Biobank Management Policy

1.0 Objective

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

2.0 Definitions

Applicant: Researcher seeking access to the IMPACT 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: Mrs. Jessica Pudwell, or her duly appointed replacement.

Biobank Project: A research study that involves access to the Material in the IMPACT Biobank. The following would be considered Biobank Projects: (1) any request to access the data stored in the IMPACT 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 IMPACT Biobank with other datasets; (3) any proposal to analyse any specimens stored in the IMPACT Biobank; (4) any proposal not led by the IMPACT Study Co-Principal Investigators that entails contact with Participants.

Communications: Any sharing of IMPACT results or information related to the IMPACT Research Platform Studies with parties outside the IMPACT 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). 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 an IMPACT 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.

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.

Funders: Organisations that contribute financially to the establishment and management of the IMPACT Biobank, whether through grants or contracts, but excluding organisations whose contribution is limited to paying access fees.

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

IMPACT Biobank Access and Utilization Agreement: A contract between Queen's University and Dr. Laura Gaudet (or her 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.

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

IMPACT Community: Investigators, staff and Trainees involved in IMPACT Research Study.

IMPACT 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.

IMPACT Publication: A communication of the results of any of the IMPACT Research Study 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. This includes the original IMPACT Study, Follow-Up Studies, and Biobank Projects.

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

IMPACT Studies Investigators: Investigators that are listed in the protocol of the IMPACT Study.

IMPACT Study: A research study entitled "IMPACT: A Prospective Cohort Study of the Impact of Opioid and Cannabis Exposure on Fetal Growth".

IMPACT Study Co-Principal Investigators: Laura Gaudet, Associate Professor, Faculty of Health Sciences, Department of Obstetrics and Gynecology, Queen's University and Shannon Bainbridge, Associate Professor, Interdisciplinary School of Health Sciences, Faculty of Health Sciences, Department of Cellular and Molecular Medicine, University of Ottawa (co-chairs of the IBMC).

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 IMPACT Biobank. Examples of specimens include cord blood, urine, and placenta tissue. Examples of data include that generated from questionnaires to the Participants, laboratory test results, chart review, and Derived Variables.

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 who participated in the IMPACT Study.

Presentation: Any disclosure of the results of any of the IMPACT Research Study 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 IMPACT Study protocol. Use of IMPACT 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 IMPACT 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-IMPACT 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 IMPACT 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 IMPACT Study.

Site Investigators: The individual or individuals with overall responsibility for the conduct of the IMPACT Study at a Site.

Specimens: Samples of biological or environmental materials obtained from Participants as part of the IMPACT Research Study.

Trainee: An undergraduate, graduate or post-doctoral student, resident or fellow supervised by an IMPACT Research Study Investigator.

3.0 Scope

This policy applies to all individuals and organizations involved in management and governance of the IMPACT Biobank, and to all individuals and organizations conducting the IMPACT Research Study.

4.0 Policy

The objectives of the IMPACT Biobank are to provide a basis for future research on pregnancy and newborn health.

To support these objectives, the IMPACT consent for Future Research on Stored Biological Samples obtained from Participants is broad enough to support a range of research on fetal growth, pregnancy and the health of mothers and their children. Biobanking is an optional part of the IMPACT study. Participants may decide not to participate in the optional biobanking research and still participate in the main study

Some of the future research may include testing on genes related to viruses. No hereditary testing will occur. Researchers also may be interested in the way that genes affect health and disease, or how the body responds to treatment.

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

- The *Canadian Charter of Rights and Freedoms,* <*http://laws-lois.justice.gc.ca/eng/const/page-15.html*>
- The *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects,* <*http://www.wma.net/en/30publications/10policies/b3/17c.pdf*>
- The *Universal Declaration on Bioethics and Human Rights* (UNESCO), <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>
- The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,*
- <*http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf*>
- The *CIHR Best Practices for Protecting Privacy in Health Research,* <*http://www.cihr-irsc.gc.ca/e/29072.html*>

4.1 Guiding Principles for Granting Access

The IBMC makes its decisions, including decisions relating to the future direction of the IMPACT 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 IMPACT Biobank.

The criteria for granting access include:

- feasibility;
- scientific value;
- minimal risk;
- availability of Material;
- contribution to the IMPACT Research Study;
- public health importance to Canadians.

The IMPACT Biobank is managed on a not-for-profit basis. The IBMC sets access fees with a view to covering the costs of operating the IMPACT 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 IMPACT Biobank and conduct Biobank Projects unless they have first obtained the approval of the IBMC and of the identified REB(s), and signed a IMPACT Biobank Access and Utilization Agreement and the IMPACT 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 IMPACT Biobank.

5.1.2 Access Fees

Biobank Projects may have to pay access fees. These fees are required to cover the costs of: (1) processing and analyzing the application to the IMPACT Biobank; (2) preparing the Material requested; and (3) helping to support the operating costs of the IMPACT Biobank over its expected life of 25 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 (IMPACT Study Investigator, Non-IMPACT Study Investigator from an institution within Canada, or Non-IMPACT Study Investigator from an institution outside of Canada). The shipping of the specimens from their storage location in the IMPACT 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 IMPACT Biobank Access and Utilization Agreement.

5.1.3 Review of Applications

Applications will be reviewed as received, and based on the availability of the IBMC 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.

5.1.4 Access Restrictions

The IBMC will approve applications for Biobank Projects that are compatible with Participants' consent.

5.1.5 Inclusion of Material from Biobank Projects

Any new data created as part of a Biobank Project must be sent for inclusion in the IMPACT Biobank (e.g., laboratory results, linkage to other datasets). In addition, the Applicant must return, at his/her expense, all remaining specimens to the IMPACT 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 IBMC 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 IMPACT 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 IMPACT Research Study have been conducted.

5.3 Destruction of the Material

The Biobank Manager will arrange to have the Material destroyed 25 years after the end of the analyses planned for the original IMPACT Study, according to procedures that are considered appropriate at that time.

Out of respect for Participants' autonomy, Participants have the right to withdraw from the IMPACT 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 Queen's University

Queen's University 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 IMPACT Biobank, including the Biobank Manager, and administers the funds received from Funders and access fees.

No one may undertake IMPACT Research unless Queen's University has negotiated a satisfactory agreement with the concerned party in consultation with the IBMC.

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 IBMC, could decide that one or more of the planned 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 IBMC

5.6.1 Composition

The IBMC consists of the following individuals:

- The Biobank Manager (non-voting);
- The IMPACT 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 IMPACT Sites and/or IMPACT Study Investigators;

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

5.6.2 Powers

The IBMC is responsible for the strategic direction of the IMPACT Biobank, and has the power to:

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

The IBMC 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 IBMC is done either by email consultation or teleconference. The applications are reviewed as received.

If members of the IBMC 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 IBMC 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 IBMC 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 IBMC 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 IMPACT Biobank. The Biobank Manager ensures that the IBMC's decisions are carried out efficiently and in compliance with any applicable norms related to safety, privacy and confidentiality.

5.8 Publications and Presentations

5.8.1 Named Authors of IMPACT Publications

No one may be a Named Author of an IMPACT Publication unless they made a substantial intellectual contribution to the work being published, by meeting all of the following criteria:

- Scholarship: significant contribution to the conception, design, execution and/or analysis and interpretation of data;
- Authorship: participation in the drafting, reviewing, and/or revising of the IMPACT Publication;
- Approval: each Named Author must review and approve the final version of the IMPACT Publication before submission, and must be able to assume public responsibility for its content.

The Named Authors are responsible for the content of the publication, including the integrity of the work and the completeness, accuracy and reasonable interpretation of the data.

Individuals who contributed to the work being published, but who do not qualify for authorship of the publication, for example, those who contributed equipment or proofread a manuscript, should be acknowledged in accordance with the journal editor's guidelines.

An Investigator may share responsibility for writing or data analysis with a Trainee who has not been involved in the process of conceptualisation or data acquisition.

5.8.2 Order of Named Authors

The order of the Named Authors in a IMPACT Publication is determined by the Lead Author on the given Research Question, in accordance with the journal's guidelines.

5.8.3 Required Acknowledgements

5.8.3.1 Funders

All IMPACT Publications must acknowledge the funders of the IMPACT Study as follows: "The IMPACT Study was supported by the Canadian Institutes for Health Research (grant # PJT-178200)". If additional funders contribute to the work, they should be included in this acknowledgement.

5.4.3.2 The IMPACT Biobank

The IMPACT Biobank must also be acknowledged as the source of any Material used in a Biobank Project.

5.9 Amendments

The IBMC 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 IMPACT Studies, and technological advances. Any amendments will be submitted to the REB of Queen's University 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 Queen's University and that party.

6.0 Additional Information

6.1 Contact Information for the Biobank Manager

IMPACT Study Coordinating Centre
Queen's Department of Obstetrics & Gynaecology Research Offices, Kingston Health Sciences Centre
76 Stuart Street, Watkins 5, Room 4-5-314
Kingston, ON
K7L 2V7
613-549-6666 x3937
jessica.pudwell@queensu.ca

6.2 Funders of the IMPACT Study

- The Canadian Institutes for Health Research

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 IMPACT Research Study

Once the planned laboratory analyses are completed, specimens are stored at the following locations:

- Urine and Cord Blood Samples - will be sent to the Study Coordinating Centre: Queen's Department of Obstetrics & Gynaecology Research Offices, Kingston Health Sciences Centre, 76 Stuart Street, Watkins 5, Room 4-5-314, Kingston, ON, K7L 2V7
- Placenta Samples - fresh biopsies and paraffin embedded blocks - will be sent to the Placenta Lab: Department of Cellular and Molecular Medicine, Faculty of Medicine, University of Ottawa, Roger Guindon Hall, Rm 2058, 451 Smyth Rd, Ottawa, ON K1H 8M5

Storage conditions:

- Freezers at -20°C or -80°C as appropriate, 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.
- Paraffin embedded blocks will be stored at room temperature.
- Access to all samples will be restricted to authorized personnel.

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 IMPACT 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.

- Results that could lead to identification of an individual participating in IMPACT cannot be published.
- Any new data generated as part of the Biobank Project will be added to the IMPACT Research Study.