**Appendix 2: Atlantic PATH Preliminary Data & Biosample Access Application Form**

*Note: The Preliminary Data & Biosample Access Application Form, provided below, will be submitted online.*

This Preliminary Data & Biosample Access application form is the first step for requests for access to the controlled data of the Atlantic Partnership for Tomorrow’s Health Study (Atlantic PATH).

The purpose of this form is to allow us to determine if we have the data and/or biosamples required for the project.

For applications that we can support, 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 Atlantic PATH Data Access Committee approval of the *Full Application*; and (c) a cost recovery access estimate and timescales.

The researcher may use this letter of assessment for funding and/or Research Ethics Board (REB) or comparable ethics review applications.

Once REB or equivalent approval (mandatory) and funding (if required) is received, the researcher must complete and submit the *Full Data & Biosample Access Application*. This form will require detailed information about the proposed research project.

Please refer to Appendix 1 for a visual depiction of this Access Process. An electronic version of this application is available on the Atlantic PATH website: [www.atlanticpath.ca](http://www.atlanticpath.ca).

Please complete this form electronically and submit by email to: info@atlanticpath.ca

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| Project Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

# Project Team

Please list principal investigator(s) (PI) and their affiliation(s). If the PI is a student, please list the Supervisor and their affiliations.

Please attach an abbreviated CV (maximum 2 pages) for the PI or the Thesis Supervisor if the PI is a student.

Is this a student thesis or project? Yes 🞎 No 🞎

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Team: Principal Investigator (PI)** | | | |
| Name |  | | |
| Affiliation(s) |  | | |
| Primary role/position |  | | |
| Mailing Address |  | | |
| City |  | State/Province |  |
| Post code |  | Country |  |
| Email Address |  | | |
| Phone number |  | Fax number |  |
| **Select one:** | **Co-Investigator 🞎 Thesis Supervisor 🞎** | | |
| Name |  | | |
| Affiliation(s) |  | | |
| Primary role/position |  | | |
| Email Address |  | Phone number |  |
| Will this person have access to data? | | Yes 🞎 No 🞎 | |
| If yes, please give rationale as to why data access is required: | | | |
| **Please attach information about additional Co-Investigators to this form.** | | | |

# Project Information

|  |  |
| --- | --- |
| **Time schedule of funding:** (Please provide specific time constraints, e.g. student project)  From \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ To \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Abstract:** Please describe the research project and its specific hypotheses (200 words or less) | |
| **Project Design** | |
| Please detail the project objectives and outcome measures. Please include specific research questions. | |
| Please describe the proposed design, methodology and analysis plan in sufficient detail to allow for the evaluation of the data request. Please include (1) how you plan to use the data to achieve the project objectives; and (2) how you plan to disseminate your research findings. | |
| Is this an ancillary project which will involve contacting Atlantic PATH participants for additional data and/or biosample collection? Yes 🞎 No 🞎  If yes, please provide details in Section 7 of this form. | |
| **Proposed Timelines** | |
| 1. when will the data be needed (if known)? 2. when will biosamples be required (if known)? 3. when will data, biosamples or physicial measures collection as part of Ancillary projects be completed? 4. when will data analysis be finished and data returned to Atlantic PATH and copies erased/destroyed? 5. When will biosamples analysis be finished and unused biosamples retuned to Atlantic PATH? 6. expected end date of project? | *Timeline:*  a.  b.  c.  d.  e.  f. |

# Data Requested

|  |  |
| --- | --- |
| **Description** | |
| **Type of data:** | Individual level de-identified data 🞎  Biosamples 🞎  New data (ancillary project) 🞎  New samples (ancillary project) 🞎  A copy of the Atlantic PATH data dictionary is available at: [atlanticpath.ca](http://www.atlanticpath.ca) |
| **Inclusion criteria** (e.g. age, sex, etc.): | |
| **Exclusion criteria** (e.g. age, sex, etc.): | |
| **Estimate** of the number of participants for whom data will be required: | |
| **Variables:** Please select desired variable domains.  Please review the detailed data dictionary available for download from [atlanticpath.ca](http://www.atlanticpath.ca) to ensure that the variable(s) of interest are part of our data holdings.  Please note that you will be required to specify the individual variables required at the Full application stage.   | **Variable Domain** | **Select** |  | **Variable Domain** | **Select** | | --- | --- | --- | --- | --- | | Demographic Information | 🞎 |  | Alcohol | 🞎 | | Family Characteristics | 🞎 |  | Tobacco Use | 🞎 | | Education | 🞎 |  | Other Types of Tobacco | 🞎 | | **Variable Domain** | **Select** |  | **Variable Domain** | **Select** | | Health Status | 🞎 |  | Environmental Tobacco Smoke | 🞎 | | Men's Health | 🞎 |  | Physical Activity | 🞎 | | Women's Health | 🞎 |  | Ethnic Background | 🞎 | | Personal Medical History | 🞎 |  | Residence | 🞎 | | Prescribed Medication | 🞎 |  | Languages | 🞎 | | Family Health History | 🞎 |  | Working Status | 🞎 | | Sleep Pattern | 🞎 |  | Household Income | 🞎 | | Sunlight | 🞎 |  | Anthropometric Measures (self report) | 🞎 | | Diet | 🞎 |  | Date Completed | 🞎 | | **I, the PI, have reviewed the data dictionary and am aware of the data available from Atlantic PATH and that the data requested meets the requirements of the proposed analysis.** | | | | 🞎 | | |

# Biosamples Requested

Does the proposed project include analysis of biosamples? Yes 🞎 No 🞎

|  |  |  |
| --- | --- | --- |
| Biosample Requirements | | |
| Inclusion criteria: | | |
| Exclusion criteria: | | |
| Type | Volume required? | Number of samples required? |
| 1. EDTA Buffy coat |  |  |
| 1. RBC |  |  |
| 1. PST Plasma |  |  |
| 1. EDTA Plasma |  |  |
| 1. Serum |  |  |
| 1. Urine |  |  |
| 1. Saliva |  |  |
| 1. Toenails |  |  |
| 1. Blood spot cards |  |  |
| Where will biosamples be stored and analyzed? List all locations if known. (Details will be required for final application) | | |

# Physical Measures Requested

Does the proposed project include analysis of physical measures? Yes 🞎 No 🞎

|  |  |
| --- | --- |
| **Physical measure** | |
| Inclusion criteria: | |
| Exclusion criteria: | |
| Type required? | Number of participants required? |
| 1. Height |  |
| 1. Weight |  |
| 1. Body fat % |  |
| 1. Blood pressure |  |
| 1. Bone density |  |
| 1. Body segmented analysis |  |

# Ancillary Studies

|  |  |  |
| --- | --- | --- |
| Does the proposed project involve contacting Atlantic PATH participants for additional data and/or biosample collection? Yes 🞎 No 🞎  Please provide copies of all data collection methods and/or instruments such as questionnaires. | | |
| Additional data collection?  No 🞎 | Yes 🞎 If yes, please select method:  Mail out questionnaire: 🞎  Online questionnaire: 🞎  In-person administration: 🞎 | |
| Additional biosample collection?  No 🞎 | Yes 🞎 If yes, please select method:  Self-collected by mail: 🞎  In-person collection: 🞎 | |
| Additional physical measures collection?  No 🞎 | Yes 🞎 If yes, please select method:  Self-report by mail: 🞎  In-person collection: 🞎 | |
| Inclusion criteria: | | |
| Exclusion criteria: | | |
| **Project Administration: Please select how you will collect additional data and/or biosamples:** | | |
| **🞎** **Option 1:**  Atlantic PATH will:   * Contact Research Participants and collect consent, data and/or biosamples. * Compile the data and provide the Approved Researcher with de-identified data and/or biosamples for analysis. | | **🞎** **Option 2:**  Atlantic PATH will:   * Contact Research Participants and provide the Approved Researcher’s contact information. * Encourage Research Participants to contact the Approved Researcher.   Approved Researcher will:   * Collect consent, data, and/or biosamples from Research Participants. |

# Conflict of Interest

|  |
| --- |
| Will the Applicant’s conduct of the research potentially result in an actual or perceived conflict of interest on the part of the Applicant? Yes 🞎 No 🞎 |
| If yes, please explain how the Applicant intends to address the potential conflict. |

# Security

In order to protect Atlantic PATH participants’ data and biosamples, Atlantic PATH requires that authorized users have sufficient security in place to safeguard Atlantic PATH data and biosamples. Atlantic PATH requires specific IT security practices to be followed to avoid any misuse or inadvertent disclosure of information that could indirectly identify research participants or disclose their private data to unauthorized individuals.

If you make local copies of Atlantic PATH controlled data, you must effectively minimize the risk that this information might be disclosed to individuals who have not agreed to the Atlantic PATH’s privacy protection conditions. All local copies will need to be destroyed at the end of the data analysis phase of the project.

|  |  |
| --- | --- |
| ***Please read carefully and check the box to indicate that you will comply:***  **All the members of our research team willfollow the security procedures below:**  Our host institution has an IT security policy that we will follow.  The data will be treated confidentially and all results derived will be confidential.  Data will be maintained in a secure physical computer system  Data will be encrypted if kept on a portable computer and/or when transferred  Only authorized persons will be given access to the minimum about of data they need. Data will be made available on a need-to-know basis.  Once data is confirmed as no longer being needed, it will be securely erased/destroyed. Old computers will be given to IT to be sanitized before disposal.  Data will be retained (back-ups) for the time specified, and then securely erased/destroyed.  Offices are locked at night and portable disk drives left in offices are encrypted. | **I will comply:**  🞎  🞎  🞎  🞎  🞎  🞎  🞎  🞎 |
| We will inform Atlantic PATH of any security incidents that may have occurred in connection with Atlantic PATH’s data and samples | 🞎 |
| We will destroy the data we receive from Atlantic PATH once the data analysis phase of the project has been completed. | 🞎 |
| We will provide a copy of all data that we collect or derive to Atlantic PATH | 🞎 |
| We will return all unused biosamples received from Atlantic PATH once the biosample analysis phase of the project has been completed | 🞎 |
| We will not conduct any analysis that was not approved by the Atlantic PATH Data Access Committee. | 🞎 |

I have been provided with, read and agree to comply with the Atlantic PATH *Data Access Policy*.

Specifically, I declare that:

1. This research will be conducted according to the Privacy, Confidentiality and Security conditions detailed in the *Access Policy.*
2. The data disclosed by Atlantic PATH will only be used for the purposes of the project approved by the Data Access Committee.
3. For data disclosed by Atlantic PATH: The research protocol will ensure the erasure and destruction of all data copies except those required for audit purposes at the end of the data analysis phase of the project.
4. For biosamples received from Atlantic PATH: The research protocol will ensure the return of all remaining biosamples at the end of the biosample analysis phase of the project.
5. Ancillary studies - copies of all data collected and/or derived, as well as portions of all biosamples collected in ancillary studies will be given to Atlantic PATH to enrich the Atlantic PATH research platform.
6. My interest in the disclosure of the personal health information or the conduct of the research will not potentially result in an actual or perceived conflict of interest on my part
7. A copy of all published reports and articles will be provided to Atlantic PATH.

|  |  |
| --- | --- |
| Name of Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

*If applicable:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Name of Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signature of Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |