Atlantic PATH
PARTNERSHIP FOR TOMORROW'S HEALTH
For the Benefit of Future Generations

# DATA & BIOSAMPLES ACCESS POLICY

# FOR APPROVED RESEARCHERS

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## 1. Introduction to the Atlantic PATH study

The Atlantic Partnership for Tomorrow's Health (Atlantic PATH) study is part of a pan-Canadian initiative known as the Canadian Partnership for Tomorrow's Health (CanPath, formerly the Canadian Partnership for Tomorrow Project). CanPath is a prospective cohort study with five regional cohorts across Canada, including Atlantic PATH, CARTaGENE (Quebec), the Ontario Health Study, Alberta's Tomorrow Project, and the BC Generations Project. A sixth cohort, the Manitoba Tomorrow Project, has started the recruitment phase of their study. The purpose of Atlantic PATH is to examine the interplay of genetic, environment, lifestyle, and behavioural factors that contribute to the development of cancer and other chronic disease within a longitudinal cohort study framework.

Over 35,000 research participants have volunteered to be part of Atlantic PATH from the four Atlantic Provinces – New Brunswick, Newfoundland and Labrador, Nova Scotia, and Prince Edward Island. Participants provided information on their health and well-being, including demographics, personal health history, family history of disease, and health behaviours. They provided a series of biosamples for long-term storage to enable laboratory analysis, including blood, saliva, urine, and toenails. Research participants also provided physical measurements including height, weight, blood pressure, grip strength, and body composition.

Participants provided consent for their information to be collected, stored, and used for research; enriched with linkage to administrative health databases (e.g., cancer registries, physician billing, hospital discharge abstracts, vital statistics, and hospital-based and community-based ambulatory care); and re-contacted as needed for future research projects (ancillary studies).

Atlantic PATH has developed and implemented a research platform containing questionnaire data on health and health-related measures, biosamples, and linkage to administrative health databases.

Atlantic PATH is committed to providing data and biosamples for the purpose of research to regional, national, and international scientific communities, adhering to the principles of transparent and facilitated access, while maintaining privacy of research participants and confidentiality of their data.

## 2. Purpose of this document

This Data and Biosamples Access Policy details the requirements and procedures for accessing Atlantic PATH data and biosamples. Bona fide researchers may review data holdings online and submit proposals for investigator-initiated research.

Applicants are strongly encouraged to submit a Preliminary Data and Biosamples Access Application form, which will be used to determine if Atlantic PATH's data holdings meet the needs of the researcher. Upon request, Atlantic PATH will write letters of support for funding applications and/or Research Ethics Board (REB) applications.

The Atlantic PATH Data Access Committee will review the Data and Biosamples Access Application Form for projects that have secured funding, if required, and have received approval from a REB or a comparable decisional committee that has been formally designated to approve and/or monitor research involving humans with the aim of protecting the rights and welfare of the research participants.

## 3. Principles of Data Access

The minimum amount of anonymized, de-identified data and biosamples required to fulfill the purpose of the research project will be considered for release. Researchers will not receive exclusive access to an analysis or question of interest, data, and/or biosamples. Students/trainees are required to have an experienced supervisor for the duration of the project.

Atlantic PATH research participants have consented to be approached for future studies. Researchers may submit an application that is an ancillary project, in part or in full, which requires the collection of additional information through questionnaires, physical measures, environmental samples, and/or biosamples.

In order to continuously enrich the research platform, researchers will be required to return data collected and/or generated within each project for integration into existing Atlantic PATH holdings.

### 4. Preliminary Data and Biosample Sample Access Application

All access forms are available at: www.atlanticpath.ca.

The purpose of the Preliminary Data and Biosample Access Application is to allow Atlantic PATH to determine if the data and/or biosamples holdings meet the needs of the researcher. This step is voluntary, however, we strongly suggest that researchers submit this application to ensure project feasibility.

Upon successful review, we will provide a letter of assessment that:

(a) confirms project feasibility and that Atlantic PATH has sufficient data and/or biosamples to meet the request;

(b) confirms that data and/or biosamples may be made available pending the Atlantic PATH Data Access Committee's approval of the Data and Biosamples Access form; and (c) a cost recovery access estimate.

Researchers may also request a letter of support for funding and/or applications to REB or comparable review bodies.

## 5. Data and Biosamples Access Application

Once a project has received REB or equivalent approval (mandatory) and funding (if required), a researcher may submit a Data and Biosamples Access form.

The Data and Biosamples Access form requires the following information:

- Details about the Principal Investigator, the project team and host institution
- Scientific Abstract and Lay summary
- Objectives, project design, and methodology
- Detailed data and biosample requirements
- Detailed budget, and funding approval, if required
- Security and confidentiality practices and policies
- REB approval and any additional approvals required
- Return of data
- Plans for results dissemination
- Project timelines
- Signatures from the Applicant and an Authorized Institutional Representative

**STEP 1: Atlantic PATH Data Access Committee Review**

The Atlantic PATH Data Access Committee will review the application and associated documents and provide their decision in writing. Approved studies will be assigned an Atlantic PATH project number and the Principal Investigator will be the Approved Researcher and their host institution will be the Approved Host Institution.

Approved studies will receive a formal letter of approval, an invoice, as well as relevant attachments including a Data Sharing Agreement (for Principal Investigators external to Dalhousie University); Confidentiality Agreement; Data Sensitivity Policy; Publications Policy; Annual Renewal/Unanticipated Events/Significant Change form; Privacy Breach form; Data and Samples Return form; and Final Report form.

**STEP 2: Access to Atlantic PATH Data**

The Approved Researcher and all members of the research team who will have access to the data must return signed Confidentiality Agreements. All documents should be sent to Ellen.Sweeney@dal.ca and hard copies mailed c/o Dr. Ellen Sweeney, Atlantic PATH, 1494 Carlton Street, 2nd Floor, Halifax, Nova Scotia, B3H 3B7.

The Approved Researcher must return the signed Data Sensitivity Policy by email to Ellen.Sweeney@dal.ca.

For researchers external to Dalhousie University, a signed Data Sharing Agreement form must be signed by the Approved Researcher and their respective institution (Approved Host Institution). This form is then signed by Dalhousie University.

Once the signed documents are complete, Atlantic PATH will transfer data by a secure File Transfer Protocol and/or biosamples will be sent by secure courier to the Approved Researcher.

The Approved Researcher will provide confirmation of receiving data and/or biosamples within 24 hours of receipt to Ellen.Sweeney@dal.ca. The related invoice must be paid within 30 days.

**STEP 3: Access Renewal Form and/or Unanticipated Event/Significant Change Report Form**

Please email a completed Access Renewal Form and/or Unanticipated Event/Significant Change Report form for review by the Atlantic PATH Data Access Committee if you wish to:

- extend the data and/or biosamples access approval timeframe;
- inform Atlantic PATH about an unanticipated event or significant change in your research that may have an impact on the data and/or biosamples or that impacts your ability to achieve the research goals; or
- inform Atlantic PATH of a significant change to the information described in the approved, original Data and Biosamples Access submission. In this case, please also submit a revised Protocol and REB approval.

**STEP 4: Return of Data and/or Biosamples**

Please follow these timeframes for return of data and/or biosamples:

1) All biosamples must be returned one year after the end of the project and/or publication;
2) The original data files provided by Atlantic PATH to the Approved Researcher must be returned to Atlantic PATH and/or all electronic files must be deleted one year after the end of the project and/or publication; and
3) An original signed Data and/or Biosamples Return form must be submitted confirming that biosamples and data have been returned and copies of all data has been destroyed.

**STEP 5: Enriching the Atlantic PATH Research Platform**

Data generated will be returned to Atlantic PATH in order to enrich the research platform. Data must be returned at the point of publication, unless otherwise agreed upon during the application process.

**STEP 6: Final Project Report**

Please submit a Final Project Report once the project has been completed. This report should concisely summarize the outcomes of the research, the research findings, as well as any access renewals and unanticipated events/significant changes that occurred during the project.

This report must be submitted within three months of project completion. This is the final document in the Atlantic PATH Data and Biosamples Access Policy and submission constitutes notice of project closure.

## 6. Ancillary Projects

Ancillary studies involve the collection of additional information and/or biosamples from Atlantic PATH research participants. A project may be completely ancillary in nature or may be partly ancillary and also involve analysis of existing Atlantic PATH data and/or biosamples.

The consent form for the Ancillary Project will be jointly developed by the Approved Researcher and Atlantic PATH, and must clearly stipulate that the project is ancillary to the Atlantic PATH Study and participation in the Ancillary Project is not required for continued participation in Atlantic PATH.

The Approved Researcher will provide Atlantic PATH with:

- participant inclusion and exclusion criteria for the project;
- informed consent documents developed for the Ancillary Project;
- all data collection instruments (e.g., questionnaires, medical records abstraction form, etc.); and
- description of the additional measurement(s) or biosamples(s) to be collected.

The Ancillary Project may be conducted in two ways:

**Option 1**

Atlantic PATH will:

- Contact research participants and collect consent, data and/or biosamples on behalf of the Approved Researcher; and

- Compile the data and provide the Approved Researcher with de-identified data and biosamples for analysis.

**Option 2**

Atlantic PATH will:

- Contact research participants, provide the Approved Researcher's contact information, and encourage participation in the ancillary project.

In Option 2, the Approved Researcher will:

- Approach Atlantic PATH participants only for the research detailed in the Data and Biosamples Access application approved by the Atlantic PATH Data Access Committee;
- Collect consent, data and/or biosamples from research participants;
- Not retain Atlantic PATH participant contact information after the completion of the ancillary project data; and
- Provide data and/or biosamples to enrich the Atlantic PATH as per the Data and Biosamples Access Policy.

An Approved Researcher will have exclusive access to any additional data and/or biosamples collected in the Ancillary Project for an agreed period of time following data collection, generally one year from when the final data point was collected. This timeframe may be extended through submission and approval of an Access Renewal Form.

Once the approved time period has elapsed, new data and all derived data or test results will become part of the Atlantic PATH research platform and will be available to other investigators for inclusion in future projects as per Data and Biosamples Access Policy.

All costs incurred in contacting participants and collection and handling of new data or biosamples will be borne by the Approved Researcher.

## 7. Privacy of Participants, Confidentiality and Security of Data

Atlantic PATH will uphold the rights of its research participants by respecting their consent, protecting their privacy, and protecting the confidentiality of their data and biosamples.

Applicants must detail their plan to secure data and biosamples received from Atlantic PATH in the Data and Biosamples Access form.

Approved researchers will also assume these obligations upon receiving the data and/or biosamples. All Project Team members who will have access to data are required to sign and return a Confidentiality Agreement. The Approved Researcher must also sign and return the Data Sensitivity Policy, and must review the Publications Policy.

Approved researchers who violate conditions for release of data or any provision of this policy, or who misrepresent the nature of data supplied to them by Atlantic PATH, will be subject to

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sanctions, which may include refusal of future access to data, seizure of the data released, and/or legal action.

The following conditions apply to all data and biosamples transferred to the Approved Researcher and allows Atlantic PATH to meet its federal and provincial legislative requirements:

Only the minimum data and/or biosamples required to fulfill the purpose outlined in the Data and Biosamples Access form will be considered for release;

- The data and/or biosamples must only be used for the purposes for which they were requested;
- The release of data and/or biosamples must be approved by the Atlantic PATH Data Access Committee;
- The data and/or biosamples must be stored, managed, and used in strict confidentiality. In doing so, all reasonable efforts to maintain the security and confidentiality of the accessed data and/or biosamples, including any copies thereof, are to be employed;
- The Approved Researcher shall retain control of the transferred data and/or biosamples at all times. The data and/or biosamples may not be distributed, sold, disclosed, transmitted, or transferred to unauthorized parties without advance approval in writing from Atlantic PATH. Any additional uses or transfer of data and/or biosamples must be approved by Atlantic PATH in advance and in writing;
- Data files and unused biosamples shall be returned to Atlantic PATH when no longer required for the purpose for which they were made available, and any copies of the data shall be destroyed. The Approved Researcher will be required to certify in writing that this has been completed;
- The Approved Researcher will be required to make their employees -- and anyone who will have access to Atlantic PATH data and/or biosamples -- aware of the importance of maintaining privacy and confidentiality. The Approved Researcher must provide Atlantic PATH with the identities of all individuals who will have access to the data and/or biosamples. All identified individuals will also be required to sign a Confidentiality Agreement, originals of which will be forwarded to Atlantic PATH prior to release of data and/or biosamples; and
- Only coded (i.e. stripped of personal identifiers) data and/or biosamples will be provided to the Approved Researcher by Atlantic PATH. The Approved Researcher must not attempt to re-identify any individual participants by any means. If the Approved Researcher involuntarily identifies a participant, this constitutes a privacy breach and Atlantic PATH must be notified immediately using the Access Renewal Form and/or Unanticipated Event/Significant Change Report form.

## 8. Atlantic PATH Data Access Request Review Criteria

The Atlantic PATH Data Access Committee will review all Data and Biosample Access applications using the following criteria:

- Feasibility of the research project;

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- Compatibility of the research project with the vision, objectives and goals of Atlantic PATH;
- The proposed work must not directly overlap with an existing/ongoing research study;
- Experience and qualifications of the Applicant(s);
- Demonstration of adequate financial and human resources to effectively complete the proposed project, and to protect the integrity/security of data and/or biosamples;
- Adequacy of the Applicants' and the Host Institutions' processes regarding privacy and confidentiality;
- Potential impact on future use of the data and/or biosamples held by Atlantic PATH;
- Potential to enrich the Atlantic PATH data and/or biological sample repositories; and Potential for harm to Atlantic PATH from the additional re-contact of participants for Ancillary Projects.

The biosamples collected from Atlantic PATH participants are a finite source and require efficient management to maximize use. Therefore, the following will also be considered:

- Whether the project is requesting rare biosamples;
- Whether the project can use previously thawed samples;
- Whether the smallest volume possible is being requested; and
- Whether the project can be integrated with other projects to conserve biosamples and/or minimize the freeze-thaw cycles.

The Atlantic PATH Data Access Committee may consult with the Atlantic PATH Data Manager and external experts as required. The Applicant may be contacted with questions and/or required revisions.

## 9. Confidentiality of Access Requests

All information submitted to Atlantic PATH will be kept confidential except as otherwise indicated in this Data and Biosamples Access Policy. Once access to Atlantic PATH data and/or biosamples is granted, the following information will be added to the Atlantic PATH website:

- Title of the research project accepted;
- Name(s) of the Investigator(s) involved, position within the host institution and credentials;
- Name(s) of the Host Institution(s) involved;
- Start Year of the project; and
- A lay summary abstract submitted by the Approved Researcher.

At the completion of the project and concurrent with publication of the scientific results, Atlantic PATH commits to help promote the research findings (e.g., listing the publication on our website, and promoting via social media).

## 10. Publication Policy

Approved Researchers must review and adhere to the Atlantic PATH Publications Policy.

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Approved Researchers are strongly encouraged to publish their research results in peerreviewed publications to benefit both the scientific community and the general population. Atlantic PATH encourages scientific publications of all types, while sustaining the highest quality of research.

Atlantic PATH must be notified of all publications and presentations using Atlantic PATH data and/or biosamples, including ancillary studies.

One or more internal Atlantic PATH investigators must be included as contributing authors on relevant dissemination materials, including manuscripts.

All publications must be submitted to Atlantic PATH prior to submission for review. The review will focus primarily on ensuring that content related to Atlantic PATH is accurate; individual participants are not identified; Atlantic PATH and CanPath are properly acknowledged; and that the analyses are within the scope of the approved Data Access Application.

Authors must acknowledge the contribution of Atlantic PATH in publications and presentations. All publications must contain the following statement:

*This research has been conducted using Atlantic PATH [data and/or biosamples], under application [insert project number here, e.g., 2019-101].*

*Funding: The data used in this research were made available by the Atlantic Partnership for Tomorrow's Health (Atlantic PATH) study, which is the Atlantic Canada regional component of the Canadian Partnership for Tomorrow's Health funded by the Canadian Partnership Against Cancer and Health Canada. The views expressed herein represent the views of the authors and do not necessarily represent the views of Health Canada.*

Although not mandatory, approved users may consider including the following statement:

*Acknowledgements: We would like to thank the Atlantic PATH participants who donated their time, personal health history and biological samples to this project. We would also like to thank the Atlantic PATH team members for data collection and management.*

## 11. Intellectual Property

Approved Researchers and their host Approved Institution agree not to make intellectual property claims on Atlantic PATH's primary data, but may choose to obtain intellectual property rights on subsequent innovations and downstream discoveries arising from such data.

If applicable, Approved Researchers are strongly encouraged to follow the *Guidelines for the Licensing of Genetic Inventions* adopted by the Organization for Economic Co-Operation and Development (OECD). Approved Researchers are expected to implement licensing policies that do not impede further research; see also the United States National Institutes of Health's document on *Best Practices for the Licensing of Genomic Inventions*.

## 12. Glossary

**Ancillary Project:** An approved investigation that involves the collection and analysis of additional data and/or biosamples from research participants upon re-contact.

**Applicant:** A Canadian or international researcher conducting research relevant to Atlantic PATH, who is applying for access to data and/or biosamples from Atlantic PATH. All applicants must be affiliated with a public or private institution conducting scientific research.

**Approved Institution:** The public or private host institution with whom the Approved Researcher is affiliated for the purpose of the research project outlined in the *Full Access Application*.

**Approved Researcher:** An Applicant who is granted access to Atlantic PATH's data and/or biosamples by the Data Access Committee.

**Atlantic PATH Participants:** Individuals in the four Atlantic Provinces (New Brunswick,

Newfoundland and Labrador, Nova Scotia, and Prince Edward Island) who volunteered to be part of the Atlantic PATH study and provided express consent for their information and biosamples to be:

1. collected, stored, and used for research;
2. linked to administrative health databases (e.g. physician billing, cancer registries, etc.);
3. updated regularly with data obtained through follow-up questionnaires and the linked administrative databases; and
4. re-contacted as needed for future research projects.

**Authorized Institutional Representative:** An individual who will act as the representative of the Approved Host Institution. The Authorized Institutional Representative is determined by the institution, but must be in a position to legally bind their Institution.

**Biosamples:** The coded biosamples made available to Approved Researchers through the Atlantic PATH access process.

**Bona Fide Researcher:** A researcher in good standing associated with a public or private research or clinical institution, and who received Research Ethics Board approval for the project for which they are applying for de-identified data.

**Confidentiality:** The responsibility of an individual to safeguard the secrecy of data concerning another individual.

**Data Sharing Agreement:** For researchers external to Dalhousie, a signed agreement between Approved Researcher(s), the Approved Host Institution, and Atlantic PATH/Dalhousie University. This Agreement outlines the terms and conditions of data access and is legally binding. A signed original must be received by Atlantic PATH before access will be granted to Atlantic PATH data holdings.

**Data Access Committee:** The Atlantic PATH Data Access Committee will act in an oversight and monitoring capacity and will review Data and Biosample Access applications. The Data Access Committee will make decisions to approve, reject or request additional information about an access request based on the criteria outlined in this Data and Biosamples Access Policy.

**Data and Biosamples Access Policy (Access Policy):** This document that outlines Atlantic PATH's principles and guidelines related to the access of its data and biosamples holdings.

**Data Types:**

**Coded (De-identified) Data**: Data provided about participants for which all identifiers have been removed and replaced by a code. Identifiable information or information that could reasonably lead to identification of an individual includes but is not limited to demographic information such as names, addresses, date of birth, and contact information.

**Derived Data:** Any and all data generated from or based upon the use of Atlantic PATH data and/or biosamples for scientific analyses.

**Linked Data:** Coded data under the control of health data custodians as prescribed by the relevant provincial legislation that has been linked to Atlantic PATH data. The source of this coded data may include provincial administrative health databases (e.g. physician billing, cancer registries, etc.).

**Privacy:** An individual's right to protection of their data against misuse or unauthorized disclosure.