CanPath
Canadian Partnership for Tomorrow's Health

CANADIAN PARTNERSHIP FOR TOMORROW'S HEALTH (CanPath)

ACCESS POLICY

Approved March 16, 2022

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1. PRELIMINARY CHAPTER

a. Canadian Partnership for Tomorrow's Health: Overview

The Canadian Partnership for Tomorrow's Health (CanPath) – the largest study of its kind ever undertaken in Canada – has enrolled more than 330,000 Canadians who have agreed to be followed for their adult lifetime, to allow researchers to explore how genetics, environment, lifestyle, and behaviour interact and contribute to the development of cancer and other chronic diseases.

Currently, this pan-Canadian project has seven participating cohorts, each under the governance of their respective institutions ("Contributing Institutions"), as listed below:

THE ATLANTIC PARTNERSHIP FOR TOMORROW'S HEALTH
Atlantic Provinces of New Brunswick, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island (http://atlanticpath.ca/), DALHOUSIE UNIVERSITY

CARTaGENE
Québec (https://www.cartagene.qc.ca/en/home), CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE

ONTARIO HEALTH STUDY
Ontario (https://ontariohealthstudy.ca/), ONTARIO INSTITUTE FOR CANCER RESEARCH

ALBERTA'S TOMORROW PROJECT
Alberta (https://myatp.ca), ALBERTA HEALTH SERVICES

BC GENERATIONS PROJECT
British Columbia (https://www.bcgenerationsproject.ca/), BC CANCER, part of the PROVINCIAL HEALTH SERVICES AUTHORITY

THE MANITOBA TOMORROW PROJECT
Manitoba (https://manitobatomorrowproject.ca), CANCERCARE MANITOBA

HEALTHY FUTURE SASK
Saskatchewan, SASKATCHEWAN CANCER AGENCY

The Contributing Institutions are collaborating to create a national infrastructure. They are working together under a common policy framework, which, while recognizing the specificity of each Contributing Institution, allows them to be part of a collective endeavour. To achieve this, the Contributing Institutions have invested significant resources to harmonize approaches, tools, and data, resulting in a pan-Canadian dataset and a suite of biosamples, the CanPath Data

and Biosamples.

The Contributing Institutions have collected health, lifestyle and environmental information from Participants for over a decade, including biosamples, as well as physical measurements such as weight and height. The information contributed by Participants over time will provide the basis to explore the reasons why some individuals develop chronic diseases or cancer while others do not.

Each Contributing Institution remains the custodian of the data and biosamples obtained from their respective Contributing Institution's participants but they have entered into an agreement with the University of Toronto to support data and biosample sharing with the scientific community through a centralized access system governed by this *Access Policy*.

The Leadership Team of CanPath (as defined below) is responsible for providing guidance and leadership to CanPath's pan-Canadian strategic directions, scientific priorities, continuing development, and oversight of operations, including the development and approval of strategic plans, and approval of operational work plans that guide CanPath's establishment, implementation, usage, and sustainability.

CanPath's operational activities are guided by a committee of the Contributing Institutions' Scientific Directors, as well as the operations leads of each cohort. This Operations Committee, also referred to as the CanPath Operations Committee in the *Data and Biosample Access Agreement*, reports its activities to the Leadership Team of CanPath.

The Access Office (as defined below) will report its activities to both the Operations Committee and the Leadership Team of CanPath.

The Access Office and the Contributing Institutions will share information about general and specific queries and access requests they receive to ensure the appropriate coordination and integration of access activities.

For more information, please visit CanPath's official website: https://www.canpath.ca.

b. Objectives

The **Purpose** of CanPath is to enhance and accelerate research for a healthier Canada.

The **Vision** of CanPath is working together for a world without chronic disease and cancer.

The **Mission** of CanPath is to provide a national platform for population-level health research in Canada and globally.

This *Access Policy* (hereafter "*Policy*") is guided by the Principles in the *Framework for Responsible Sharing of Genomic and Health-Related Data* (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685158/) of the Global Alliance for Genomics

and Health. It covers all *Access Applications* from researchers seeking access to CanPath Data and/or Biosamples (see Section 4 b). This *Policy* will be publicly available on the CanPath Portal, along with the *Publications Policy* and the *Intellectual Property Policy*.

2. GUIDING PRINCIPLES

In alignment with its Mission and Values, and as further described in Section 4, CanPath seeks to share its resource with both national and international scientific communities by:

- **Promoting the common good** by maximizing collaborative research for the benefit of all;
- Ensuring the **generation of high-quality research**;
- Making CanPath 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 CanPath database**, including through the **return of quality derived data** by researchers; and
- Managing access to CanPath Biosamples to **balance current and future needs**.

3. DEFINITIONS

Access Committee (AC): the independent committee that reviews and makes decisions on applications for access to CanPath Data and/or Biosamples. Its composition and purpose are set out in its terms of reference, as amended from time to time.

Access Office: the office that responds to queries, manages the access process, and receives and processes *Access Application Forms* from national and international researchers seeking to access CanPath Data and/or Biosamples. It hosts the Access Officer (AO), CanPath Data Manager, CanPath Administrative Assistant, and National Biosamples Coordinator (NBC).

Access Officer (AO): the officer that heads the Access Office and assesses *Access Application Forms* and associated documentation from national and international researchers for administrative completeness and ethics-related issues, responds to feasibility queries submitted prior to the application, provides relevant support during the application process, and prepares the feasibility assessment form. The AO's roles and responsibilities are further defined in the terms of reference for this position, as amended from time to time.

***Access Policy*:** the policy governing access to CanPath Data and Biosamples, which, together with the *Intellectual Property Policy*, *Publications Policy* and *Data and Biosamples Access Agreement ("Access Agreement")*, outline CanPath's access requirements and the obligations of the Approved User and Approved Institution(s). It forms an integral part of the *Access Agreement*.

Applicant: a researcher applying for access to CanPath 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, etc.), 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 CanPath Data and/or Biosamples has been granted by the Access Committee. It will be listed on the publicly available CanPath website along with a lay summary of the project.

Approved User: an Applicant granted access to CanPath Data and/or Biosamples by the Access Committee.

Biosamples: the coded biosamples made available to researchers through the CanPath Access Process.

Coded Data and Biosamples: data and biosamples, also referred to as materials in the *Access Agreement*, for which identifiers have been removed and replaced by a code.

Contributing Institutions: refers to collectively, all of the following institutions that have contributed or will contribute their Institution Data and Biosamples for the purposes of the CanPath: BC Cancer, Part of the Provincial Health Services Authority in respect of The BC Generations Project; Alberta Health Services, a corporation established under the Regional Health Authorities Act (Alberta), in respect of Alberta's Tomorrow Project; Saskatchewan Cancer Agency, in respect of Health Future Sask; CancerCare Manitoba in respect of the Manitoba Tomorrow Project; Ontario Institute for Cancer Research in respect of the Ontario Health Study; Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine) in respect of the CARTaGENE Project; Dalhousie University in respect of The Atlantic PATH Project, and such other institutions that become a contributing institution and sign a Data and Biosample Sharing Agreement with the Partnership.

Harmonized Data: datasets stated in the Data and Material Sharing Agreement between CanPath and the regional cohorts, including:

- Baseline Health and Risk Factors Questionnaire Data
- Baseline Health and Risk Factors Questionnaire – Additional Diseases Data
- Baseline Mental Health Questionnaire Data
- Baseline Physical Measures Questionnaire Data

- CanPath Follow-up Questionnaire Data
- CanPath Occupational History Questionnaire Data
- Pre-analytical data related to biological samples
- Genotyping data from the national funded genotyping project
- COVID-19 Questionnaire (2020)
- COVID-19 Serology Questionnaire (2021)
- COVID-19 Additional Serology Questionnaires (2021-2022)
- COVID-19 Serology Analysis Results (2021-2022)

CanPath Access Process: the process governed by the *Access Policy* and implemented through the Access Office, Access Committee and approved operating procedures. It is the process for gaining access to CanPath Data and/or Biosamples and is composed of three steps: 1) Administrative Assessment, 2) Feasibility Assessment, 3) Access Committee Review.

CanPath Data and Biosample Access Agreement ("*Access Agreement*"): a signed agreement between and among the Approved User, the Approved Institution(s) and the University of Toronto that sets out the terms and conditions of access to and use of CanPath Data and/or Biosamples. The *Access Agreement* legally binds its signatories in conformity with this *Policy*. The University of Toronto acts on behalf of the Contributing Institutions.

CanPath Data and Biosample Access Application Form ("*Access Application Form*"): the form submitted to the Access Office by the Applicant (via the CanPath Portal) to request access to CanPath Data and/or Biosamples (also referred to as material in the *Access Agreement*). It includes, among other things, a description of the Applicant's research project and research team.

CanPath Leadership Team: the team provides guidance and leadership to CanPath's pan-Canadian strategic directions, scientific priorities, continuing development, and oversight of operations, including the development and approval of strategic plans, and approval of operational work plans that guide CanPath's establishment, implementation, usage, and sustainability. The Leadership Team is composed of the CanPath Executive Leads (National Scientific Director, National Scientific Co-Director, and Executive Director), Regional Scientific Directors, with support from members of the National Coordinator Centre staff. This team receives advice from the National Strategic Advisory Council (NSAC), a committee of the CanPath funders, sponsors and contributing institutions, and from the International Scientific Advisory Board (ISAB).

CanPath Operations Committee: the committee composed of the Scientific Directors and Operations Leads from each regional cohort, the CanPath Executive Director, the CanPath National Scientific Director, the Ethical, Legal and Social Issues Standing Committee Chair, the Harmonization Standing Committee Chair, the Biosamples Standing Committee Chair, and the National Coordinating Centre Research Operations Manager. Its composition and purpose are set out in its terms of reference, as amended from time to time.

Data: the coded data made available to researchers through the CanPath Access Process.

Data Manager: the person responsible for managing the data within the National Data Repository and preparing invoices/datasets for Approved Users.

Expedited Access Review: for applications requesting use of Harmonized Data, the application will be reviewed by the Chair of the Access Committee or a delegated Access Committee member. The Access Committee Chair, or delegate, will review the application package and complete the Harmonized Data Access Review Form for submission to the Access Office.

Full Committee Review: for applications requesting more than Harmonized Data (e.g., data linkage, biosamples), the application will be reviewed by a quorum of Access Committee members at a bimonthly meeting.

Guiding Principles: the philosophy of CanPath that seeks to share its resource with both national and international scientific communities. See Section 2 of this Policy for a list of CanPath Guiding Principles.

Harmonized Data: the Harmonized Data includes information related to health and risk factors, mental health, physical measures, and biological sample pre-analytical data collected by the British Columbia Generations Project, Alberta's Tomorrow Project, The Manitoba Tomorrow Project, Ontario Health Study, CARTaGENE (Quebec), and Atlantic Partnership for Tomorrow's Health Study.

Intellectual Property Policy: the policy aims to promote a wide and accessible distribution of knowledge through the use of Data and/or Biosamples and lays out the parameters regarding intellectual property claims by Approved Users and Approved Institutions. It is an integral part of the *Access Agreement*.

Large Ask: Biosample requests of >500 µL for non-DNA samples or >2 µg for DNA samples.

National Biosamples Coordinator (NBC): the coordinator responsible for providing and presenting the consolidated biosample assessment for all received *Access Application Forms* involving biosamples. The NBC will also assist, where necessary, the Access Officer regarding biosample queries. The NBC is a member of the Access Office. The NBC's roles and responsibilities are further defined in its terms of reference.

National Coordinating Centre (NCC): manages all aspects of operation for CanPath, including housing the Access Office, distributing funds to regional cohorts, secretariat duties for all committees and working groups, and entering into access agreements with partner institutions.

Participants: individuals who consented to donate their data and/or biosamples to the CanPath Contributing Institutions.

Publications Policy: the policy aims to encourage scientific publication of all types while

sustaining the highest quality research. It provides Approved Users with guidance on authorship and how best to acknowledge the use of CanPath Data and/or Biosamples. It is an integral part of the *Access Agreement*.

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

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

Re-Identification: The possibility of identifying a Participant based on a unique combination of data and/or other information.

University of Toronto (University): the University of Toronto became the scientific home for CanPath on April 1, 2019 and manages all aspects of operations for CanPath, including housing the Access Office and entering into access agreements with Approved Institutions.

4. ACCESS POLICY: OBJECTIVES AND SCOPE

a. Objectives

Large interoperable datasets promote the efficient, economical and ethical study of the role of genes, lifestyle and the environment in health and disease. CanPath recognizes the importance of data and biosamples sharing, publications, and presentations at scientific meetings.

The *Access Policy* has been developed and implemented to enable informed and efficient collaboration; encourage fair, timely and transparent access to CanPath Data and/or Biosamples for high-quality research; and ensure that CanPath Data and/or Biosamples are used in a scientific and ethical manner. The *Policy* is implemented through approved CanPath access procedures.

CanPath is committed to sharing CanPath Data and/or Biosamples and knowledge with both the national and international scientific communities in conformity with the informed consents provided by its Participants. The principles of data and biosamples access and sharing guide and enable high-quality scientific research (see Section 2 – Guiding Principles). Scientific data and knowledge are common goods and should be shared within an appropriate framework. CanPath's biosamples constitute a finite resource and the project has created procedures to ensure that this resource is optimally used, according to its long-term research goals of CanPath.

CanPath neither discriminates between Applicants based in Canada or abroad nor between Applicants based in public or private institutions. Moreover, no exclusive or preferential access will be given to any Applicant(s) or Approved Users(s).

CanPath recognizes the need for and importance of providing access to its Data to the CanPath Contributing Institutions and committee scientists for the purpose of quality assurance and cohort description.

b. Scope

This *Policy* highlights the various requirements for accessing CanPath Data and/or Biosamples. The Data include, but are not limited to, data generated from self-administered and interviewer-assisted questionnaires, physical measures, socio-demographic and environmental data, and data derived from environmental samples, biosamples and their derivatives. The CanPath Biosamples include, but are not limited to, serum, whole blood, plasma, and urine. Only Coded Data and/or Biosamples will be released to Approved Users.

Access to CanPath Data and/or Biosamples is granted for an agreed period. This period is set out in the *Access Agreement*. Upon expiration, Applicants can ask for renewal through the Access Office.

5. ACCESS LIMITATIONS

The data and biosamples collected or generated by CanPath will be made available to researchers employed within, or otherwise contractually bound to, public and private institutions that conduct scientific research and that meet the requirements of this *Policy*. Requests to access CanPath Data and/or Biosamples by law enforcement bodies or governmental agencies, for purposes other than research projects aligned with CanPath Guiding Principles, will be resisted within the limits of the law. Approved Users will be given access to CanPath Data and/or Biosamples for the period agreed upon in the *Access Agreement*, with the possibility of subsequent renewals.

The CanPath Data and/or Biosamples may not be used to address any questions other than the one(s) approved in Schedule A of the *Access Agreement*.

Access to CanPath Data and/or Biosamples is limited to the Approved Users, who have signed the *Access Agreement* and Research Staff members named in the *Access Agreement*, along with the Approved Institution(s), all of whom are bound by its terms and conditions.

6. PRIVACY OF PARTICIPANTS

The potential risk of individual re-identification requires safeguarding the privacy of the Participants and the confidentiality of their data and biosamples, while respecting their consent to participate in high-quality research by facilitating access and collaboration.

Approved Users must comply with the security practices and procedures outlined in the *Access Application Form*.

Approved Users must also store, manage, and use CanPath Data and/or Biosamples while using all reasonable efforts to maintain the security and confidentiality of the accessed data (including any copies thereof) and biosamples.

Approved Users must not attempt to re-identify any individual Participant by any means unless consented to by Participant. If the Approved User involuntarily identifies a Participant, the Access Office must immediately be informed in writing, and this identifying information must be destroyed.

7. ACCESS DOCUMENTS

a. CanPath Data and Biosample Access Application Form

To access CanPath Data and/or Biosamples, an Applicant must complete and submit the *CanPath Data and Biosample Access Application Form* along with the submission of the required documents:

- Detailed Research protocol containing specific research questions/aims
  - Protocol should include justification of requested variables, statistical analysis, etc.
- Approval Letter by a Research Ethics Board for submitted Research protocol
- 2-Page CV of the Principal Applicant
- Proof of scientific peer-review of Research protocol, such as a review by a funding agency, if applicable
- Evidence of funding, if applicable

This application will be received by the Access Office.

b. CanPath Data and Biosample Access Agreement

CanPath Data and/or Biosamples will be released to the Approved User after the Approved User, and the Approved Institution(s) have signed the *Access Agreement and paid all access fees*. The *Access Agreement* legally binds its signatories.

c. Annual Progress Report Form

To keep CanPath informed of the progress of the project, Approved Users will be required to complete this form within 30 days prior to the anniversary date of the Approved User's execution of the *Access Agreement*.

d. Amendment Form

Approved Users who successfully applied for CanPath Data and/or Biosamples but wish to make changes to their Approved Research Project must submit an *Amendment Form*. For example, an Amendment form is required for adding new Research Staff.

e. Final Report Form

Once an Approved Research Project has ended, Approved Users must submit a *Final Report* to the Access Office. This *Final Report* requires a summary of the research findings, confirmation that derived data has been submitted to CanPath, held CanPath data is destroyed, Biosamples were either destroyed or returned, as well as comments and suggestions to improve CanPath's access procedures.

8. REVIEW OF APPLICATIONS

a. General Procedure

CanPath General and Feasibility Queries

All initial queries should be submitted to access@canpath.ca. The Access Office will interact directly with researchers to provide information and responses to any queries submitted prior to the *Access Application Form*. These queries can include discussing the requirements for preparing the application with an Applicant, where requested, and establishing the conformity of a potential *Access Application* with the Guiding Principles of the CanPath and if the proposed project is likely to qualify for access to CanPath Data and/or Biosamples.

The Access Office will continue to interact with the Applicant throughout the process. The Access Office will also consider requests from researchers applying for funding and seek letters of support from CanPath.

CanPath Access Application Process

Applications for CanPath Data and/or Biosamples will be completed online by the Applicant (via the CanPath Portal). The Applicant must register as a user and provide all required forms and information to the Access Office.

After the submission fee has been received by the Access Office, the *Access Application Form* and other required documentation will initially be reviewed to verify administrative completeness. If the application or submitted documentation is incomplete, it will be returned to the Applicant.

Access review does not perform the same role as scientific peer review, such as might occur when a research project is submitted for review by a federal funding agency. That an applicant project has been subject to prior peer review is one factor among several that the AO and AC may consider in assessing applications for CanPath access. That a project has been reviewed by a funding agency would tend to indicate that a project poses a relatively low reputational risk to CanPath and is reviewable under the expedited access process, if it requests Harmonized Data.

The complete *Access Application Form* and other required documentation will then be assessed

for key operational aspects, including: the availability and feasibility of providing the requested data and/or biosamples; whether the *Access Application Form* provides sufficient details on how the requested data/biosamples are to be used; whether the research objectives are clearly stated and achievable with the proposed methods and timelines; what results will be returned to CanPath; and whether the applicants have demonstrated they have the required resources to complete the proposed research.

This Feasibility Assessment will be led by the Access Office. For Expedited Review, the AO will conduct the Feasibility Assessment at the same time as the Administrative Assessment. For Full Access Committee Review, All Scientific Directors, or Regional operations staff as delegated, of the regions in which data and/or biosamples are being sought will be offered the opportunity to take part in the assessment within a given timeframe. Additional scientific experts may be called upon if required (see Section 9. Confidentiality of Applications). If it is deemed that modifications are needed to the *Access Application Form* or submitted documents, the Access Office will contact the Applicant.

The AO will prepare a package, including a summary along with the application and supporting documentation and provide it to the AC. The AC will decide on whether to approve, conditionally approve or reject access to CanPath Data and/or Biosamples based on the criteria set forth below (Section 8.b.). For the Expedited review procedure more specifically, see the criteria below (section 8.b). In the case of a conditional approval or a rejection, the Applicant will be notified with an explanatory document outlining the reasons for the decision. Rejected *Access Application Forms* will have to be resubmitted (see Section 8 c for more information).

Should an application request only Harmonized Data, an Expedited Access Review will be completed upon recommendation by the Access Office. The AC Chair, or AC member delegate, will decide on whether to approve, conditionally approve, reject, or recommend the application for Full Access Committee Review. Outcomes for 'approve,' 'conditionally approve,' and 'reject' will follow the same process as Full Access Committee Reviews.

Upon approval, the Approved User will be notified and required, along with the Approved Institution(s), to sign the *Access Agreement*. The *Access Agreement* is a legally binding agreement that specifies the requirements for access to CanPath Data and/or Biosamples and any other project-specific requirements. Lay summaries of Approved Research Projects will be published on the CanPath website.

Follow-up with the Applicant, both before and after approvals, will be ensured by the Access Office.

b. Criteria for Review for the AC

All completed *Access Application Forms*, associated documentation, Administrative Assessment, and Feasibility Assessment will be forwarded to the AC Chair for Expedited Review and all members for Full Access Committee Review. Both types of AC review apply the following criteria in making the final decision on the access request:

- 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 both the Guiding Principles of CanPath and the informed consents signed by the Participants (see Section 2 of this *Policy*);
- The Access Office has provided proof of administrative completeness and availability of CanPath Data and/or Biosamples;
- The Access Office Administrative Assessment and the Feasibility Assessment conducted by the CanPath Scientific Directors, or their delegates, has established that the *Access Application Form* meets the following requirements:
    - The research project has been deemed scientifically sound, and its objectives are concise enough to constitute a single research project;
    - The existence of adequate resources to effectively complete the research project has been established (e.g., funding, collaborators and staff);
    - Sufficient justification for the need for the data and/or biosamples requested has been provided; and
    - The provision of the requested biosamples is justified based on the assessment of the value of returned data, the scientific contribution of the research project (required to be extraordinary in the event of a *Large Ask)*, the potential impact of providing the samples on future needs for the biosamples and the risk of sample depletion.

All criteria must be met.

c. Expedited Review

The AO will invite one Scientific Director or Regional Operations Staff to conduct the Feasibility Assessment alongside the Access Office.

The AO will recommend applications for Expedited Review if:

a. the applicant is requesting access only to Harmonized Data; and
b. the proposed research poses a low reputational risk to CanPath, assessed in reference to the proposed research question and the project's scientific merit.

The AO, in deciding whether to recommend an application for Expedited Review, may consider the following factors:

a. That the proposed project has been evaluated through a recognized scientific review or peer review process;
b. That there is evidence that the project has financial support; and
c. That the Research Team has sufficient membership and expertise to complete the analysis.

The AO will consult the Chair of the AC if there is uncertainty about the level of risk associated with an *Access Application Form*.

Note: The first two points must be satisfied for an application to be considered for Expedited Review; the remaining factors are supplemental considerations.

The AC Chair, or AC member delegate, when conducting an Expedited Review, can request that the full AC complete the review at the next bi-monthly teleconference if they feel further scrutiny is needed. A summary of approved access requests resulting from any Expedited Reviews will be provided for review at the bi-monthly teleconference of the AC.

d. Full Access Committee Review

Access Application Forms that do not meet the criteria for Expedited Review, or are recommended for full review by the AC Chair, will be reviewed by the full AC membership at a bi-monthly teleconference. The following criteria will be considered to determine if the *Access Application Form* is considered for regular review:

- Requests for data other than datasets listed as 'Harmonized data';
- Access to biosamples is requested;
- Application does not have proof of evaluation through a scientific review or peer review process;
- Research question addresses a potentially contentious research question (e.g., compares outcomes by ethnicity or community, potentially negative impact on subsets of participants) or with a high risk of reidentification; and
- Request includes administrative health linked data to be provided at the regional level.

When considering *Access Application Forms* requesting access to CanPath Biosamples, the following criteria will be considered:

- The research study has been deemed scientifically sound;
- The existence of adequate resources to effectively complete the research project has been established (e.g., funding, collaborators, staff);
- Sufficient justification for the need for the CanPath Biosamples requested has been provided; and
- The provision of the requested Biosamples is justified based on the assessment of the value of returned data, the scientific contribution of the research project (required to be extraordinary in the event of a Large Ask), the potential impact of providing the samples on future needs for the Biosamples and the risk of sample depletion.

All criteria must be met for the AC to approve the request.

e. Resubmission Process

The Applicant can resubmit the Access Application Form, addressing the initial reasons for refusal, for a second review.

9. CONFIDENTIALITY OF APPLICATIONS

All information on research projects submitted to CanPath will be kept strictly confidential

within the Access Office and access personnel at Contributing Institutions (note: all individuals have signed a Confidentiality Declaration before information is shared). Once access is granted, the following information will be added to the CanPath website:

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

Information related to queries and/or access requests may be shared, under confidentiality, with access personnel at Contributing Institutions and those providing additional support and/or scientific expertise to the Access Office.

Upon completion of the Approved Research Project, a lay summary of the results submitted by the Approved User will also be added to the CanPath website as per the *Access Agreement* and potentially used in other communications materials to promote CanPath.

10. COMPETING RESEARCH

Prior to submitting an Access Application Form, applicants are strongly encouraged to collaborate with researchers studying similar topics, either on their own or through the CanPath Scientist Forum on canpath.ca.

In the event similar applications are received concurrently by CanPath, each application will be considered and evaluated separately. Proposals that only require access to data will not be compared against each other.

There will be no exclusivity of access for data-only research projects.

11. PUBLICATIONS POLICY

The *Publications Policy* reflects the Guiding Principles outlined in Section 2 of the *Access Policy*. This *Publication Policy* is publicly available on the CanPath Portal.

12. INTELLECTUAL PROPERTY POLICY

The *Intellectual Property Policy* reflects the Guiding Principles outlined in Section 2 of the *Access Policy*. This *Intellectual Property Policy* is publicly available on the CanPath Portal.

13. POSTING OF DERIVED DATA

CanPath recognizes the importance of enriching its database. Approved Users obtaining access to CanPath Data and/or Biosamples will be required to provide a copy of their derived data, along with detailed methodology and/or metadata, back to CanPath as per the *Access Agreement*.

The exact nature of the derived data and the timeframe in which they must be provided will be determined during the review process and included as part of the *Access Agreement*. Such data will become an integral part of the CanPath Data and will be made available to other Approved Users. This will allow future investigators access to such enriched data and enable them to build upon previous research.

The need to protect intellectual property (e.g., patents) or pre-publication results may have corresponding constraints on public disclosure of derived data. In such a situation, and where the provided timeframe before public disclosure is insufficient, the Approved User may apply for an extension through the Access Office and as agreed upon in the *Access Agreement*.

14. DESTRUCTION OF DATA AND BIOSAMPLES

After the Approved Research Project is completed and the results are submitted for publication, the Approved User will be permitted to archive the transferred data for the period required by the nature of the Approved Research Project for peer review and audit purposes. No further analysis of the data may occur unless an amendment for the time extension has been submitted and approved.

The timeframe in which the CanPath Data ought to be destroyed (or not) will be determined during the review process and will be included as part of the *Access Agreement* while respecting the informed consents provided by Participants. The Approved User shall certify that the transferred Data (and all copies thereof) have been destroyed via signed letter on their Approved Institution letterhead confirming the destruction of data emailed to the Access Office. Biosamples are required to be destroyed or returned as requested by the Access Office after the Approved User completes and submits the mandatory *CanPath Study Biosample Closure Form-Part 1* a minimum of 6 weeks prior to study closure.

15. REPORTING

The Access Office requires the following reports from the Approved User: 1) an Annual Progress Report for research projects lasting more than one year; 2) renewed REB approval letter; 3) a Final Report; 4) an Amendment Form for any and all changes to the Approved Research Project; and, if Biosamples were requested, 5) a CanPath Study Biosample Closure Form – Parts 1 & 2.

a. Annual Progress Report

Approved Users for whom access has been granted for more than one year must complete an Annual Progress Report. The latter aims to keep the Access Office up-to-date with ongoing research projects using CanPath Data and/or Biosamples (general status of the project, complications encountered, etc.).

The Annual Progress Report must be submitted within 30 days prior to the anniversary date of

the Approved User's execution of the *Access Agreement*. An Annual Progress Report template will be emailed to the Approved User by the Access Office.

b. Final Report

Once an Approved Research Project has ended, Approved Users must submit a *Final Report* to the Access Office. The *Final Report* will contain a summary of the research findings and any resulting benefits for the public, as well as comments and suggestions from Approved Users to improve CanPath's access procedure. More specifically, it should contain the following elements:

- Title of the Approved Research Project;
- Name(s), status, and credentials of the Approved User;
- Name(s) of the Approved Institution(s) involved;
- Summary of key findings and potential benefits of the study. This information will be published on the CanPath website and used for promotional, educational and presentation purposes;
- List of publications, abstracts, presentations and other relevant output;
- Future output from CanPath Data and/or Biosamples;
- Status of CanPath Data and/or Biosamples (destroyed, returned, archived); and
- Status of derived data delivery to CanPath.

A Final Report template will be emailed to the Approved User by the Access Office.

c. Amendment Form

As set out in further detail in the *Access Agreement*, the Approved User must inform the Access Office of any changes to the Approved Research Project or the status of the Approved User or Approved Institution for continued approval. Moreover, if a new member of the Research Staff is named either in addition to or in replacement of the Approved User, the latter must notify the Access Office via an *Amendment Form*. They must be approved by the Access Office and enter into an *Access Agreement* with the University of Toronto.

This Amendment Form must be completed and submitted to the Access Office in the case of unanticipated events and/or changes during an Approved Research Project that may affect the Approved User's ability to achieve their research goals or change the information initially provided in the *Access Application Form*. Any perceived or real threat or changes to the security, integrity, or confidentiality of the CanPath Data and/or Biosamples, however, must immediately be reported to the Access Office, in compliance with the *Access Agreement*.

To facilitate this reporting process, the Access Office will evaluate the Amendment Form to determine the appropriate Access Committee Review. Non-substantial changes, such as administrative changes, to an Approved Research Project will be approved by the Access Officer and included in a modifications log. Substantial changes will be provided to the AC Chair for decision.

Examples of unanticipated events and/or changes include, but are not limited to, the following:

- Impossibility to complete the Approved Research Project (e.g., loss of funding; lapse of the Research Ethics Board's approval; loss or change of scientific direction);
- Changes to the information provided by the Approved User in the *Access Application Form*;
- Additional data is needed; or
- Any other changes that render full compliance with this *Access Policy* or the signed *Access Agreement* impossible.

d. Destruction of CanPath Data and/or Biosamples

Upon request of the Access Office and as stipulated in the *Access Agreement*, the Approved User must submit *a CanPath Study Biosample Closure Form – Parts 1 & 2* to the Access Office. This Final Report will certify that the transferred CanPath Data and all copies thereof have been destroyed or archived along with notification in writing to that effect from the Institution to the Access Office. If CanPath Data is archived, the Access Office will require notification of destruction in writing at the end of the archival period.

16. FINANCIAL CONDITIONS

The Approved User shall reimburse CanPath for any reasonable costs incurred in preparing and sending the CanPath Data and/or Biosamples to the Approved User. This amount will be determined by the Access Office and serve as a condition for access through the *Access Agreement*.

17. AMENDMENTS TO THIS *ACCESS POLICY*

This *Access Policy* may be amended from time to time. Changes to this *Access Policy* may be submitted by any member of the Access Office, the AC or the Access Infrastructure Working Group. Proposed changes will be reviewed by the Operations Committee and, where required, will be approved by the Leadership Team. Any amendments to this *Access Policy* will be made publicly available on the CanPath Portal. Approved Users will remain bound by the terms and conditions of the *Access Agreement* signed.

This *Access Policy*, along with the *Intellectual Property* and *Publications Policies*, will undergo a yearly review.