Atlantic PATH

DATA & BIOLOGICAL SAMPLES ACCESS POLICY

RESEARCHERS

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

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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 Project (CPTP). The CPTP is a prospective cohort study with five regional cohorts across Canada (the Atlantic PATH, the Alberta Tomorrow Project, the Ontario Health Study, CARTaGENE (Quebec), and the BC Generations Project).

The purpose of the Atlantic PATH Study is to examine the interplay of genetic, environment, lifestyle, and behavioural factors that contribute to the development of chronic diseases within a longitudinal cohort study framework. Diseases include, but are not limited to, cancer, heart disease and diabetes, while associated factors include socioeconomics, obesity, health-seeking behaviours, and health outcomes.

The goal of The Atlantic PATH Study is to develop and make available a Research Platform containing self-report data on a number of health and health-related measures in addition to biological samples and linked to past, present and future provincial health utilization and related data.

Over 30,000 research participants have volunteered to be part of the Atlantic PATH Study from the four Atlantic Provinces – New Brunswick, Newfoundland and Labrador, Nova Scotia, and Prince Edward Island. They have provided express consent for their information to be collected, stored, and used for research; enriched with linkage with provincial health databases (e.g. physician billing, hospital discharge), death registries and cancer registries, updated for the next 30 years; and re-contacted as needed for future research projects (ancillary studies).

The research 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 biological samples for long-term storage to enable laboratory analysis in the future, including blood, saliva, urine and toenails. Research participants also provided a number of physical measurements including height, weight, blood pressure, grip strength, and body composition.

The Atlantic PATH Study is committed to releasing data and biological samples 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 *Access Policy* details the requirements and procedures for accessing the Atlantic PATH Research Platform. *Bona fide* researchers may review data holdings online and submit proposals for investigator-initiated research.

The application process has two stages. Upon review of a *Preliminary Data & Biological Samples Access Application*, the Atlantic PATH Study will issue a letter of feasibility and a quote outlining reasonable costs incurred in preparing and transferring Data and/or Biological Samples; these may be used to support funding and/or Research Ethics Board applications (see Appendix 2). The Atlantic PATH Data & Biological Samples Access Committee will review *Full Data & Biological samples Access Applications* (see Appendix 3) for projects that have secured funding, if required,

and have received approval from a Research Ethics Board (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 research participants.

3. Principles of Data Access

The minimum amount of de-identified data and biological samples 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 biological samples. Students or trainees are required to have an experienced supervisor for the duration of their project.

Atlantic PATH research participants have consented to be approached for future studies and/or biological specimens' collection. 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 biological samples.

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. The timeframes for data return and eventual release to other researchers will be agreed upon with the principal investigator for each project.

4. Preliminary Data & Biological Sample Access Application

Please refer to Appendix 1 for a visual depiction of this Access Process. All *Data & Biological Sample Access forms* are available at: www.atlanticpath.ca

Data holdings: Please review the Questionnaires, Data Dictionary and Variables list.
Biological Samples: Please review the Standard Operating Procedures used for biological samples collection.

The purpose of the *Preliminary Data & Biological Sample Access* application (Appendix 2) is to allow us to determine if we have the data and/or biological samples that you require. 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 biological samples to meet the request;
(b) confirms that data and/or biological samples may be made available pending Atlantic PATH Data & Biological Samples Access Committee (DAC) approval of the *Full Application Form*; and
(c) a cost recovery access estimate and timeframes.

You may use this letter of assessment for funding and/or applications to research ethics board (REB) or comparable review bodies.

5. Full Data & Biological Samples Access Application

Once your project has received REB or equivalent approval (mandatory) and funding (if required) you may submit a *Full Data & Biological Samples Access Application* (Appendix 3). Please attach the relevant sections of your research proposal.

The *Full Data & Biological Samples Access Application* will generally require the following information:

1. Details about the Principal Investigator, the project team and host institution
2. Project information: Scientific Abstract and Lay summary
3. Project design, methodology, purpose & objectives, significance & benefits
4. Detailed data requirements
5. Biological samples requirements with justification, biomarker of interest stability, plans for transportation, security and storage
6. Details of the laboratory identified to analyse the biological samples
7. Ancillary project details
8. Detailed budget, and funding approval if required
9. Security and confidentiality practices and policies
10. REB approval and any additional approvals required
11. Plans for results dissemination
12. Proposed timelines

STEP 1: Atlantic PATH Data & Biological Samples Access Committee (Atlantic PATH DAC) review
The Atlantic PATH Atlantic PATH Data & Biological Samples Access Committee will review the application and associated documents and notify you of their decision in writing. Any refusals will be accompanied by reasons for the refusal. 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.

STEP 2: Access to Controlled Atlantic PATH Data
Once the data and/or biological samples request has been finalized, the Approved Researcher will receive an invoice and two forms by email.
The Approved Researcher must submit the following:

- full payment of the cost recovery invoice;
- three documents with original signatures (scanned signatures will not be accepted):
    - *Data & Biological Samples Access Agreement* (the "*Access Agreement*") signed by the Approved Researcher and an Authorized Institutional Representative from the Approved Host Institution;
    - If applicable, a *Material Transfer Agreement* signed by the Approved Researcher and a representative of the laboratory equipped to perform the analysis; and
    - Copy of the Atlantic PATH *Full Data and Biological Samples Access Application* (as submitted to the Atlantic PATH Data & Biological Samples Access Committee).

Please mail the documents to:

c/o Jason Hicks, Atlantic PATH, 1494 Carlton Street, Halifax, Nova Scotia, B3H 3B7.

Only when full payment and documents are received, Atlantic PATH will set-up a secure FTP protocol for data transfer and/or send the biological samples by secure courier to the Approved Researcher.

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 (Appendix 4) for Atlantic PATH Data & Biological Samples Access Committee review if you wish to:

- extend the data and/or biological samples access approval timeframe;
- inform us about an unanticipated event or significant change in your research that may have an impact on the project data and/or biological samples and impacts your ability to achieve the research goals;
- inform us of a significant change to the information described in the approved, original *Full Data & Biological samples Access Application* submission. Please also submit a revised Protocol and REB approval.

STEP 4: Return of Data and/or Biological Samples
Please follow these timeframes for return of data and/or biological samples:

- All biological samples must be returned upon completion of samples analysis; and
- All data must be returned at the end of the data analysis phase and all copies that are not required to be archived for peer review and audit purposes must be destroyed;
- A copy of any and all data derived or collected must be provided for incorporation into the Atlantic PATH Research Platform at the end of the data analysis phase. This data will be made available for future researchers one year after publication of the original project or in a mutually agreed timeframe;
- Original signed *Data and/or Biological Samples Return form* (Appendix 6) confirming that biological samples and data have been returned and copies of all data has been destroyed must be submitted prior to publication.

STEP 5: Final Project Report
Please submit a *Final Project Report* (Appendix 7) once the project has ended. This report should concisely summarize the outcomes of the research, the research findings and other details specified in the *Access Agreement*, 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 & Biological Samples Access Process and submission constitutes notice of project closure.

6. Ancillary Projects

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

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 criteria for the project;
- informed express consent documents developed for the Ancillary Project;

- all data collection instruments (e.g., questionnaires, medical records abstraction form, etc.);
- description(s) of the additional measurement(s) or biological samples(s) to be collected.

The Ancillary Project maybe conducted in two ways. The Approved Researcher must specify which Option they will use for their research project.

Option 1:
Atlantic PATH will:

- Contact research participants and collect consent, data and/or biological samples on behalf of the Approved Researcher; and
- Compile the data and provide the Approved Researcher with de-identified data and biological samples 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 *Full Data & Biological Sample Access Application* approved by the Atlantic PATH Data & Biological Samples Access Committee;
- Collect consent, data and/or biological samples from research participants;
- Not retain Atlantic PATH participant contact information as part of the ancillary project data; and
- Provide data and/or biological samples to Atlantic PATH as per the *Data & Biological Sample Access Agreement*.

Approved Researcher(s) will have exclusive access to any additional data and/or biological samples collected in the Ancillary Project for an agreed time period following collection. This time period will be outlined in the *Access Agreement* and will generally be one year from when the final data point was collected. This time-frame 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 database and will be available to other investigators for inclusion in future projects as per this *Access Policy*.

All costs incurred in contacting participants and collection and handling of new data or biological samples 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 biological samples. Approved Researchers will also assume these obligations upon signing the *Data and Biological Sample Access Agreement*.

Approved Researchers are responsible for ensuring that all Project Team members who will have access to the data and/or biological samples are aware of the terms of the *Data and Biological Sample Access Agreement*, especially with respect to confidentiality

Applicants must detail their plan to secure data and biological samples received from Atlantic PATH in the *Full Data & Biological Sample Application Form* (see Appendix 3).

Applicants 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 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 biological samples transferred to the Approved Researcher which allows Atlantic PATH to meet its federal and provincial legislative requirements:

- Only the minimum data and/or biological samples required to fulfill the purpose outlined in the *Full Data and Biological Sample Access Application form* will be considered for release;
- The data and/or biological samples must only be used for the purposes for which they were requested and release approved by the Atlantic PATH Data & Biological Samples Access Committee;
- The data and/or biological samples 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 biological samples, including any copies thereof, are to be employed;
- The Approved Researcher shall retain control of the transferred data and/or biological samples at all times, as delineated in the *Access Agreement*. The data and/or biological samples 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 biological samples must be approved by Atlantic PATH in advance and in writing;
- Data files and unused biological samples 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 applicant 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 biological samples -- aware of the importance of maintaining privacy and confidentiality; and
- Only coded (i.e. stripped of personally-identifying information) data and/or biological samples 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 *Privacy Breach Report* form (Appendix 5).
- In the event of a Privacy Breach, the Approved Researchers must complete and submit the *Privacy Breach Report* form to the Atlantic PATH Study.

8. Atlantic PATH Data & Biological Samples Access Request Review Criteria

The Atlantic PATH Data & Biological Samples Access Committee will review *Full Data & Biological Sample Applications* using the following criteria:

- Feasibility of the research project;
- Compatibility of the research project with the vision, objectives and goals of Atlantic PATH;
- 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 biological samples;
- Adequacy of the Applicants' and the Host Institutions' processes regarding privacy and confidentiality;
- Potential impact on future use of the data and/or biological samples 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; and
- The Atlantic PATH Data & Biological Samples Access Committee will offer suggestions for combining similar proposals requiring biological samples.

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

- Whether the project is requesting rare biological samples;
- 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 biological samples and/or minimize the freeze-thaw cycles.

The Atlantic PATH Data & Biological Samples Access Committee may consult with the Atlantic PATH Data Quality Manager, Laboratory 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 *Access Policy*. Once access to Atlantic PATH data and/or biological samples is granted, the following information will be added to a public registry on 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, a lay summary of the results submitted by the Approved Researcher will be added to this public registry. This will include links to any published results – either to a Pub Med link or pdf of the completed paper if public access is allowed.

10. Publication Policy

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

Atlantic PATH reserves the right to nominate its investigators as authors to be included in publications arising from its data.

All conference papers, abstracts and publications that use data and/or biological samples from Atlantic PATH should be submitted to Atlantic PATH upon publication or acceptance to a conference.

Authors *must* acknowledge the contribution of Atlantic PATH in their publications or presentations where data and/or biological samples from Atlantic PATH were used. All publications and presentations must contain the following sentence:

> "The data (or portions of 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 Project funded by the Canadian Partnership Against Cancer and Health Canada. The observations and opinions expressed herein are those of the authors and do not necessarily represent those of Atlantic PATH, Canadian Partnership Against Cancer, or Health Canada. We thank the participants in the Atlantic PATH Study."

Upon publication, a copy of the publication (or a web-link in the case of online publications) must be sent to the Atlantic PATH. This will be added to the publically accessible registry as allowed by copyright rules.

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.

Approved Researchers are strongly encouraged to follow the *Guidelines for the Licensing of Genetic Inventions* (http://www.oecd.org/dataoecd/39/38/36198812.pdf) adopted by the Organization for Economic Co-Operation and Development (OECD). Approved 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* (https://www.gpo.gov/fdsys/pkg/FR-2005-04-11/pdf/05-7247.pdf).

12. Glossary

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

Applicant: a Canadian or international researcher conducting research relevant to Atlantic PATH and who is applying for access to data and/or biological samples 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* and who has or will sign the *Access Agreement*.

Approved Researcher: an Applicant who is granted access to Atlantic PATH's data and/or biological samples by the Data Access Committee for the timeframe specified in the *Access Agreement*.

Associated Data: information related to the standard operating procedures, equipment specifications, reagents used, storage conditions, and quality assurance details of Atlantic PATH biological specimen collection, processing, and storage. This does not include any Atlantic PATH data related to Research Participants or Atlantic PATH-derived data.

Atlantic PATH Participants / Research Participants: individuals who volunteered to be part of the Atlantic PATH Study in response to media campaigns in the four Atlantic Provinces (New Brunswick, Newfoundland and Labrador, Nova Scotia, and Prince Edward Island) and provided express consent for their information and biological samples to be:

1. collected, stored, and used for research;
2. linked to provincial administrative health databases (e.g. physician billing, etc.), Vital Statistics and Cancer Registries;
3. updated regularly with data obtained through the linked provincial 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 with respect to the *Access Agreement.* The Authorized Institutional Representative is determined by the institution but must be in a position to legally bind their Institution.

Biological Samples: biological samples such as red blood cells, serum, plasma, DNA from buffy coat or saliva, blood spots, toenails, and urine with associated pre-analytical data from a unique, but not directly identifiable, individual made available to Approved Researchers and/or laboratory equipped to perform the analysis detailed in the Access Application in accordance with the *Access Agreement* and/or the *Material Transfer Agreement*.

***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 & Biological Samples Access Agreement (Access Agreement): a signed agreement between Approved Researcher(s), the Approved Host Institution, and Atlantic PATH that will be sent to Approved Researchers. This Agreement outlines the terms and conditions of access to Atlantic PATH's data, as well as any and all linked data held by Atlantic PATH under the control of health data custodians as prescribed by the relevant provincial legislation. This Agreement is legally binding and a signed original must be received by Atlantic PATH before access will be granted to Atlantic PATH holdings and/or linked data held by Atlantic PATH under the control of health data custodians as prescribed by the relevant provincial legislation.

Data Access Committee: The Data Access Committee (Atlantic PATH Data & Biological Samples Access Committee) will act in an oversight and monitoring capacity and will review *Full Access Applications*. The Atlantic PATH Data & Biological Samples Access Committee will make decisions to approve, reject or request additional information about an Access Request based on the criteria outlined in this *Access Policy*.

Data & Biological Samples Access Policy (Access Policy): this document that outlines Atlantic PATH's general principles and guidelines on access to its databases and biological samples. This *Access Policy* is an integral part of the *Access Agreement*.

Data Types:

Coded (De-identified) Data: Data provided about individuals for which all identifiers have been removed and replaced by a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., individuals are assigned a code name and the custodian retains a list that links the code name with the particular individual's actual name so data can be re-linked if necessary.) Custodians who have access to the code and the data will be considered to have identifiable information.
Identifiable information or information that could reasonably lead to identification of an individual includes, but is not limited to: demographic information such as names, contact information, and donation of biological samples.

Derived Data: any and all data generated from or based upon the use of Atlantic PATH data and/or biological samples 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, etc.), Vital Statistics and Cancer Registries.

Effective Date: the date when all parties (i.e., Atlantic PATH, the Approved Researcher and Approved Institution) have signed an *Access Agreement* and/or *Material Transfer Agreement*.

Eligible Research Projects: Research projects for which the applicant has secured funding, if required, and has received approval from a Research Ethics Board (REB).

Forms:

Preliminary Data & Biological Samples Access Application Form (Preliminary Access Application Form): an application for *bona fide* researchers interested in accessing Atlantic PATH holdings and/or linked data held by Atlantic PATH under the control of health data custodians as prescribed by the relevant provincial legislation. The researchers must be in the grant application phase and seek a support letter. This application is reviewed for feasibility and impact assessment. A cost recovery access budget and timescales will also be provided.

Full Data & Biological Samples Access Application Form (Full Access Application Form): a document completed by the Applicant(s), when requesting access to Atlantic PATH's data and/or biological samples, as well as any and all linked data held by Atlantic PATH under the control of health data custodians as prescribed by the relevant provincial legislation. It includes,

among other things, details about the Applicant's research project, research team and the plan to ensure the security and confidentiality of the requested data and/or biological samples.
If an Applicant has not secured funding and/or ethics approval, they may submit a Preliminary Access Application Form.

Access Renewal Form and/or Unanticipated Event/Significant Change Report form (Access Renewal Form): an application for continued access to Atlantic PATH holdings and/or linked data for an additional one-year term and to highlight any changes since the last application or renewal. This form and accompanying documents must be submitted one month prior to the project end date identified in the *Access Agreement*.
This form may also be used to report changes that modify the accuracy and scope of the initial information provided in the *Full Access Application Form*. Must be completed and submitted to the Atlantic PATH Data & Biological Samples Access Committee if unanticipated events and/or significant changes occur during an approved research project that may: impact the project data and/or biological samples; impact the ability of the Approved Researcher(s) to achieve the research goals; that represents a significant change to the information initially provided in the *Full Data & Biological Samples Access Application.*
This form may be submitted at any time during the course of the research.

Reporting a Privacy Breach: a document used to report the details of a privacy breach. Atlantic PATH will forward a copy of the submission to all Privacy and Information Commissioners for the provinces from which participant data may have been compromised.

Data and/or Biological Samples Return form: a document used to describe the data and/or biological samples being returned at the end of their respective analysis phases. This forms also details destruction of data copies.

Final Project Report: Document used by the Approved Researcher to provide details of the course of the research and the main findings. Submission indicates completion of the research project.

Holdings: are coded (de-identified) data and biological samples associated with unique, but not directly identifiable, individuals. These data include, but are not limited to, responses to self- and interviewer-administered questionnaires, physical measures, new variables created during analysis, biological samples data, and data derived from biological specimens. These data do not include, unless otherwise specified, Atlantic PATH holdings linked to provincial administrative health databases (e.g. physician billing, etc.), Vital Statistics and Cancer Registries.

Material Transfer Agreement: a signed agreement between a laboratory equipped to perform the analysis detailed in the Full Access Application and Atlantic PATH. This Agreement outlines the terms and conditions of the work to be performed to enrich Atlantic PATH holdings. The Agreement legally binds its signatories.

Personal Health Information: Identifying information about an individual, whether living or deceased, in both recorded and oral/unrecorded forms, if the information:

(i) relates to the physical or mental health of the individual, including family history, health care history and status, and genetic information about the individual,

(ii) relates to the application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,

(iii) payments or eligibility for a health care program or service in respect of the individual, including eligibility for coverage under an insurance or payment arrangement with respect to health care,

(iv) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,

(v) is the individual's registration information, including the individual's health-card number,

(vi) identifies an individual's substitute decision-maker, or

(vii) is collected in the course of, and is incidental to, the provision of a health care program or service or payment for a health care program or service,

(viii) relates to a drug, a health care aid, device, product, equipment or other item provided to an individual under a prescription or other authorization issued by a health care provider.

"Personal information" does not include aggregated information about a group of individuals where there is no reasonable expectation an individual could be identified.

Privacy: An individual's right to protection of the data regarding her/him against misuse or unauthorized disclosure.

Re-Identify: the process of linking de-identified data to a research participant.

Research: A systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research.

Research Ethics Board (REB): An REB established and operating in conformity with the Tri-Council Policy Statement. A body of researchers, community members, and others with specific expertise (e.g. research ethics, or relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices. Also denotes 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 research participants

13. List of Appendices

Appendix 1: Atlantic PATH Data & Biological Samples Access Process (included here)

<u>Please see the Atlantic PATH website for the following appendices:</u>

Appendix 2: Atlantic PATH Preliminary Data & Biological Samples Access Application Form

Appendix 3: Atlantic PATH Full Data & Biological Samples Access Application Form

Appendix 4: Atlantic PATH Access Renewal Form and/or Unanticipated Event/Significant Change Report form

Appendix 5: Atlantic PATH Reporting a Privacy Breach

Appendix 6: Atlantic PATH Data and Biological Samples Return form

Appendix 7: Atlantic PATH Final Project Report

Appendix 1: Atlantic PATH Data & Biological Samples Access Process