.ca/). Between 2009 and 2017, the OHS recruited over 225,000 Ontario residents over the age of 18 to complete health-related questionnaires online, with follow-up questionnaires administered over time to follow their health as they age. Physical measures and Biosamples, including blood and urine, have also been collected by the OHS from a subset of participants. Details of recruitment and the demographics of the cohort are described elsewhere (see Kirsh, et al., 2022, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10321700/).

This *Access Policy* details the various procedures and requirements for accessing Data and/or Biosamples from the OHS. The following guiding principles underpin access to the OHS research platform:

- **Promoting the common good** by maximizing collaborative research for the benefit of all;
- Ensuring the **generation of high quality research**;
- Making Data and Biosamples available to the research community to **advance scientific knowledge**;
- **Respecting the legal rights and legitimate interests** of all stakeholders involved (e.g., families, populations, researchers and funders);
- **Protecting the privacy** of the Participants and the **confidentiality** of their Data;
- Promoting **transparency, responsibility, interoperability** and **fairness**;
- Ensuring **accountability** and **oversight**;
- **Enriching the content of the database**, including through the **return of quality derived data** by researchers; and
- Managing access to Biosamples to **balance current and future needs**.

The OHS is part of a pan-Canadian initiative known as the Canadian Partnership for Tomorrow's Health (CanPath). CanPath includes prospective longitudinal cohort studies in seven regions across Canada (Alberta's Tomorrow Project, the Atlantic Partnership for Tomorrow's Health, the BC Generations Project, the Manitoba Tomorrow Project, the Ontario Health Study, Quebec's CARTaGENE project and Healthy Future Saskatchewan). Applicants interested in accessing Data and Biosamples from two or more CanPath regional cohorts are encouraged to visit the CanPath Access Portal (see https://portal.canpath.ca/) for more information.

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2. Definitions

Access Committee (AC): a monitoring committee that will review and approve or deny access requests and provide overall oversight.

***Access Policy*:** the policy that governs access to Data and/or Biosamples, outlining the OHS's access requirements and the obligations of the Approved User(s) and Approved Institution(s). It forms an integral part of the *Data and Biosample Access Agreement* or the equivalent Supplemental Agreement.

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 5 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 the OHS, once created, Aggregate Data do not include personal health information.

***Amendment Form*:** the form submitted to the OHS by the Approved User if there is a change to the Approved Research Project. This form must also be submitted if the Approved Research Project undergoes a research ethics amendment.

Annual Update: a document submitted by the Approved User on each anniversary of the Effective Date of the *Data and Biosample Access Agreement*, or the equivalent supplemental agreement, over the course of the project timeline identified in the approved *Data and Biosample Access Application Form* or *OHS-ICES Application Form.* The *Annual Update* allows the Approved User to provide the OHS with an update on the status of the Approved Research Project and to highlight any changes since the last approval or report.

Applicant: a researcher conducting health-related research applying for access to Data and/or Biosamples. All Applicants must be affiliated with an institution (public or private).

Approved Institution: the institution (legal entity), public or private (e.g., university, foundation, industry), under which the Approved User is conducting the Approved Research Project or otherwise contractually binding the Approved User.

Approved Research Project: the project for which access to Data and/or Biosamples has been granted by the AC. It will be listed on the publicly available OHS website along with a lay summary of the project.

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Approved User: an Applicant who is granted access to Data and/or Biosamples by the AC.

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

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

Biosample(s): biological samples such as red blood cells, serum, plasma, DNA from buffy coat or saliva, urine and dried blood spot (DBS) cards with Associated Data from unique, but not directly identifiable, individuals made available to Approved Users in accordance with the *Data and Biosample Access Application Form* or *OHS-ICES Application Form.*

***Bona Fide* Researcher:** a qualified researcher who has a formal relationship with a research organization that requires compliance with appropriate research governance systems and ethical standards.

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

Data: coded data associated with unique, but not directly identifiable, individuals made available to Approved Users in accordance with the *Data and Biosample Access Application Form* or *OHS-ICES Application Form.*

***Data and Biosample Access Agreement*:** a signed agreement between the Approved User(s), the Approved Institution(s) and the Ontario Institute for Cancer Research (in respect of the OHS) that sets out the terms and conditions of access to Data and/or Biosamples and must be signed before these Data and/or Biosamples can be transferred. The agreement legally binds its signatories.

***Data and Biosample Access Application Form*:** the form submitted by the Applicant to request access to Data and/or Biosamples. It includes, among other things, a description of the Applicant's research project and the Research Team.

***Data and Biosample Access Renewal Form*:** a document completed by an Approved User prior to the end of their Approved Research Project. The *Data and Biosample Access Renewal Form*

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allows the Approved User to apply to extend their access to Data and/or Biosamples for their Approved Research Project for up to three additional years.

Data Linkage: a process through which data from external sources (e.g., administrative health data, environmental indicators) are linked with Data and/or Biosamples from the OHS.

Derived Data: any and all data, information and any other matter or deliverable arising from or based upon the use of Data and/or Biosamples including any Record-Level Data, generated by Approved Users as part of an Approved Research Project.

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

***Final Report*:** a form completed by an Approved User at the end of an Approved Research Project to report the outcomes of the Approved Research Project and to provide feedback on the OHS access process.

Host Institution: the legal entity that engages and hosts the Applicant. See also "Approved Institution."

ICES: ICES is a not-for-profit research institute encompassing a community of research, data and clinical experts, and a secure and accessible array of Ontario's health-related data. See https://www.ices.on.ca/.

Intellectual Property (IP): "Intellectual Property" or "IP" means any intellectual property, including without limitation, any invention, innovation, new and useful art, product, service, discovery, process, methodology, pattern, machine, process of manufacture or composition of matter or formula therefore, a new life form, work, material, computer software, compilation of information in whatever medium whatsoever, attendant Know-how, trade secrets, confidential information or any new and useful improvement thereof whether or not protected or protectable by patent or registration of industrial design or trademark and all copyright (including the benefit of any moral rights), patents, trademarks (including any goodwill), industrial design rights and applications and registrations for any of the foregoing and any other intellectual property, including any creations of the mind, the rights of which are protected or are capable of being protected by applicable law.

Linked Data: Data from the OHS that have been linked with data from external sources (e.g., administrative health data, environmental indicators) via Data Linkage.

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***OHS-ICES Application Form*:** the form submitted by the Applicant to request access to Data and/or Biosamples that are linked to administrative data (e.g., OHIP billing codes) through ICES. It includes, among other things, a description of the Applicant's research project and the Research Team.

OICR Executive Leadership: the individuals responsible for overseeing the administration, programs and strategic plan of the Ontario Institute for Cancer Research (OICR). These individuals report to the OICR Board of Directors, the governing body that sets policies for corporate management and oversight of OICR.

Ontario Health: formerly Cancer Care Ontario, a division of Ontario Health that acts as the Ontario government's principal cancer advisor. Ontario Health collects and manages comprehensive healthcare data sets, including the Ontario Cancer Registry. See https://www.ccohealth.ca/en.

Ontario Health Study (OHS): a research platform supporting research on cancer and on other chronic diseases, within the national Canadian Partnership for Tomorrow's Health. See https://www.ontariohealthstudy.ca/.

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 https://oicr.on.ca/.

Participants: individuals who have consented to participate in the OHS and have contributed Data and/or Biosamples.

***Project Feasibility Assessment Form*:** the form completed by researchers requesting a Letter of Support (LoS) and/or cost estimate for a grant or ethics submission. The form may also be completed by researchers seeking a general feasibility assessment prior to submitting a *Data and Biosample Access Application Form* or *OHS-ICES Application Form*.

Record-Level Data: coded-data about a single individual generated by an Approved User(s) as part of an Approved Research Project.

Research Team: those individuals who are listed in the *Data and Biosample Access Application Form* or *OHS-ICES Application Form*, and who are approved by the AC to have access to the Data and/or Biosamples for the purpose of conducting the Approved Research Project.

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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* or *OHS-ICES Application Form.*

***Supplemental Agreement to Access OHS Data and Biosamples at ICES*:** a signed agreement between the Approved User(s), the Approved Institution(s) and the Ontario Institute for Cancer Research (in respect of OHS) that sets out the terms and conditions for an Approved Research Project that involves access to Data and/or Biosamples as well as Data Linkage via ICES. The agreement legally binds its signatories and must be signed before Data, Linked Data and/or Biosamples can be made available to the Approved User(s).

***Supplemental Agreement to Access OHS Data at ICES*:** a signed agreement between the Approved User(s), the Approved Institution(s) and the Ontario Institute for Cancer Research (in respect of OHS) that sets out the terms and conditions for an Approved Research Project that involves access to Data as well as Data Linkage via ICES. This agreement legally binds its signatories and must be signed before Data and/or Linked Data can be made available to the Approved User(s).

Unanticipated Event: an event that takes place during an Approved Research Project, that may have an impact on the Data, Biosamples, Derived Data and/or the ability of the Approved User to achieve their research goals. These events include, but are not limited to, situations of compromised data or material security, integrity or confidentiality, loss of funding, or breaches of ethics.

***Unanticipated Events Form*:** the form submitted to the OHS by the Approved User to report any Unanticipated Events that occur during the course of their Approved Research Project.

3. Overview

Through the generous contributions of its Participants, the OHS offers a valuable resource of Data and Biosamples available to researchers to pursue investigator-initiated research. The OHS data sharing framework is built on the informed consent of its Participants whose contributions make possible the advancement of knowledge and enable research investigations. Further, the OHS recognizes the importance of having analyses of its Data and Biosamples published in peer-reviewed journals in a timely manner and presented at scientific meetings and conferences. The purpose of this *Access Policy* and its appendices is to establish the principles, policies and procedures by which access to Data and Biosamples (and to Linked Data where implied or explicitly stated) is sought and granted and to the Derived Data generated from their analysis. This document has been developed and implemented in order to: encourage fair, timely and

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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.

Collaboration amongst researchers is strongly encouraged to maximize access to and use of Data and Biosamples. Access to Data and Biosamples is time-limited and for approved analyses only. Proposals will be accepted for access to questionnaire, physical measures, genotype data, biosample analytes, community-level data and environmental exposures, and biorepository materials. Only de-identified Data and Biosamples will be provided to investigators. An Access Committee (AC) will review and evaluate access requests and oversee access to Data and Biosamples. During the review process, consideration will be given to the scientific merit of the research project, the potential impact on Participants and appropriate use of limited resources (e.g., 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.

It is possible for additional Data and/or Biosamples to be collected through ancillary studies. Ancillary studies must be conducted in collaboration with the OHS. As such, researchers must contact access@ontariohealthstudy.ca if they have a proposal for an ancillary study.

It is intended that this *Access Policy* be clear and transparent and implemented in a manner which is proportionate, accountable and fair. The *Access Policy* provides a framework for addressing and determining access issues. The *Access Policy* does not prescribe what will be done in every circumstance because the OHS cannot predict the nature of every access request that will be submitted over the long-term. Sufficient flexibility has been built into the *Access Policy* to address both expected and unexpected issues, and the *Access Policy* will be revised periodically to reflect practical experience and evolving standards and best practices.

4. General Process for Access Requests

The OHS is committed to sharing its Data and Biosamples with the national and international scientific communities, and to the principles of transparent and facilitated access to Data and Biosamples by *Bona Fide* Researchers. These Data include, but are not limited to, responses to self- and interviewer-administered questionnaires, physical measures and data derived from Biosamples. Investigators who wish to develop a proposal for access to Data and/or Biosamples are strongly encouraged to review the information for researchers on the OHS website (see https://www.ontariohealthstudy.ca/for-researchers), and to contact the OHS if they have questions. **All forms that must be submitted to the OHS over the lifecycle of the access request are available on the OHS website.**

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All *Bona Fide* Researchers are invited to submit a *Project Feasibility Assessment Form* prior to grant submissions. If the Applicant's request is accepted, the OHS will forward the Applicant a letter of support including: (a) acknowledgement of receipt of the 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 a formal access request and approval from the AC; and if requested (d) an estimate of the cost to access the requested Data and/or Biosamples.

A formal access request using the *Data and Biosample Access Application Form* should be submitted once funding, if required, has been confirmed and the Applicant has received approval from their local Research Ethics Board or its equivalent. Each access request will be reviewed by the OHS to check completeness of documentation and project feasibility, as well as assess potential impact(s) of the proposed project. Access requests that demonstrate requisite feasibility will be reviewed by the AC. Additional reviewers or external bodies may be consulted at the discretion of the AC or the OHS to evaluate the proposal.

Upon approval of an access request, the OHS will notify the Applicant, forwarding a copy of the *Data and Biosample Access Agreement* to the now Approved User(s). Once the Approved User(s) and their Authorized Institutional Legal Representative(s) sign the Agreement and applicable access fees have been paid, access to Data and/or Biosamples will be granted for the time period specified in the Agreement. The end date of the proposed project timeline included in the approved *Data and Biosample Access Application Form* will serve as the termination date for the Agreement. For Approved Research Projects that will be completed over multiple years, the Approved User is required to submit an *Annual Update* each year of the project to provide an update on its status.

If additional time is needed to complete the Approved Research Project, Approved Users can apply to extend their access to Data and/or Biosamples for up to three additional years using the *Data and Biosample Access Renewal Form* prior to the end date specified in the *Data and Biosample Access Agreement*. The Approved User is still required to submit an *Annual Update* each year for access extensions greater than one year in length.

Data and Biosamples will only be released to Approved Users. There will be no exclusive access granted to any one party. To facilitate maximal use of Biosamples, Approved Users will have exclusive access to any Derived Data from analyses of Biosamples for a period of one year. Once this time period has elapsed, the Derived Data must be shared with the OHS and will become part of the OHS database, even if the results of analyses have not yet been published. These Derived Data will be made available to other Applicants (see Section 11).

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Upon completion of the project, the Approved User must submit a *Final Report*. Where applicable, the OHS will request a *Certificate of Destruction* from the Approved User after any agreed upon archival period has ended.

a. Requests for Linked Data

Applicants requesting to link Data and/or Biosamples with information in administrative or medical databases will require approval from the custodians of these databases and must comply with their requirements. Please contact the OHS for additional information and direction.

Ontario Cancer Registry

If the Applicant wishes to access data held by Ontario Health, including but not limited to Ontario Cancer Registry (OCR) data, they may request these data from Ontario Health (see https://www.ccohealth.ca/en/request-data-for-research). Separate access requests must be made to both Ontario Health and the OHS for these projects. Upon approval of the request by both the OHS and Ontario Health, the Approved User will enter into separate agreements with each organization. In turn, many aspects of the process described in the previous section will still apply to these requests.

ICES

A copy of OHS Data has been transferred to ICES to facilitate Linked Data analyses at ICES. Please refer to the ICES website (https://www.ices.on.ca/) for a detailed list of the administrative data available for Data Linkage. Applicants interested in linking OHS Data with administrative data (e.g., OHIP billing codes) at ICES are required to fill out an *OHS-ICES Application Form* in lieu of the *Data and Biosample Access Application Form*, and to request a confirmation of feasibility from ICES. If the request includes accessing Biosamples following a Linked Data analysis (i.e., Biosamples will be selected based on characteristics found or confirmed in the administrative data), the OHS Principal Investigator must be named as a co-applicant in the research ethics application for the project. The Applicant is strongly encouraged to contact the OHS prior to submitting the *OHS-ICES Application Form* so that the OHS can provide guidance on the required steps and their appropriate sequence. Upon approval of an access request that involves Data Linkage at ICES, the Approved User may be required to sign the *Supplemental Agreement to Access OHS Data at ICES* or the *Supplemental Agreement to Access OHS Data and Biosamples at ICES* and potentially a separate agreement with ICES. In turn, many aspects of the process described in the previous section will still apply to these requests. Analysis of OHS Data linked to administrative data at ICES are subject to the privacy and information security policies and procedures in place at ICES. Access will be granted for the time period specified in the approved *OHS-ICES Application Form*, with the end date of the project timeline proposed in the form serving as the termination date for the applicable access agreement.

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Please see Sections 7 and 8 for more information on the forms and access request review process referenced in this section.

5. Access to Data and Biosamples

a. Who is eligible to access Data and Biosamples

The Data, Derived Data and Biosamples in the custody of the OHS will be made available to public and private institutions that conduct scientific research. The OHS encourages access requests regardless 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 research.

Access requests may also be submitted for student/trainee projects with an experienced supervisor required to be present for the duration of these projects. The student/trainee's supervisor must be the Principal Applicant and is responsible for signing the *Data and Biosamples Access Agreement* if the access request is approved.

b. Limits of Data and Biosample access

Requests to access individual-level Data or Biosamples for non-research-related uses, including by law enforcement bodies or governmental agencies, may only be disclosed as required by law. Exclusive access to Data will not be granted to any party.

Access to individual-level Data and Biosamples by commercial and/or private industry groups will be considered on a case-by-case basis. Presently, the OHS is required to obtain ethics approval from its Research Ethics Board for each collaboration with private industry involving access to individual-level Data and Biosamples. Applicants from commercial and/or private industry groups are strongly encouraged to contact the OHS for additional information and direction.

c. Overlapping project proposals

Multiple access requests for overlapping initiatives may be approved by the AC when the request does not include the analysis of Biosamples. The Applicant is encouraged to review the descriptions of approved access requests available on the OHS website, and to seek collaboration with researchers sharing a similar research interest or pursuing a similar research question. The AC or the OHS Access Office may offer suggestions for combining similar proposals and may prioritize specific access requests if multiple overlapping requests for Biosamples are received.

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d. Access periods

Approved Users will be given access to Data and/or Biosamples for the period specified in the *Data and Biosample Access Agreement* or the equivalent supplemental agreement, with the possibility for subsequent renewals. It is expected that an Approved Research Project will be completed within three years of approval. If a longer timeframe is required, justification must be provided in the *Application Form*.

e. Limits of Data and Biosample use

The Data and/or Biosamples may not be used for any purpose other than for the Approved Research Project outlined in the *Application Form*. The Approved User must inform the OHS of any changes to the Approved Research Project and request approval to modify the Approved Research Project prior to implementing any changes. Changes to Approved Research Projects are requested using the *Amendment Form* and may be reviewed by the AC depending on the nature of the changes. If approved, these changes may need to be reflected in an amendment to the Approved User's Research Ethics Board and the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

Further information on limits of Biosample use are detailed in Section 8c.

6. Privacy of Participants

a. Safeguarding Data and Biosamples

The OHS will uphold the rights of its Participants by respecting their consent and by protecting their privacy and the confidentiality of their Data and Biosamples. Approved Users accessing Data and Biosamples will also assume these obligations.

The Approved User must make all reasonable efforts to maintain the security and confidentiality of the accessed Data and/or Biosamples, including any copies or derivatives made by the Applicant. The Approved User may not disclose, transmit or transfer any Data, Biosamples or Derived Data to unauthorized individuals. The Approved User shall retain control of the transferred Data and Biosamples and any Derived Data, as delineated in the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

When requesting access to Data and/or Biosamples, Applicants must confirm that reasonable security measures are in place and shall detail their plan to secure Data and/or Biosamples received from the OHS in the *Application Form*.

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Only coded Data and/or Biosamples will be provided to the Approved User by the OHS. The Approved User must not attempt to re-identify any Participants by any means. If the Approved User involuntarily identifies a Participant, this constitutes a privacy breach and the OHS must be notified immediately using the *Unanticipated Events Form*.

If the Approved User requires support from a service provider or commercial laboratory to complete the Approved Research Project, the Approved User must ensure that the service provider or commercial laboratory complies with the provisions of the *Data and Biosample Access Agreement* or the equivalent supplemental agreement. Any services agreement with a service provider or commercial laboratory must include provisions around privacy, confidentiality and data destruction that are aligned with such provisions in the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

b. Return of Incidental Findings

As a general principle, the OHS will not return individual research results to Participants from analyses conducted by Approved Users. Nevertheless, given the duration of the OHS and the impossibility of foreseeing the nature of projects that may be conducted using Data and/or Biosamples, Approved Users should be aware of the possibility that the OHS may decide to return validated results back to individual Participants if such information is determined to be critical for the care of those Participants. Decisions regarding the return of incidental findings, including whether incidental findings will be returned, what specific findings will be returned, and how those findings will be returned, will be made in consultation with appropriately qualified medical advisors, the OHS Principal Investigator and individuals with relevant expertise (e.g., genetic counselling) and any relevant Research Ethics Boards or comparable decisional committees. If results of analyses are returned to Participants, communications will be managed by the OHS and not by the Approved User who, in keeping with the OHS *Access Policy*, will not have access to any contact information for Participants.

7. Access Documents

The following section outlines the documentation that must be received from the Applicant. Copies of all access-related documents and associated correspondence will be stored securely in electronic or paper format. Records will be retained for the duration of the OHS.

a. Project Feasibility Assessment Form

Applicants seeking a letter of support for grant or ethics submissions or a cost estimate for a potential project are directed to submit a *Project Feasibility Assessment Form*.

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When a *Project Feasibility Assessment Form* is received, a project feasibility and impact assessment is conducted and, if requested, a cost estimate for accessing Data and/or Biosamples is generated. When requesting a letter of support, Applicants should submit their *Project Feasibility Assessment Form* at least 10 business days prior to the grant deadline. Along with the *Project Feasibility Assessment Form,* Applicants are encouraged to submit a draft letter of support describing their research project and indicating how the OHS will support their research. This draft will be edited as required by the OHS.

Please note that a letter of support does not grant access to the Data and/or Biosamples, it does not grant exclusivity of use for specific Data and/or Biosamples, and it does not reserve Biosamples for any potential Applicant.

b. Data and Biosample Access Application Form/OHS-ICES Application Form

To request access to Data and/or Biosamples, an Applicant must complete the *Data and Biosample Access Application Form* or, if Data Linkage via ICES is desired, the *OHS-ICES Application Form*. The appropriate form will be submitted by the Applicant along with the following documents:

- Research protocol*
- The full submission to and official letter of approval by a Research Ethics Board or comparable decisional committee*
- 2-page curriculum vitae (CV) of the Principal Applicant
- Evidence of scientific peer-review of the research protocol (if applicable)
- Evidence of funding (if applicable)
- Confirmation of feasibility from ICES (required only if Data Linkage via ICES is requested)

*In exceptional circumstances, the OHS may accept access requests without research ethics approval if an application for ethics review has been submitted to a Research Ethics Board or comparable decisional committee. However, the access request will not be fully approved until an official research ethics approval letter has been submitted to the OHS. Furthermore, it should be noted that receipt of research ethics approval for a proposed project does not guarantee access to Data and/or Biosamples.

The complete application package will be reviewed by the AC.

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c. Data and Biosample Access Agreement and Equivalent Supplemental Agreements

Upon approval of a *Data and Biosample Access Application Form* by the AC, the Approved User(s) and their Authorized Institutional Legal Representative(s) will be required to sign and comply with the *Data and Biosample Access Agreement*.

For an approved *OHS-ICES Application Form*, the Approved User(s) and their Authorized Institutional Legal Representative(s) may be required to sign and comply with an appropriate supplemental agreement in lieu of the *Data and Biosample Access Agreement*.

d. Annual Update

If the Approved Research Project will be completed over more than one year, the Approved User may be required to submit an *Annual Update* on each anniversary of the Effective Date of the *Data and Biosample Access Agreement* or the equivalent supplemental agreement, over the course of the project timeline identified in the approved *Data and Biosample Access Application Form* or *OHS-ICES Application Form*. Along with the *Annual Update* the Approved User must submit an official letter of ethics renewal by a Research Ethics Board or comparable decisional committee.

In the event of a privacy breach or other unusual circumstance, the OHS may require the Approved User to provide reports on a more frequent basis.

e. Data and Biosample Access Renewal Form

The *Data and Biosample Access Renewal Form* is to be used by Approved Users who have successfully applied for access to Data and/or Biosamples and who wish to access these Data and/or Biosamples beyond the initial approval period. Approved Users may request an extension of up to three years in the form. The *Data and Biosample Access Renewal Form* must be submitted at least two months prior to the end date identified in the *Data and Biosample Access Agreement* or the equivalent supplemental agreement. Along with the *Access Renewal Form*, the Approved User must submit an official letter of ethics renewal by a Research Ethics Board or comparable decisional committee.

f. Final Report

Once an Approved Research Project has ended, Approved Users must submit a *Final Report* to the OHS. The *Final Report* requires the Approved User to provide: a summary of the research findings; details regarding study closure; and comments and suggestions to improve the OHS's access procedures. The *Final Report* must be submitted within three months of project completion.

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g. Unanticipated Events Form

An *Unanticipated Events Form* must be completed and submitted to the OHS if, during an Approved Research Project, there are any Unanticipated Events that may have an impact on the Data, Biosamples, Derived Data and/or the ability of the Approved User to achieve the goals of their Approved Research Project.

Examples of Unanticipated Events include, but are not limited to, the following:

- Impossibility to complete the Approved Research Project (e.g., loss of funding; lapse of ethics approval; loss or change of scientific direction);
- Unreported changes to the information provided by the Approved User in the *Data and Biosample Access Application Form* or *OHS-ICES Application Form*;
- Compromised data or material security, integrity or confidentiality;
- A breach of ethics; or
- Any other changes/events that render it impossible to maintain full compliance with this *Access Policy* or the signed *Data and Biosample Access Agreement*/equivalent supplemental agreement.

The Approved User must notify the OHS of a breach of ethics and/or compromised data/material security, integrity or confidentiality at the first reasonable opportunity by email and telephone call. The *Unanticipated Events Form* must then be submitted to the OHS within 48 hours of the event.

h. Certificate of Destruction

Upon request by the OHS and as stipulated in the *Data and Biosample Access Agreement* and the *Supplemental Agreement to Access OHS Data and Biosamples at ICES*, the Approved User must submit a *Certificate of Destruction* to the OHS. The *Certificate of Destruction* will confirm that the transferred Data and/or Biosamples and any copies have been destroyed. The *Certificate of Destruction* must be submitted within one year of the end of the Approved Project (see Section 13).

i. Amendment Form

If there is a change to the study design or protocol of the Approved Research Project (e.g., addition of new variables, updates to research objectives/queries), or if additional individuals will have access to individual-level data, an *Amendment Form* must be submitted to the OHS. This form must also be submitted if the project requires a research ethics amendment. In the case of a research ethics amendment, the Approved User must submit an official letter of approval by a Research Ethics Board or comparable decisional committee alongside their completed *Amendment Form.*

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If there is an amendment to change the Approved User or to add a Research Team member from a different institution, the new Approved User and/or Research Team member will be required to sign the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

Significant Changes, including requests for additional Data and/or Biosamples, to an Approved Research Project will be considered on a case-by-case basis and may require approval by the AC. If the Significant Change(s) requested substantially alters the Approved Research Project, the Approved User may be required to submit a new application form with accompanying fees.

If approved, changes requested using the *Amendment Form* may need to be reflected in an amendment to the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

8. Review of Access Requests

a. Access Committee

The AC will act in an oversight capacity. The AC will review *Data and Biosample Access Application Forms* and *OHS-ICES Application Forms*, along with any supporting documentation, and make decisions to approve, reject or request additional information regarding access requests. The OHS may engage additional subject matter experts that are appointed to the AC on an ad hoc basis for the review of specific access requests in order to ensure an appropriate review process.

b. Criteria for Review

Upon receipt of an access request, the OHS will complete an administrative review and follow-up with the Applicant, if necessary, to ensure:

- The research study is in conformity with the informed consent(s) signed by the Participants;
- Thorough completion of the *Data and Biosample Access Application Form* or *OHS-ICES Application Form* (e.g., all collaborators listed on supporting documents have been included in the Research Team; all requested Data and/or Biosamples have been described clearly, with justification provided for each type and amount; planned methods for statistical analysis have been described; sample size justification has been included);
- Availability of the requested Data and/or Biosamples and their applicability to the research question;

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- Inclusion of a research protocol that relates directly to the access request and specifically outlines the analysis of OHS Data and/or Biosamples;
- Inclusion of evidence of funding and/or peer-review, if applicable;
- Status of research ethics approval;
- Consistency between the research ethics submission and approval letter, the research protocol and the information provided in the *Data and Biosample Access Application Form* or *OHS-ICES Application Form*;
- Inclusion of other supporting documents (e.g., Applicant's CV); and
- The Applicant and the Host Institution has confirmed adequate policies and processes regarding privacy, information security and confidentiality are in place.

Once administrative completeness has been achieved, the access request will then be assessed by the AC. The AC considers the following criteria in making the final decision on an access request:

- The Applicant is a *Bona Fide* Researcher (i.e., evidence that the researcher has relevant experience and qualifications);
- The proposed research plan is clear, novel and demonstrates scientific excellence;
- The Applicant and co-investigators have relevant experience and qualifications to execute the proposed study;
- The research study is compatible with the vision and ultimate goal of the OHS and its funders;
- The Applicant has adequate financial and human resources (collaborators and staff) to effectively complete the proposed study;
- The proposed study has a potentially beneficial impact on the future use of the Data and/or Biosample repositories;
- Any other criterion that the OHS deems suitable to add to the list.

All criteria must be met.

The AC also assesses the access request's potential to enrich the Data and/or Biosample repositories in making its final decision.

Applications for projects focused on particular subsets of participants or communities, or may involve a high risk of reidentification, may undergo additional review. The OHS encourages Applicants with research questions concerning particular communities to engage with those communities about their research question prior to submitting their Application.

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c. Requests for Access to Biological Samples

Some 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, and multiplex assay approaches that minimize volume requirements are preferred. The OHS may suggest alternative assays that use a smaller amount of Biosamples than the assays indicated by the Applicant. Applicants must indicate if the desired analyses can be completed using more than one sample type (e.g., serum or plasma) to allow for selection from the most abundant type of available Biosamples.

Priority for studies requesting Biosamples will be given to studies that are novel and exhibit scientific excellence as determined by the AC. In order to efficiently manage and maximize use of the Biosamples, however, the following criteria will also be considered; the project:

- Does not make use of Biosamples from those Participants with the fewest Biosamples;
- Uses thawed Biosamples whenever possible;
- Uses the smallest Biosample volume possible;
- Includes analytes that have not been previously measured in the same Biosample set;
- Includes a proposed analyte analysis and/or methodology that present(s) a high probability of providing accurate results;
- Includes significant justification if the request is for >500µL for non-DNA Biosamples or >2µg for DNA Biosamples; and/or
- Can be integrated with other studies to conserve Biosamples or minimize freeze-thaw cycles.

In general, access requests will not be accepted from Applicants who wish to access Biosamples to test methodologies, test laboratory/analytical equipment, perform pilot studies, or for other activities that are not consistent with the goals of the OHS. However, discovery research may be permitted if the justification for using Biosamples from Participants is sufficiently robust.

Approved Users are prohibited from using Biosamples in any experiments involving humans or in contact with any cells or other materials to be infused into humans. Biosamples will not be released for use in animal research or research with recombinant DNA.

For approved Biosample access requests, the Biosamples will be shipped to the laboratory specified in the *Application Form*. Relevant shipping details and the staggered release of Biosamples will be coordinated between the OHS and the Approved User. Within one Business Day of receiving a shipment of Biosamples, the Approved User must confirm with the OHS that the shipments containing Biosamples have been received. If there is no acknowledgement of

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receipt, subsequent shipments will not be sent. Subsequent Biosample release may also be dependent upon successful analysis of initially released Biosamples, including demonstration of assay reproducibility.

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* or *OHS-ICES Application Form*. This will be discussed with the Applicant at the time of study approval before signing the *Data and Biosample Access Agreement* or the equivalent supplemental agreement.

If a request for Biosamples is approved, the Approved User acknowledges that the Biosamples provided by the OHS may contain viruses, latent viral genomes or other infectious agents. The Approved User will undertake to treat such Biosamples as if they are not free from contamination and to ensure that all Biosamples are handled by appropriately trained personnel under laboratory conditions that incorporate adequate biohazard containment. From the time of receipt, the Approved User is fully responsible for the safe and appropriate handling of the Biosamples.

d. Resubmission Process

In the case of a refusal or incomplete application, the Applicant will be notified by the OHS.

Incomplete Applications

If the Application is incomplete or more details are requested, the Applicant will be allowed to resubmit his/her *Application Form* with the necessary information/documentation/approvals.

Application Refusals

If the Applicant is refused, the Applicant can resubmit a new *Application Form*, addressing the comments relayed by the AC. Any refusal will be accompanied by reasons for the refusal and resubmission will be permitted. If the AC 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.

In case of dispute, the Applicant's concerns may be taken to additional members of the OHS AC, the CanPath AC, or OICR's Executive Leadership. The decision of OICR's Executive Leadership is final.

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e. CanPath Access Requests with OHS Data

Applicants submitting access requests to CanPath for Harmonized Data may include Data that are available only through the OHS and are not part of the CanPath Harmonized Data. All access requests for CanPath Harmonized Data must be directed to CanPath's Access Office (see the CanPath Access Portal here: https://portal.canpath.ca/).

To streamline the access request process, in cases where Applicants to CanPath have requested OHS Data that are not included in the CanPath Harmonized Data, the OHS will honour any access approval granted by the CanPath Access Committee. These Applicants will be considered Approved Users under this *Access Policy* and will not be required to submit a separate *Data and Biosample Access Application Form* to the OHS for the OHS Data included in their CanPath access request.

Upon approval by the CanPath Access Committee, Approved Users and their Authorized Institutional Legal Representative(s) are required to sign a separate OHS *Data and Biosample Access Agreement* to receive the OHS Data. The access period for OHS Data will follow the period specified in the CanPath *Data and Biosample Access Agreement*. OHS Access fees may be applied to the OHS Data.

The OHS will honour the CanPath Annual Progress Report(s) and Final Reports submitted by Approved Users for their Approved Research Projects. Similarly, the OHS will honour approved CanPath Amendment Forms where amendments affect the overall Approved Research Project, including renewed access to Data. In cases where Approved Users wish to amend their Approved Research Project in ways that specifically affect OHS Data (e.g., requesting additional OHS Data), they must submit an OHS *Amendment Form* to the OHS. All Derived Data, including Record-Level Data, and supporting documentation resulting from analysis of OHS Data must be returned to the OHS. Approved Users are required to submit a *Certificate of Destruction* to the OHS for the OHS Data as stipulated in the OHS *Data and Biosample Access Agreement*.

Unanticipated Events involving a breach of ethics and/or compromised data/material security, integrity or confidentiality must be reported to the OHS as well as to CanPath at the first reasonable opportunity by email and telephone call. Approved Users must submit an OHS *Unanticipated Events Form* to the OHS within 48 hours of the event.

9. Confidentiality of Research Projects Submitted

All information about Approved Research Projects and access requests submitted to the OHS will be kept confidential except as otherwise indicated in this *Access Policy*. Once access to Data

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and/or Biosamples is granted, the following information will be added to the publicly available OHS website:

- Title of the Approved Research Project;
- Name(s) of the investigator(s) involved;
- Name(s) of the institution(s) involved;
- Project approval date; and
- A lay summary of the scientific abstract submitted by the Applicant.

Upon completion of the project, a lay summary of the results submitted by the Approved User will be added to the OHS's publicly accessible website along with links to any publications, if available, as well as shared in participant newsletters. The OHS reserves the right to edit or modify any summaries submitted to suit the needs of the OHS website and/or other publicly available material.

As a member of CanPath, the OHS may share limited information within CanPath for the purposes of reporting interest in the resource. If an OHS access request overlaps with other CanPath requests, additional communication may occur within CanPath to properly facilitate the request.

10. Publication Policy

Approved Users are strongly encouraged to publish the results of their Approved Research Projects to benefit both the scientific community and the general population. The OHS encourages Approved Users to seek publication in peer-reviewed open access journals.

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

All publications and abstracts, including electronic submissions that use Data and/or Biosamples from the OHS, should be submitted to the OHS Access Office *at least two weeks before* they are initially submitted to a journal or conference. Likewise, presentations should be submitted at least one week prior to the presentation date. The OHS will review the submission to ensure that no individuals or communities are identified and that the analyses included are within the scope of the approved *Application Form*. The OHS must be informed of any substantive changes made to submitted manuscripts.

All cell sizes less than 5 must be suppressed prior to sharing any results. This applies to any

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results, including from imputed data, represented as counts, rates, percentages, or in any other form where the exact numbers can be inferred from other information presented (e.g., from a table or graph). Cell sizes less than 5 may be collapsed into other categories or replaced with "<5" or "less than 5".

To ensure that all work using OHS Data and/or Biosamples is easily identified, including in electronic searches, the OHS encourages Approved Users to include "Ontario Health Study" as a keyword and in the abstract of any publications and presentations.

Authors must acknowledge the contribution of the OHS in their publications or presentations where Data and/or Biosamples from the OHS are used. Please contact the OHS Access Office for the most up-to-date acknowledgement.

For projects involving Linked Data, additional acknowledgements in publications may be required by the custodians of the data to which OHS Data and/or Biosamples have been linked.

The OHS does not allow Data, including Derived Data and Record-Level Data, to be stored in repositories outside of the OHS. Journals that request Data to be shared into a repository should be provided with the following statement:

> *"Data and biosamples from the Ontario Health Study (OHS) are available to researchers through the OHS access process. Additional information can be obtained by contacting access@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. Detailed information about presentations utilizing OHS Data and/or Biosamples must also be provided to the OHS (e.g., authors, title of presentation, date, and name of conference).

Approved Users are also encouraged to use the results of their Approved Research Projects in policy briefings and other related documents, as appropriate. These documents should be shared with the OHS to keep the OHS informed of the outputs of its Data and/or Biosamples. The OHS may provide support in refining the briefings, if desired by the Approved User.

11. Posting Derived Data

The OHS recognizes the scientific importance of improving the depth and breadth of its database. In order to achieve this goal, Approved Users accessing Data are required to submit

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Derived Data, including Record-Level Data, and associated documents to the OHS upon submission of the *Final Report.*

Biosamples are a finite resource. To facilitate proper management of Biosamples, Approved Users will have exclusive access to the Record-Level Data generated by the analysis of Biosamples for a period of one year. After this year, Approved Users are required to submit Derived Data, including Record-Level Data, and associated documents to the OHS even if the results of these analyses have not yet been published. The one-year period of exclusive access to the Record-Level Data resulting from the analysis of Biosamples will begin following the submission of the *Annual Update* reporting the analyses. Time elapsed in the event of a late submission of the *Annual Update* will be included in the one-year period of exclusive access. The OHS may provide reporting templates for returning supporting documentation. All Biosample analysis data are to be returned in both the raw format (initial data generated from laboratory instrument) and the analyzed format (analysis extracted from raw data) and are to be accompanied by a completed Derived Data report that will be provided by the OHS.

Derived Data will be made available by the OHS to other Approved Users that have successfully applied for access to Data and/or Biosamples through the established process. 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 more than one year is required, the Approved User may apply to the OHS for an extension by completing the *Data and Biosample Access Renewal Form*.

12. Intellectual Property

The objective of the OHS is to maximize public benefit from the Data and Biosamples collected by the OHS and its collaborators. Accordingly, Data and Biosamples will remain as accessible as possible. Therefore, Approved Users and Approved Institutions agree not to make Intellectual Property claims on the 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* (available at: https://www.oecd-ilibrary.org/science-and-technology/oecd-guidelines-for-the-licensing-of-genetic-inventions_9789264018273-en-fr) adopted by the Organisation for Economic Co-Operation and Development (OECD). Approved Users are expected to implement licensing policies that do not impede further research; see also the *Framework for Responsible Sharing of Genomic and Health-Related Data* (available at:

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685158/) by the Global Alliance for Genomics and Health.)

It is not the responsibility of the OHS to inform Approved Users of any in progress, approval pending or approved Intellectual Property claims or proprietary rights of any third parties.

13. Archiving or Destruction of Data

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 one (1) year from submission of the *Final Report*. Approved Users must submit a *Certificate of Destruction* once the archival period has ended and the Data and/or Biosamples have been destroyed. A plan for archiving or destruction of Data and/or Biosamples must be specified in the *Application Form*. If institutional policy of the Approved User requires a longer archival period, the dataset analyzed by the Approved User can be archived with the OHS for an additional period of time. The OHS does not have control over archiving/destruction of datasets accessed at ICES; this will be managed through the Approved User's separate agreement with ICES.

14. Compliance

The Approved User and the Approved Institution shall comply with: the *Access Policy* (as amended from time to time); the *Data and Biosample Access Agreement* or the equivalent supplemental agreement, and any renewals thereof; any requirements set out by the AC and/or OICR's Executive Leadership, as needed (see Section 8); any applicable requirements of OICR; and all applicable laws and regulations in regard to the subject matter of this *Access Policy*.

The Approved User shall report any deviation from full compliance with the *Access Policy* and the *Data and Biosample Access Agreement* or the equivalent supplemental agreement, using the *Unanticipated Events Form*.

In case of failure to comply with the provisions of this *Access Policy* and/or the *Data and Biosample Access Agreement* or the equivalent supplemental agreement, 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* or the equivalent supplemental agreement and legal action against the Approved User and Approved Institution, including a claim to recover damages. Approved Users who fail to comply with this

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Access Policy and/or the *Data and Biosample Access Agreement* or the equivalent supplemental agreement may risk being denied future access to OHS Data and Biosamples.

15. Financial Conditions

The OHS will provide Data and/or Biosamples to Approved Users on a partial cost-recovery basis. An estimated cost can be provided after review of the *Project Feasibility Assessment Form*. The final amount will be determined by the OHS and will be specified in the *Data and Biosample Access Agreement* or the equivalent supplemental agreement. Where Data Linkage is involved, the Approved User will be responsible for covering any fees collected by the custodians of those databases.

In addition to any fees charged for access to Data and/or Biosamples, Approved Users will be responsible for covering any costs related to packing and shipping Biosamples, including the return of any remaining/unused Biosamples to the OHS. Approved Users will also be responsible for any costs relating to securing permits, licenses or other documentation required to ship the Biosamples. Any taxes levied will also be covered by the Approved User.

16. Public Relations

All press releases describing research based on analyses of Data and/or Biosamples should be approved by the OHS prior to release. OHS/OICR Communications also may decide to pursue public relations opportunities about noteworthy activities or publications involving the OHS Data and Biosamples, and will expect lead authors to agree to these opportunities and to make themselves available for related media events. The OHS may also ask lead authors to prepare a summary of manuscripts incorporating analyses of Data and/or Biosamples to include in reports to stakeholders and future funding applications for core support of the OHS.

Approved Users are encouraged to promote their Approved Research Projects and associated findings on social media platforms. To amplify the reach of dissemination efforts, Approved Users are directed to tag the OHS on Facebook (@OntarioHealthStudy) or LinkedIn (@Ontario Health Study).

17. Amendments to the Access Policy

This *Access Policy* will be reviewed at least every two years, or more frequently as needed. Amendments must be approved by OICR's Executive Leadership. In case of amendments to this

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Access Policy, a new version will be provided to all researchers who have inquired about access to Data and/or Biosamples.