**APPLICATION FORM FOR ACCESS TO MIREC BIOBANK**

## 1.0 Objective

The MIREC Biobank contains data and specimens from the MIREC Research Platform Studies, which include the original MIREC Study, Follow-Up Studies, and Biobank Projects. This Application is used to request data and/or specimens for research purposes from the MIREC Biobank, as administered by the MIREC Biobank Management Committee (hereafter referred to as “MBMC”).

The objectives of the MIREC Biobank are to provide a basis for future research on:

1. Maternal and child exposure to priority environmental chemicals;
2. Fetal growth, pregnancy and the health of mothers and their infants/children;
3. Health risks, if any, that are associated with various measures of chemical exposures, and;
4. Potential mechanisms of toxicity and markers of susceptibility for adverse pregnancy and child outcomes.

The criteria for granting access include: feasibility, scientific value, minimal risk, availability of specimens, contribution to the MIREC Research Platform Studies, and public health importance to Canadians.

The MIREC Biobank operates on a cost-recovery basis. The fees to access the MIREC Biobank are determined by the MBMC and will be used to cover the operating costs of the MIREC Biobank as well as its maintenance over 30 years. The MIREC Biobank does not allow access by insurers or employers.

## 2.0 Definitions

**Applicant:** Researcher seeking access to the MIREC Biobank, for a proposed project, identified hereafter as “Applicant”. Generally the Principal Investigator of the proposed project. There may be one Co-Applicant, identified hereafter as “Applicant 2”, who will share the responsibility of the Biobank Project.

**Biobank Project:** A research study that involves access to the Material in the MIREC Biobank. The following would be considered Biobank Projects: (1) any request to access the data stored in the MIREC Biobank by an individual who was not a Co-Investigator on the studies in which the data were collected; (2) any proposal to link data in the MIREC Biobank with other datasets; (3) any proposal to analyse any specimens stored in the MIREC Biobank; (4) any proposal not led by the MIREC Study Co-Principal Investigators that entails contact with Participants.

**End-Users**: All individuals who will have access to the Material. Access is limited to those who require it in order to meet the objectives of the Biobank Project.

**Individual-level data**: Information at the level of individual participants.

**Material**: Data and specimens stored in the MIREC Biobank. Examples of specimens include blood, urine, hair, cord blood and meconium. Examples of, data include that generated from questionnaires to the Participants, laboratory test results, clinical measurements, Biobank Projects, and Derived Variables.

**MIREC Data**: Information about Participants that includes that obtained from questionnaires, images, clinical tests, medical chart abstractions, linkage to external Ecological Datasets (e.g., ambient air pollution, municipal drinking water analysis) and the laboratory analysis of their specimens.

**Secure Server**: A server that encrypts information sent and received over a network.

**Team Member**: An individual (including staff and trainees) who will work with the Material on this Biobank Project.

**Theme Leader:** The MIREC Research Platform Study Investigator who contributed intellectually to the creation of the data element (e.g., question, chemical measurement) associated with a Theme. Theme Leaders were identified on the basis of their contributions to specific aspects of the MIREC Research Platform Studies protocols, Case Report Forms, the development of Derived Variables or creation of laboratory test results. If retiring or no longer participating in MIREC, he/she may designate the new theme leader.

## 3.0 Restrictions on use of the MIREC data and specimens

**Work with MIREC Data**

* MIREC Data contain no personal identifiers such as names or contact information. Nonetheless, the Individual-level Data are considered confidential, and their use is subject to strict rules.
* The individual-level data can never leave the Canadian territory. Among the data, there is a subgroup of non-sensitive information that could not lead to indirect identification of a participant, by matching criteria such as address, age, sociodemographic and health information. Special permissions may be granted for this group of data if the need can be justified.
* As participants in the MIREC Study are not necessarily a representative sample of the population of the various recruitment sites, no site-specific biomonitoring or health results for participants can be published or presented.
* Results that could lead to identification of an individual participating in MIREC cannot be published.
* Any new data generated as part of the Biobank Project will be added to the MIREC Research Platform Studies.

**Work with MIREC specimens**

* Targeted sub-population sampling of banked specimens is not allowed. Therefore, an Applicant requesting specimens must perform the proposed laboratory analyses for the full set of specimens requested.
* Access to specimens requested by an Applicant is not guaranteed until the project has completed all the steps.
* Any leftover specimens remaining after the project’s planned analyses must be returned to the MIREC Biobank.

## 4.0 PROCESS FOR APPLYING TO ACCESS THE MIREC BIOBANK

**Step 1:** The Applicant submits a preliminary application (Form 1) to the Biobank Manager.

**Step 2:** The MBMC determines if the preliminary application is suitable for further consideration and then informs the Applicant of its decision, including feedback to be considered in the full application. The MBMC also consults with the MIREC Research Platform Theme Leaders for content under their responsibility (see “MIREC Research Platform Knowledge Transfer Policy” for details). Approved preliminary applications will be provided with a cost estimate.

**Step 3:** If the preliminary application is approved by the MBMC, the Applicant can submit a full application (Form 2) to the Biobank Manager.

**Step 4**: The MBMC reviews the full application and, based on its merit, either a) approves the proposed project as submitted; b) asks for clarifications and/or revisions, prior to approving, or c) refuses the proposed project, providing reasons. If approved, the MBMC will provide a letter of provisional support to the Applicant, indicating if the requested data/specimens are currently available, and what the associated costs for the project would be to access the Biobank.

**Step 5**: If the full application is approved by the MBMC, the Applicant must:

* 1. Provide proof of funding for the project (including Biobank fees).
	2. Obtain ethics approval from Health Canada and his/her institution and provide copies of the approvals.

**Step 6**: The MBMC confirms that the requested data/specimens are still available and that no new major scientific advance has occurred that would lead the MBMC to question the need for the proposed work.

**Step 7:** The Applicant and his/her team sign the MIREC Biobank Access and Utilization Agreement and the MIREC Data End-User Acknowledgement for Biobank Applicants.

**Step 8:** The release of the data/specimens by the Biobank Manager.

**Note:** *If changes need to be made to an approved project, the Applicant must complete an Amendment Request (Form 3, last page) and obtain approval of the MBMC and the REBs prior to implementing these changes.*

**Overview of steps to access the MIREC Biobank**

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| --- | --- | --- |
| Applicant: |  | MBMC: |
| Step 1Submit a preliminary application |  |  |
|  |  | **Step 2**Review by MBMC and consultation with theme leaders |
| Step 3Submit a full application |  |  |
|  |  | **Step 4**Review by MBMC |
| Step 5Submit proof of funding and REB approvals |  |  |
|  |  | **Step 6**Final confirmation by MBMC |
| Step 7Signing of Agreement and Acknowledgement |  |  |
|  |  | **Step 8**Release of data/specimen |

**Form 1: PRELIMINARY APPLICATION TO REQUEST ACCESS TO THE MIREC BIOBANK**

**Provide the following information in order for the MIREC Biobank Management Committee to conduct a preliminary assessment of the proposed project.**

1. Applicant
	* Family (last) name:
	* Given (first) name and initial:
	* Institution, department, title and mailing address:
	* Work, cell phone and fax numbers:
	* Email address:
	* Contribution to proposed project:
2. Applicant 2 (if applicable)
	* Family (last) name:
	* Given (first) name and initial:
	* Institution, department, title and mailing address:
	* Work, cell phone and fax numbers:
	* Email address:
	* Contribution to proposed project:
3. Research Team Member(s). Provide name, position and institution. Specify role and contribution to the project:
4. Proposed research question(s):
5. Scientific justification:
6. MIREC Biobank specimens requested, if applicable
	* Complete and attach the MIREC SPECIMEN SELECTION TOOL.
7. MIREC Data requested
	* Complete and attach the MIREC DATA SELECTION TOOL.
	* Specify the predictors, the outcome and other covariate information of interest:
8. Contribution of the proposed project to the MIREC Biobank objectives (see page 1):
9. Acknowledgement of the “Restrictions on use of the MIREC Data and Specimens”:
	* Check box to confirm that the Applicant understands and can comply with the restrictions: Yes [ ]
* **Please complete the above fields. Save the document in RTF format and email to** **mirec.project@recherche-ste-justine.qc.ca****.**

**Form 2: FULL APPLICATION TO REQUEST ACCESS TO THE MIREC BIOBANK**

**Use the Preliminary Application document that was submitted and approved. Edit the Preliminary Application, including the data and specimen selection tools, if needed. All changes to the previously approved application must be done using the track changes feature.**

* **Provide the following information in order for the MIREC Biobank Management Committee to conduct a full assessment of the proposed project.** Was the preliminary application revised? Yes [ ]  No [ ]
	+ If yes, specify which parts of the preliminary application were revised: Preliminary Application form / MIREC DATA SELECTION TOOLS / MIREC SPECIMEN SELECTION TOOL
	+ Justify the changes:
* Project title:
* Plain language summary: Provide a short, plain language (grade 8) description of the project suitable for the general public in no more than 250 words, avoiding scientific jargon. This information may be used in publications (MIREC newsletter, MIREC website, etc.):
* Scientific abstract (350 words maximum):

 **Research Protocol:**

* Background and relevance to public and population health (1,500 words maximum):
1. Introduction and rationale of proposed project:
2. Research objectives and hypotheses
3. Public health significance
4. Rationale as to why MIREC Biobank data and/or specimens (as opposed to other data sources) are needed to answer the research questions.
* Methods (1,500 words maximum)
1. Population of interest – why is the MIREC cohort population ideally suited to address the research project objectives?
2. Rationale for the use of the requested data variables.
3. Rationale for the use of the requested specimens, including why alternate approaches would not work or how the project could not be completed without the requested specimens.
4. Analytes of interest and their storage stability in the matrix (urine, blood, meconium, hair, etc.) requested;
5. Techniques and equipment for analyses
6. Potential problems, alternative strategies and/or benchmarks of success for laboratory analyses (if applicable).
* Statistical analyses (1,500 words maximum):
1. Describe the proposed statistical analyses
2. Provide sample size/power calculations for the major outcomes of interest, if applicable.
* Limitations of proposed research project (maximum 500 words):
* Linkage to external data. Specify if external data are to be linked to the MIREC Data. If yes, describe:
1. The external data and its source(s), including any variables that will be linked, any new variables that will be created and added to the MIREC datasets:
2. Mechanism of protecting the privacy and confidentiality of MIREC participants:
* Publication venues (i.e., dissemination plan) :
* Has funding been secured for this project? Yes [ ]  No [ ]
	+ If yes, attach proof of funding
	+ If no, specify the decision date and funding agency:
* Status of research ethics board review
* Provide a copy of any scientific peer review that was conducted on the proposed research project and the investigators’ response.
	+ If no scientific peer review is currently available, please explain why:
* Research Team Member(s). Provide name, position and institution. Specify role and contribution to the project:
* Project timeline:
1. Start date (yyyy/mm)
2. End date (yyyy/mm)
* Return of data to the MIREC Biobank:
1. Describe what kinds of variables will be generated by the project (e.g., results of laboratory analysis, derived variables, any variables created from linkage with non-MIREC datasets)
2. Format of the data that will be returned to the Biobank
3. Estimated date (yyyy/mm)
* Return of specimens to the MIREC Biobank (if applicable):
1. Estimated date for the return of left over specimens to the Biobank (yyyy/mm):
2. Estimated volume in each container;
3. Storage, handling and transport conditions to maintain integrity of specimens.
* Research location:
1. Address of laboratory (i.e., where samples will be analysed). Provide justification for laboratory (i.e., experience and expertise of personnel, available facilities, infrastructure and equipment, certifications held by lab, validated lab techniques for analyte of interest, etc.).
* Include a list of abbreviations used in the application
* Declare any conflicts of interest
* How did you find out about the MIREC Biobank?
* Acknowledgement of the “Restrictions on use of the MIREC Data and Specimens” (**cf p. 2**):
* Check box to confirm that the Applicant understands and can comply with the restrictions: Yes [ ]

**Checklist of required documents (send all documents to** **mirec.project@recherche-ste-justine.qc.ca****)**

[ ]  Completed full application form in RTF format

[ ]  Revised preliminary application, if applicable, in RTF format

[ ]  Scanned copy of the signature page.

[ ]  Up-to-date condensed CV of the Applicant, Applicant 2 and all Team Members, with publications and research funded from the past five years only.

[ ]  Completed *SPECIMEN SELECTION TOOL (track change version), if applicable.*

[ ]  Completed *DATA SELECTION TOOL (track change version).*

[ ]  Peer reviewers’ comments, if available.

[ ]  Funding approval, if available.

**SIGNATURE PAGE FOR FULL APPLICATION TO THE MIREC BIOBANK**

**Applicant**

**By signing below, I declare that all information provided in this application is complete and correct.**

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**Name of Applicant Signature Date**

**Institutional Representative**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Authorized Person Title of Authorized Person**

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**Signature Location Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Institution**

***If a second Applicant, complete below:***

**Applicant 2**

**By signing below, I declare that all information provided in this application is complete and correct.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Applicant Signature Date**

**Institutional Representative 2**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Authorized Person Title of Authorized Person**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature Location Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Institution**

**Form 3: AMENDMENT REQUEST TO AN APPROVED BIOBANK PROJECT**

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| ⇒ | **Use the approved Application document, and edit as needed, using the *track changes feature*.** |  |

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| --- | --- | --- |
| ⇒ | **Provide a summary and justification of the revised project:** |  |

* **Attach the revised Application document in RTF format and email to** **mirec.project@recherche-ste-justine.qc.ca**
* **Attach the revised *SPECIMEN SELECTION TOOL (track change version).***
* **Attach the revised *DATA SELECTION TOOLS (track change version).***
* **Attach a scanned copy of this signed page**

**Declaration and Signature of Applicant(s)**

**By signing below, I declare that all information provided in this amendment request is complete and correct.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Applicant (1) Signature Date**

**If a second Applicant, complete below**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Applicant 2** (e-signature accepted) **Date**

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| --- |
| **To be filled out by the Biobank Manager before providing new Material** |
| **Sent Theme Leader Consultation email: ☐****If overlap identified, sent confirmation e-mail of discussion regarding identified overlap of data analysis plans: ☐****If Applicant is a Trainee, received confirmation email from supervisor: ☐****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Name of Biobank Manager Signature Date** |