**Preliminary Data and Biosample Access Application Form**

This Preliminary Data and Biosample Sample Access application form is the first step for requests for access to the Atlantic Partnership for Tomorrow’s Health Study (Atlantic PATH) Research Platform.

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

For applications that we can support, we are able to provide an 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 Access Committee approval of the *Data and Biosample Access Application Form*; and

(c) a cost recovery access estimate.

Once Research Ethics Board (REB) or equivalent approval is received, the researcher must complete and submit the *Data and Biosample Access Application Form* which will require detailed information about the proposed research project.

**Please submit by e-mail to Ellen.Sweeney@dal.ca**

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

# Project Team

Please list principal investigator(s) (PI), co-investigators and their affiliation(s). Please attach an abbreviated CV (maximum 2 pages) for the PI or the supervisor if the PI is a student.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 applicable, please include information about additional Co-Investigators.]** | | | |
|  | | | |

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# Project Information

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| **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. | |
| Will this project involve contacting Atlantic PATH research participants for additional data and/or biosample collection, i.e., an ancillary project? 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 and/or physical measures collection as part of Ancillary projects be completed? 4. When will data analysis be finished? 5. When will biosamples analysis be finished and unused biosamples retuned to Atlantic PATH? 6. What is the expected end date of the project? 7. When will data be returned to Atlantic PATH and original copies erased/destroyed? | *Timeline:*  a.  b.  c.  d.  e.  f.  g. |

# Questionnaire Data Requested

|  |  |
| --- | --- |
| **Description** | |
| **Type of data:** | Individual level de-identified data 🞎  Biosamples 🞎  Linkage Data 🞎  New data collection (ancillary project) 🞎  New biosamples collection (ancillary project) 🞎 |
| **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 review the questionnaires (CPTP Core Questionnaire, Questions Unique to the Atlantic Provinces, Follow up Survey) available online. Please select the desired variable domains from the list below.   | **Variable Domain** | **Select** |  | **Variable Domain** | **Select** | | --- | --- | --- | --- | --- | | Demographic Information | 🞎 |  | Alcohol Use | 🞎 | | Family Characteristics | 🞎 |  | Tobacco Use | 🞎 | | Education | 🞎 |  | Other Types of Tobacco | 🞎 | | 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-reported) | 🞎 | | Diet | 🞎 |  | Date Completed | 🞎 | | |
|  | |

# Biosamples Requested

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

|  |  |  |
| --- | --- | --- |
| Biosample Requirements | | |
| Inclusion criteria: | | |
| Exclusion criteria: | | |
| Type | Volume required? (if relevant) | 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? (Additional 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. Percent body fat |  |
| 1. Blood pressure |  |
| 1. Bone density |  |
| 1. Body segmented analysis |  |

# Linkage Data

Does the proposed project include linkage to administrative health data (e.g., cancer registry)? Yes 🞎 No 🞎

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| --- |
| Inclusion criteria: |
| Exclusion criteria: |

# Ancillary Studies

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| --- | --- |
| Does the proposed project involve contacting Atlantic PATH research 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: | |

|  |  |
| --- | --- |
| **Ancillary Studies Administration: Please select how you will collect additional data and/or biological samples.** | |
| **🞎** **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 details of the project and 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

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

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# Security & Confidentiality

In order to protect Atlantic PATH research 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:** | **I will comply:** |
| 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 amount of data they need. Access 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 archive/audit purposes for the time specified, and then securely erased/destroyed. | 🞎 |
| Offices are locked at night and portable disk drives left in offices are encrypted. | 🞎 |
| Atlantic PATH will be informed of any security, privacy or confidentiality incidents that may occur in connection with the data and biosamples. | 🞎 |
| Copies of all data derived from the analysis of data and/or biosamples, or collected in an ancillary study will be provided to Atlantic PATH. | 🞎 |
| Once the biosample analysis phase of the project has been completed, all unused biosamples will be returned to Atlantic PATH; all parts not returned will be destroyed. | 🞎 |

# Applicant Declaration

I have read and agree to comply with the Atlantic PATH Access Policy.

Specifically, I declare that:

1. This research will be conducted according to the privacy, confidentiality and security conditions detailed in the *Atlantic PATH Data and Biosamples Access Policy*.
2. The data received from Atlantic PATH will only be used for the purposes of the project approved by the Access Committee. The research protocol will ensure the erasure and destruction of all data copies except those required for audit/archive purposes at the end of the data analysis phase of the project.
3. The research protocol will ensure the return of all remaining biosamples received from Atlantic PATH at the end of the biosample analysis phase of the project.
4. Copies of all data collected and/or derived in all approved research projects, including ancillary studies will be given to Atlantic PATH to enrich the Atlantic PATH research platform.
5. 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.
6. A final report will be submitted to Atlantic PATH within three months of publication.
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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |