**Atlantic PATH**

**Data and Biosample Access Application Form**

**Request for access to data/biosamples to support research**

**[Applicant, Institution]**

**regarding**

**[Title of Proposed Research]**

**[Date of submission of Research Application Form]**

### Documents Required

***1***: Completed Research Application Form – request for access to data/biosamples to support research

***2***: Copy of REB Approved Research Protocol

***3***: REB decision letter

***4***: Evidence of Funding (e.g. copy of letter of award from granting agency), if applicable

***5:*** Brief CV of Principal Applicant (2 pages)

***6:***  Proof of Scientific Peer Review (if available)

**Please send application with completed Schedules 2-6 and any other relevant supporting materials by email to:** Ellen.Sweeney@dal.ca.

PLEASE NOTE THAT INCOMPLETE APPLICATIONS WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

**Atlantic PATH Data and Biosample Access Application Form**

This Access Application Form is to be used by all researchers seeking access to Research Data and/or Biosamples, referred to as Material in the Data and Material Sharing Agreement. Please refer to the Atlantic PATH Access Policy for the meaning of all capitalized terms used in this form.

Applicants should review the Access Policy before completing this Access Application Form.

Applicants must complete all mandatory sections and provide supporting documentation before the access request will be considered. Access Applications will not be reviewed until funding has been secured and all required ethics documents have been submitted. Further information on Atlantic PATH’s review and approval process can be found in the Access Policy and on the Atlantic PATH website.

Upon approval of an access request by the Access Committee, access to Research Data and/or Biosamples will be granted for the timeframe set out in the approved Access Application Form and the Access Agreement. An Annual Progress Report must be completed to access and use Research Data and/or Biosamples beyond a one-year period.

The title of the Approved Research Project, name(s) of the Approved User, their status and credentials, and the name(s) of the Approved Institution(s submitted by the Applicant will be added to the Atlantic PATH website.

**SECTION 1: CONTACT AND RESEARCH PROJECT INFORMATION**

1. Name, institution, and contact details of the Applicant (Principal Applicant)

Please include a full postal address and a valid e-mail address. If you have more than one affiliation, only provide the contact information pertaining to the institution you are affiliated with for the purpose of the research project.

*If a graduate student is the PI, please also provide the same information for the Supervisor.*

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| **Name** |  |
| **Position**  |  |
| **Educational Qualifications (PhD, MD, etc.)** |  |
| **Institution** |  |
| **Telephone Number** |  |
| **E-mail Address** |  |
| **Institutional Mailing Address** |  |

1. Name, institution, and contact details of the Authorized Institutional Legal Representative

Please include a full postal address and a valid institutional e-mail address for your Authorized Institutional Legal Representative. This individual must be in a position to legally bind the institution.

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| **Name** |  |
| **Position**  |  |
| **Institution** |  |
| **Institutional E-mail Address** |  |
| **Telephone Number** |  |
| **Institutional Mailing Address** |  |

1. Names, institutions and contact details of the members of the Research Team working with the Applicant

Please provide details for all members of the Research Team working with the Principal Applicant who would have access to the requested Research Data and/or Biosamples in order to work on the research project (e.g. co-investigators, collaborators, research assistants, study coordinators, lab technicians and students).

| **Name and Position** | **Primary Institution** | **Institutional Email Address** | **Role in the Research Project** | **Access to Individual Level Data****(Y/N)** | **Access to Biosamples****(Y/N)** |
| --- | --- | --- | --- | --- | --- |
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1. Names and contact details of Service Providers and Commercial Laboratories

☐ This application involves a service provider or commercial laboratory that will require access to the requested Research Data and/or Biosamples.

Please provide the details of all service providers and commercial laboratories that will have access to the requested Research Data and/or Biosamples in order to work on the research project. All service providers and commercial laboratories will need to meet the terms and conditions of the Access Agreement.

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| **Service Provider or Commercial Laboratory Name:** |
| Mailing Address |  |
| Contact Name |  |
| Title |  |
| Institutional E-mail Address |  |
| Telephone Number |  |
| Website address (if available)  |  |

**SECTION 2: RESEARCH PROJECT**

1. Title

|  |  |
| --- | --- |
| **Title of Research Project** |  |

1. Research Project Time Table

|  |  |
| --- | --- |
| **Start Date** |  |
| **End Date** |  |

This proposal is a request for access to data onlyYes ☐ No ☐

1. Research Category/Type

Check the items that best describe the type of research project that would be conducted using the Research Data and/or Biosamples (more than one may apply).

|  |  |
| --- | --- |
| ☐ Genetic studies☐ Gene-by-Environment☐ Environment Association☐ Case-control study☐ Descriptive study ☐ Surveillance study ☐ Data linkage  | ☐ Risk score or index development☐ Biomarker validation or discovery☐ Study using data from multiple cohorts (e.g., data pooling project)☐ Other (*specify*): |

1. Scientific Abstract

Please provide a clear scientific description of the research project, its specific hypotheses, methodology and deliverables. Be sure to explain how the Research Data and/or Biosamples would be used, and how the project meets the objectives of Atlantic PATH. Word limit is 500.

1. Lay Summary of Project

Please provide a short description of the project for the general public. Scientific jargon and acronyms should be avoided as much as possible. Word limit is 500.

1. Research Participants

|  |  |
| --- | --- |
| Total number of Research Participants requested: |  |
| Inclusion criteria |  |
| Exclusion criteria |  |
| Stratification or grouping: |  |
| Any additional parameters required: |  |
| **For case-control studies:** |
| Matching criteria: |  |
| Case-control ratio: |  |

Please describe the design and methodology of the proposed project, including the primary outcome measures and the methods that will be used to analyze the study data. This section should include justification for the sample size requested.

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**SECTION 3: FUNDING AND SCIENTIFIC REVIEW**

1. Funding

Please answer the following questions regarding the funding and scientific review of your research project.

**Has financial support been granted?**

Yes ☐ No ☐

**From which funding body?**

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| **Funding Start Date:**  |  |
| **Funding End Date:** |  |

**Has the project been evaluated by a recognized peer review process?**

Yes ☐ No ☐

**Who evaluated the project?**

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*\*Please note that Access Application will not be reviewed until funding has been secured.*

1. Ethics Approval

Has this study been approved by a research ethics board 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?

Yes ☐ No ☐

If yes, please provide the following supporting documents specifically related to this access application:

☐ Research Ethics Board (REB) approved research protocol

☐ Decision letter from a Research Ethics Board (REB) or comparable decisional committee (English or French; an institutional approval number should also be provided if available)

If no, please specify arrangements for obtaining the appropriate approvals.

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The Access Office reserves the right to request further documentation related to the Research Ethics Review from the Applicant, where necessary. It is the Applicant’s responsibility to ensure that all local/national ethical requirements have been met prior to submission

*\*Please note that Access Application will not be reviewed until all required ethics documents have been submitted.*

**SECTION 4: DATA AND BIOSAMPLES**

1. Biosamples

☐ Not applicable – access to Biosamples is not requested.

Please describe the required type and amount of biosamples needed to support this research project. Standard information is provided when biological samples are requested.

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| BIOSAMPLES AVAILABLE IN ALL CPTP REGIONS AND NATIONAL |
| **Biosample type** | SST: serum | EDTA: plasma | EDTA: RBC | Urine | DNA\* |
| **Unit** | µL | µL | µL | µL | µg |
| **# of Participants** |       |       |       |       |       |
| **Total # of Tests** |       |       |       |       |       |
| **# of biomarkers** |       |       |       |       |       |
| **Total Required Assay Volume or Amount** |       |       |       |       |       |
| **Total Required Dead Volume or Amount** |       |       |       |       |       |
| **Total Volume or Amount Requested** |       |       |       |       |       |
| **Preferred Delivery Year** |       |       |       |       |       |
| ADDITIONAL BIOSAMPLES AVAILABLE REGIONALLY* PST: Plasma (Atlantic PATH)
* Toenails (Atlantic PATH)
* Saliva (Atlantic PATH)
 |
| **Biosample type** |  |
| **Unit** |  |
| **# of Participants** |  |
| **Total # of Tests** |  |
| **# of biomarkers** |  |
| **Total Required Assay Volume or Amount** |  |
| **Total Required Dead Volume or Amount** |  |
| **Total Volume or Amount Requested** |  |
| **Preferred Delivery Year** |  |

\*DNA may be extracted from blood or saliva

Does freeze/thaw affect the planned analysis?” [ ]  No [ ]  Unknown [ ] Yes

If yes, number of acceptable freeze/thaw events:      (provide supporting evidence below for this pre-analytical restriction)

☐ Biosample pre-analytical restriction(s) required.

Describe and justify the need for biosample pre-analytical restrictions:

For this research proposal, have you applied for biosamples from another source? ☐ Yes ☐ No

If yes, where?

Status of the request: ☐ Approved ☐ Pending ☐Declined ☐Future Request

Total number of samples requested from other source:

**Biomarker information (required for each biomarker):**

Describe the biomarker/category of biomarkers proposed for analysis including its usual range(s) measured in an adult population for the biosample type being requested and the anticipated results for the biosamples. Provide evidence that the biomarker/category of biomarkers in the proposed biosample type measurement is stable and that a single time point analysis provides a reliable representation of the question being asked. If this information is available within your submitted research proposal you may reference the page(s) where the information can be found.

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**Methodology information (required for each assay):**

Describe the proposed methodology for biosamples analysis that will be performed for each requested biosamples. This should include what methodologies are available and the rationale for using the proposed assay. Include the reagent source. Provide evidence of the assay’s performance and list 2 to 5 publications where this quality has been demonstrated. If the methodology information is available within your submitted research proposal you may reference the page(s) where the information can be found.

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1. Laboratory Analyses

☐ Not applicable – access to Biosamples is not requested.

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| Provide evidence of the laboratory’s assay usage record, preliminary data and/or publications: Assay #1: assay #1 Laboratory name: laboratory name# of years laboratory has performed the assay: # years# of assay tests conducted on average per year by the laboratory: # of assayLaboratory’s intra-assay % CV from a recent publication or analysis: intra-assayLaboratory’s inter-assay % CV from a recent publication or analysis: inter-assayProvide other relevant laboratory qualifiers, as applicable for the assay: qualifiersAssay #2: assay #2 Laboratory name: laboratory name# of years laboratory has performed the assay: # years# of assay tests conducted on average per year by the laboratory: # of assayLaboratory’s intra-assay % CV from a recent publication or analysis: intra-assayLaboratory’s inter-assay % CV from a recent publication or analysis: inter-assayProvide other relevant laboratory qualifiers, as applicable for the assay: qualifiersAssay #3: assay #3 Laboratory name: laboratory name# of years laboratory has performed the assay: # years# of assay tests conducted on average per year by the laboratory: # of assayLaboratory’s intra-assay % CV from a recent publication or analysis: intra-assayLaboratory’s inter-assay % CV from a recent publication or analysis: inter-assayProvide other relevant laboratory qualifiers, as applicable for the assay: qualifiers |

☐ I acknowledge that biosamples may be released in a staggered and conditional release upon approval

1. List of Variables

Select the dataset(s) that specifically support the research project that you have identified above. Number of participants will vary per dataset. You will also need to select the specific variables.

[ ] Baseline Health and Risk Factor Questionnaire (“Core Questionnaire”)

[ ] Baseline Mental Health

[ ] Baseline Physical Measures

[ ] Genotype Data

[ ] Regional Datasets (“Questions Unique to the Atlantic Provinces”)

[ ] Environmental Exposure Data

[x] Linkage to Administrative Health Databases (e.g., cancer registry)

[ ] Linkage to Administrative Health Databases (e.g., cancer registry)

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| --- | --- | --- | --- |
| Variable | Level of Identification | Why is this | Data Source |
| element required in the analysis? | Level of identification required? |
| *e.g. Age*  | *Age of each person >30* | *To calculate age adjusted incidence rates* | *Categorized age variable cannot be used for calculating age adjusted incidence rates* | *Atlantic PATH* |
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**Supplementary information**

Please specify any other information requested

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1. Data Linkage

Will data from other sources be utilized to complete the proposed project? Please list all data linkages required to complete the proposed project, and where these data are held.

☐ Not applicable –Data and/or Biosamples will not be linked with data from other sources.

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**SECTION 5: RETURN OF DATA**

1. Return of Data

Please provide a brief description (100 words) of the derived data that will be returned to Atlantic PATH generated during the analyses undertaken for your research project using Research Data and/or Biosamples analysis. Data that must be returned include new variables issued from assay results (if applicable) and derived variables generated from existing variables using an expression including all intermediates of these derived variables. For example, a derived variable can be an index combining several variables (e.g. risk scores) or a numeric variable created by doing the sum of values stored in two or more numeric variables.

The Derived Data must be returned in the analytical format used to create your final working dataset such as SAS (.sas), SPSS (.sps), .CSV or the equivalent, along with the data dictionary or codebook. The Derived Data must include the original anonymized IDs supplied by Atlantic PATH.

All biosample analysis data is to be returned in both raw (initial data generated from laboratory instrument) and analyzed (analysis extracted from raw data) formats and is to be accompanied by a completed [CPTP Derived Data Report](https://portal.partnershipfortomorrow.ca/samples). Raw and analyzed data for the assay’s standards and controls are also to be provided.

**SECTION 6: SECURITY**

**Information Technology (IT) Security Assessment**

To avoid any privacy breaches, you must follow reasonable IT security practices and procedures. You must not disclose any Research Data to third parties who have not agreed to Atlantic PATH’s privacy requirements. You must ensure that this is also the case for research staff and any external collaborators mentioned in Section 1. To be eligible for access, all boxes from A to F must be checked.

☐ A. My institution has a formal IT security policy.

☐ B. I will store Research Data in secure physical computer systems. If Research Data is stored on portable computers (whether laptops or other mobile devices), it must be encrypted to avoid any unauthorized disclosure in case the portable system is lost or stolen.

☐ C. I will implement appropriate access security to ensure that only the authorized individuals mentioned in Section 1 of this Access Application Form be allowed to access the Research Data. This requires, for example, that if Research Data is stored on a shared computer system or on a file server, that it be password or encryption-protected. If Research Data is stored on a network-accessible computer, there should be measures in place to prevent access by computer hackers or contamination by viruses and spyware. Moreover, if the computer(s) that hold Research Data are backed up, the backed up media must also be encrypted and stored in a secure location.

☐ D. I understand that anyone (mentioned in Section 1 of this Access Application Form) who will use Research Data should be trained in the responsible use of Research Participant information and be familiar with the terms and conditions of the Access Policy, this Access Application Form and the Access Agreement. I am responsible for ensuring research staff comply with these terms and conditions.

☐ E. I understand that upon completion of my research project, I must destroy all local copies, including backups, of the Research Data by the date specified in the Access Agreement.

☐ F. I must also either store my analysis code or send a copy of it to Atlantic PATH in case of potential needs to reproduce my variables or findings at a later date.

**Biosamples Security Assessment**

[ ]  Not applicable – access to Biosamples is not requested.

To avoid any privacy breaches, you must follow reasonable biosamples security practices and procedures. You must ensure that this is also the case for research staff and any external service providers and commercial laboratories mentioned in Section 1. To be eligible for access, all boxes from A to E must be checked.

☐ A. My institution has a biosamples security policy.

☐ B. The services provider(s) and/or commercial laboratory(ies), if applicable, each has a formal biosamples security policy.

☐ C. I will implement appropriate access security so as to ensure that only the authorized individuals mentioned in Section 1 of this Access Application Form are able to access the Material. This requires, for example, that Material be stored in a room with restricted access and, if not, in a locked freezer/refrigerator.

☐ D. I understand that anyone (mentioned in Section 1 of this Access Application Form) who will use Material should be trained in the responsible use of Research Participant information and be familiar with the terms and conditions of the Access Policy, this Access Application Form and the Access Agreement. I am responsible for ensuring Research Staff comply with these terms and conditions.

☐ E. I understand that upon completion of my research project, I may be asked to either destroy or return Material, as per CPTP's request.

**SIGNATURE**

**Principal Applicant:**

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| --- | --- | --- | --- |
| Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Position | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Supervisor (if the Principal Applicant is a graduate student)**

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| --- | --- | --- | --- |
| Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Position | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Authorized Institutional Legal Representative of the host institution:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Position | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Checklist of Required Documents**

Please attach the following required documentation before submitting your application.

☐ Completed Access Application Form (this form)

☐ Copy of REB Approved Research Protocol

☐ Decision letter from a Research Ethics Board (REB) or comparable decisional committee (English or French; an institutional approval number should also be provided, if available)

☐ Evidence of funding, if available

☐ Brief CV of Principal Applicant (2 pages)

☐ Brief CV of Supervisor (2 pages), if Principal Applicant is a graduate student

☐ Proof of scientific peer-review (if available)

**Please e-mail both a word document version and a PDF of the signed *Atlantic PATH Data and Biosample Access Application Form* to Ellen.Sweeney@dal.ca.**

|  |  |
| --- | --- |
|  | Cohorts |
| ATP | BCGP | CaG | OHS | PATH |
| Biosample Type | Red Top: Serum | ACD: whole blood in DMSO | ACD: whole blood in DMSO | Ficoll separated lymphocytes in DMSO/FBS | ToenailsSaliva |
|  |  | PST: plasma |  | PST: plasma |
|  |  | NaCitrate: Plasma |  |  |
|  |  | Pax-Gene: Tempus |  |  |

**Appendix: Biosamples Available Select Regions**