MIREC Biobank Management Policy

1.0 Objective
The objectives of this policy are to define the organisational structure and governance of the MIREC Biobank, as well as policies and procedures for management of the data and specimens stored in the MIREC Biobank.

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 Manager: Ms. Nicole Lupien, or her duly appointed replacement (mirec.project@recherche-ste-justine.qc.ca).

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.

CHU Sainte-Justine: The Centre hospitalier universitaire Sainte-Justine, a public healthcare institution in Montreal, Quebec, governed by the Act respecting Health Services and Social Services, RSQ, c S-4.2.

Communications: Any sharing of MIREC results or information related to the MIREC Research Platform Studies with parties outside the MIREC Community.

Derived Variable: A new variable created as a function of existing variables and/or by applying mathematical functions (e.g. BMI from weight and height, age groups, molar sum of PCBs). The original variables contain the raw data obtained from Participants or the laboratory results.

Designated Non-Sensitive Information: a subgroup of the Individual-level data that cannot indirectly lead to identification of a Participant, by matching criteria such as address, age, sociodemographics and health information, or date of delivery.

Designated Principal Investigator (hereafter referred to as “Designated PI”): The investigator who assumes responsibility for the Research Question in a MIREC Data request or Biobank application.

Designated Sensitive Information: a subgroup of the Individual-level data that could indirectly lead to identification of a Participant, by matching criteria such as address, age, sociodemographics and health information, or date of delivery. Designated Sensitive Information must not leave Canada.

Ecological Datasets: Group-level data for defined geographical regions that were collected by a government agency to monitor and compare regions on certain factors, such as air pollution, municipal drinking water constituents, greenspace, average income, etc.

End-User Acknowledgement: A document whereby each individual who will have access to the Material agrees to certain restrictions on its use and disclosure.

Follow-Up Studies: Research studies which involve contact with Participants, including MIREC-ID, MIREC-CD3, MIREC CD-Plus, and any future studies that follow any of the cohort established in the MIREC Study in a longitudinal fashion and are led or co-led by at least one of the MIREC Study Co-Principal Investigators.

Funders: Organisations that contribute financially to the establishment and management of the MIREC Biobank, whether through grants or contracts, but excluding organisations whose contribution is limited to paying access fees.
Human Milk Biobank Management Sub-Committee: A duly constituted committee, composed of Health Canada employees, that is responsible for the specific management of the human milk specimens stored in the MIREC Biobank.

Individual-Level Data: information at the level of individual participants. These data include the Designated Sensitive Information as well as the Designated Non-Sensitive Information.

Internal Data Access: Access to Individual-Level Data that are not considered a Biobank access. These data are used in a Primary or Secondary Data Analysis.

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 tests, Biobank Projects, and Derived Variables.

MIREC Biobank: A collection of data, biological and environmental specimens obtained in the course of the MIREC Research Platform Studies that have been stored for future research with the consent of Participants.

MIREC Biobank Access and Utilization Agreement: A contract between CHU Sainte-Justine and Dr. William Fraser (or his duly appointed replacement) on the one hand, and the organisation requesting access to Material and, when applicable, the individual requesting access to the Material on the other hand, that sets out the conditions under which Material is to be transferred and used by the Applicant, and the obligations of the parties to the Agreement.

MIREC Biobank Management Committee (hereafter referred to as “MBMC”): A duly constituted committee with the composition set forth herein that is responsible for the strategic direction of the MIREC Biobank.

MIREC Community: Investigators, staff and Trainees involved in MIREC Research Platform Studies.

MIREC Data: Information about Participants that includes that obtained from questionnaires, images, clinical tests, medical chart abstractions, physical exams, linkage to external Ecological Datasets (e.g., ambient air pollution, municipal drinking water analysis) and the results of laboratory analysis of their specimens. These data include the Individual-level Data and grouped Data.

MIREC Publication: A communication of the results of any of the MIREC Research Platform Studies in the form of a manuscript for submission to a journal or another medium, such as an oral presentation, a poster, a thesis or dissertation.

MIREC Research Platform Studies: Research studies that involve the use of Material from the MIREC Biobank, including the original MIREC Study, Follow-Up Studies, and Biobank Projects.

MIREC Studies: The original MIREC Study and any Follow-Up Studies that are not Biobank Projects.

MIREC Studies Investigators: Investigators that are listed in the protocol of the original MIREC Study or any Follow-Up Studies (MIREC-ID, MIREC-CD3, MIREC-CD Plus, and MIREC-ENDO).

MIREC Study: A research study entitled “Maternal-Infant Research on Environmental Chemicals (MIREC): A National Profile of In Utero and Lactational Exposure to Environmental Contaminants” whereby the initial cohort and MIREC Biobank were created.

MIREC Study Co-Principal Investigators: William Fraser, Professor, Clinical Epidemiologist, University of Sherbrooke and CHU Sainte-Justine; and Tye Arbuckle, Senior Epidemiologist & Research Scientist, Health Canada; permanent members (or their designates) and co-chairs of the MBMC.

Participant Identifier (hereafter referred to as “Participant ID”): A unique numerical identifier comprised of the 2-digit Site number and 3-digit number assigned chronologically at each site (e.g. 01-001).

Participants: Parents and their infants/children who participated in the MIREC Study. In Follow-Up Studies or Biobank Projects, Participants may also include informants such as siblings, legal guardians, and school teachers.
**Presentation:** Any disclosure of the results of any of the MIREC Research Platform Studies in the form of a conference abstract, or oral/poster presentation to an audience containing individuals who are not part of the investigative team or the presenter’s institution.

**Primary Data Analysis:** Research Questions that were specifically identified in the approved MIREC or Follow-Up Study protocols. Use of MIREC data to answer these Research Questions are considered an Internal Data Access.

**Research Ethics Board (hereafter referred to as “REB”):** A committee constituted in accordance with applicable laws, regulations, and policies that is responsible for the ethical assessment and approval of all research involving human subjects.

**Research Question:** An answerable inquiry into a specific concern or issue that is the first step in developing a research project.

**Secondary Data Analysis:** Data analysis for Research Questions that cross themes and/or were not specifically identified in the approved MIREC or Follow-Up Study protocol, as long as the proposed data analysis involves all of the following: a) the Research Question fits within the scope of investigating the health of mother and infant/child; b) there is no linkage with non-MIREC datasets or new analysis of specimens; and c) the analysis is led by an individual who is a Co-Investigator (or their Trainee) on the MIREC or Follow-Up Study protocol in which the data were collected. Data used in this type of analysis are considered an Internal Data Access.

**Site:** Any institution that recruited or followed Participants in the MIREC Study and/or Follow-Up Studies.

**Site Investigators:** The individual or individuals with overall responsibility for the conduct of the MIREC Study or Follow-Up Studies at a Site.

**Specimens:** Samples of biological or environmental materials obtained from Participants or their environment as part of the MIREC Research Platform Studies.

**Trainee:** An undergraduate, graduate or post-doctoral student, resident or fellow supervised by a MIREC Research Platform Studies Investigator.

### 3.0 Scope

This policy applies to all individuals and organizations involved in management and governance of the MIREC Biobank, and to all individuals and organizations conducting MIREC Research Platform Studies.

### 4.0 Policy

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

- Maternal and child exposure to priority environmental chemicals;
- Fetal growth, pregnancy and the health of mothers and their infants;
- Health risks, if any, that are associated with measured concentrations of chemicals; and
- Potential mechanisms of toxicity and markers of susceptibility for adverse pregnancy and child outcomes.

To support these objectives, the MIREC consent for Future Research on Stored Biological Samples obtained from Participants is broad enough to support a range of research on new emerging contaminants, fetal growth, pregnancy and the health of mothers and their children.

The MIREC Biobank is managed in accordance with the highest ethical standards and the principles set forth in:

- The Quebec *Charter of Human Rights and Freedoms*, CQLR, c C-12 , [http://canlii.ca/t/hxt9](http://canlii.ca/t/hxt9) retrieved on 2014-10-15;

4.1 Guiding Principles for Granting Access

The MBMC makes its decisions, including decisions relating to the future direction of the MIREC Biobank, on the basis of these standards, objectives and the best available scientific evidence. Only research studies that entail, at most, a minimal risk to Participants will be granted access to the MIREC Biobank.

The criteria for granting access include:

• feasibility;
• scientific value;
• minimal risk;
• availability of Material;
• contribution to the MIREC Research Platform Studies;
• public health importance to Canadians.

The MIREC Biobank is managed on a not-for-profit basis. The MBMC sets access fees with a view to covering the costs of operating the MIREC Biobank. To help preserve the integrity and volume of the specimens for future users, part of the access fees will pay for the micro-aliquoting of specimens.

5.0 Procedures

5.1 Access

5.1.1 General Conditions

No one may access the MIREC Biobank and conduct Biobank Projects unless they have first obtained the approval of the MBMC and of the identified REB(s), and signed a MIREC Biobank Access and Utilization Agreement and the MIREC Data End-User Acknowledgement for Biobank Applicants. The steps to apply for access to the Material are described in the Application Form for Access to MIREC Biobank.

5.1.2 Access Fees

Biobank Projects will have to pay access fees. These fees are required to cover the costs of: (1) processing and analyzing the application to the MIREC Biobank; (2) preparing the Material requested; and (3) helping to support the operating costs of the MIREC Biobank over its expected life of 30 years. The assessment of the fees for a specific Biobank Project is based on numerous factors, including the rarity of the requested Material, the complexity of the Biobank Project, and the category of Applicant (MIREC Study Investigator, Non-MIREC Study Investigator from an institution within Canada, or Non-MIREC Study Investigator from an institution outside of Canada). The shipping of the specimens from their storage location in the MIREC Biobank to the laboratory conducting analyses, as well as the returning of the unused or leftovers to the storage location will be paid directly by the Applicant. The specific cost of access for a Biobank Project will be indicated in the MIREC Biobank Access and Utilization Agreement.

5.1.3 Review of Applications

Applications will be reviewed as received, and based on the availability of the MBMC members. Applicants can expect the approval process to take a minimum of three months before the release of the Material. Questions can be directed to the Biobank Manager (mirec.project@recherche-ste-justine.qc.ca).
5.1.4 **Access Restrictions**
The MBMC will approve applications for Biobank Projects that are compatible with Participants’ consent.

No subsets of specimens stored in the MIREC Biobank will be provided: any laboratory analysis must be conducted on the full set available, with the exception of the human milk and maternal hair specimens collected as part of the MIREC Study.

MIREC samples cannot be used for validating the precision of a laboratory method. Repeat analyses are not allowed. In the case where the laboratory is confident that specific individual test results are not valid, these results should be replaced by a code from the preset list provided by the Biobank Manager.

5.1.5 **Special Considerations for Milk Specimens**
Requests to access the human milk specimens must also be approved by the Human Milk Biobank Management Subcommittee, which will evaluate the merit of the request for the human milk.

5.1.6 **Inclusion of Material from Biobank Projects**
Any new data created as part of a Biobank Project must be sent to CHU Sainte-Justine for inclusion in the MIREC Biobank (e.g., laboratory results, linkage to other datasets). In addition, the Applicant must return, at his/her expense, all remaining specimens to the MIREC Biobank with information on the handling and processing of the specimens (e.g., freeze-thaw cycle, storage temperatures, volume remaining).

5.2 **Use, Confidentiality and Storage of the Material**
The Biobank Manager is responsible for ensuring that Material is stored under secure conditions in line with current good practices, and ensuring that specimens are stored under optimal conditions that are scientifically appropriate. To that end, the MBMC can adopt and update storage policies and procedures, and make all necessary arrangements for the storage of Material, including arranging to have third parties store the Material. For Biobank Projects, the storage and shipping requirements for the Material will be outlined in the MIREC Biobank Access and Utilization Agreement.

All Material is identified only by a Participant ID and stored separately from any identifying information such as the Participant’s name or address.

Additional information concerning storage of the Material is presented in section 6.3.1. Specimens are stored in one of the locations mentioned in section 6.3.1 after analyses planned as part of approved MIREC Research Platform Studies have been conducted.

5.3 **Destruction of the Material**
The Biobank Manager will arrange to have the Material destroyed 30 years after the end of the analyses planned for the original MIREC Study, according to procedures that are considered appropriate at that time. These analyses are still ongoing.

Out of respect for Participants’ autonomy, Participants have the right to withdraw from the MIREC Biobank at any time. Upon request, the Biobank Manager will arrange to have any stored Material from the Participant destroyed as soon as reasonably possible. This Material will therefore be unavailable for any new Biobank Project and future Follow-up Studies.

5.4 **Role of CHU Sainte-Justine**
CHU Sainte-Justine is the coordinating center and custodian of the Material, and a party to the access agreement. It employs the personnel responsible for coordinating the central operations of the MIREC Biobank, including the Biobank Manager, and administers the funds received from Funders and access fees.

No one may undertake MIREC Research unless CHU Sainte-Justine has negotiated a satisfactory agreement with the concerned party in consultation with the MBMC.
5.5 Communication of Results to Participants

The results of analyses of the specimens are generally not communicated to Participants. However, the REBs involved in reviewing a Biobank Project, in collaboration with the Public Health authorities and the MBMC, could decide that one or more of the planned chemical analyses or clinical tests may be significant to the Participant’s health.

This determination will be based on the following criteria:

- A chemical or clinical test has a generally accepted limit above which it can be significant to the Participant’s health; and
- Effective preventive or therapeutic measures are available to address the issue identified.

The Applicant of the Biobank Project must notify the Biobank Manager as soon as any such result is obtained. The Biobank Manager ensures that the results are communicated to the Participant concerned, typically through the Site or the Site Investigator and, if appropriate, the Participant’s treating physician.

5.6 MBMC

5.6.1 Composition

The MBMC consists of the following individuals:

- The Biobank Manager (non-voting);
- The MIREC Study Co-Principal Investigators or their designates;
- One person with legal and ethical expertise in the management of health data, databanks and biobanks (non-voting);
- Three representatives of the MIREC Sites and/or MIREC Studies Investigators;
- One representative of Health Canada’s biomonitoring working group;
- One representative of Health Canada’s Food Directorate.

The two MIREC Study Co-Principal Investigators or their designates are permanent members of the MBMC. The remaining members are nominated by the MBMC and serve five-year terms with the possibility of renewal. None of the members of the MBMC, with the exception of the Biobank Manager, will receive wages for their participation on the committee.

The three members of the MBMC that are Health Canada employees sit on the committee as employees of the Crown (public officers) and not in their own personal capacity. Accordingly, these public servants have a duty to always act in the best interest of the Crown. Information they receive as a result of participation on the MBMC will be discussed with other federal officials as necessary. Any information received may be subject to an Access to Information Request and therefore possibly be disclosed in accordance with the Act (subject to exceptions).

5.6.2 Powers

The MBMC is responsible for the strategic direction of the MIREC Biobank, and has the power to:

- Make all decisions of a scientific or administrative nature concerning the operation, maintenance and continuation of the MIREC Biobank, including updating the MIREC Biobank Management Policy, the MIREC Research Platform Knowledge Transfer Policy, the MIREC Biobank Access and Utilization Policy, the MIREC End-User Acknowledgement and application forms, as needed;
- Set priorities for the use of the MIREC Biobank;
- Approve, reject, or propose modifications to Biobank Projects that propose to use Material, and establish access fees for Biobank Projects;
- Review and approve annual and final progress reports submitted by the Applicant of the Biobank Project.

The MBMC is also responsible for establishing rules and procedures to address the following matters, and updating such procedures as necessary:
• Inventorying and tracking of specimens;
• Auditing of the specimen tracking system to ensure that the information it contains is accurate.

5.6.3 Meetings
The review of a Biobank Project by the MBMC is done either by email consultation or teleconference. The applications are reviewed as received.

If members of the MBMC feel that external scientific advice is needed on a particular application, they may seek that advice prior to making a decision.

In order to be approved, a Biobank Project will need the support of the majority. Therefore a tied vote will be considered as a refusal. The MBMC will provide comments to the Applicant, who will be free to re-submit once the comments have been addressed.

5.6.4 Conflicts of Interest
Members of the MBMC should inform the committee about any potential conflicts of interest and provide the committee with an opportunity to determine whether they should participate in the assessment of a research project. However, they would not be allowed to vote on the application. A member of the MBMC who is an Applicant, Co-Applicant, or supervises an Applicant on a proposed Biobank Project is an example of conflict of interest.

5.7 Biobank Manager
The Biobank Manager is responsible for the day-to-day operations of the MIREC Biobank. The Biobank Manager ensures that the MBMC’s decisions are carried out efficiently and in compliance with any applicable norms related to safety, privacy and confidentiality. The Biobank Manager may recommend that CHU Sainte-Justine hire personnel or purchase equipment in order to further the objectives of the MIREC Biobank.

5.8 Publications and Presentations
Publications and presentations based on MIREC Research Platform Studies are governed by the MIREC Research Platform Knowledge Transfer Policy. No one may publish or report results that were derived from the use of Material from the MIREC Biobank, except in compliance with the MIREC Research Platform Knowledge Transfer Policy.

5.9 Amendments
The MBMC may amend this policy from time to time, as it deems appropriate. Amendments may be necessary for reasons including legislative changes, the need to accommodate future MIREC Studies, and technological advances. Any amendments will be submitted to the REB of CHU Sainte-Justine and of Health Canada, and will not become effective unless their approval is obtained. The Biobank Manager will send any such approved amendments to all concerned parties, and the conditions under which they become binding will be established through written agreements between CHU Sainte-Justine and that party.

6.0 Additional Information

6.1 Contact Information for the Biobank Manager
MIREC Study
CHU Sainte-Justine
3175, Côte-Sainte-Catherine
Montreal, Quebec
Canada  H3T 1C5
Tel: 514-345-4931, ext. 4267
mirec.project@recherche-ste-justine.qc.ca
6.2 Funders of the Original MIREC Study
• Health Canada;
• The Canadian Institutes for Health Research;
• The Ontario Ministry of the Environment.

6.3 Current Arrangements for Handling of the Material
All Material is stored in locked rooms with access limited to authorized personnel. All specimens are handled and stored in such a manner as to preserve their integrity.

6.3.1 Storage of Specimens from MIREC Research Platform Studies
Once the planned laboratory analyses are completed, specimens are stored at the following locations:
• Breast milk: Health Canada (Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch, Food Research Division, Sir Frederick Banting Research Centre, 251 Sir Frederick Banting Driveway, 3rd floor, Ottawa, Ontario);
• All other specimens: CHU Sainte-Justine.

Storage conditions:
• Freezers at -20°C or -80°C as appropriate, with padlocks and access restricted to authorized personnel, with back-up power and alarm systems for power failures, and an on-call service at all times to secure the specimens in case of freezer failure. Hair samples are stored at room temperature, in a locked filing cabinet.

6.3.2 Storage of the Data
Type of server:
• Secure, with restricted access and regular back-ups.

Restrictions on use and transfer of data:
• No personal identifiers are accessible for analysis. Nonetheless, the individual-level data are considered confidential, and their use is subject to strict rules.
• To protect the privacy and confidentiality of MIREC Participants and their families, Individual-level Data are managed strictly. Designated Sensitive Information can never leave the Canadian territory. However, permission may be requested to use Data that are not Designated Sensitive Information outside of Canada, if the need can be justified and a commitment made to Data security.
• 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.

6.3.3 Arrangements for Data Entry
• Typically, Sites ship Participants’ coded Material to CHU Sainte-Justine, where the data are entered and specimens are tracked and stored;
• In some MIREC Studies, such as MIREC CD3, Participants directly responded to questionnaires on a secure website, and the data are then transferred to the secure server;
• Future MIREC Studies may involve other mechanisms for data entry as provided for in their protocols. Only mechanisms that comply with current good practices will be adopted.