Biobank Access and Utilization Policy

1.0 Objective

The objectives of this policy are to define the procedures for accessing the data and specimens stored in the IMPACT Biobank, and the conditions and obligations imposed on those gaining access.

2.0 Definitions

Agreement: the IMPACT Biobank Access and Utilization Agreement.

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.

Approved Users: Individuals who have a legitimate need to access the Material for the purposes of the Biobank Project and who have signed the IMPACT End-User Acknowledgement (hereafter referred to as "**End-User Acknowledgement**").

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.

Coded Material: Material in a form in which the individual to whom it pertains is identified by an arbitrary code, and in which all information that could reasonably reveal the identity of that individual has been removed. The link between the code and the identification of the participant is kept securely by the Provider and IMPACT study sites.

Confidential Information: Communications, documents or information related to the Biobank Project that are not IMPACT Data and that originate in a confidence that they will not be disclosed, and if disclosed, would result in harm or damage for one of the Parties.

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.

Individual-level Data: Information at the level of individual participants.

Institution: Institution with which the Applicant is affiliated and who will be responsible for overseeing the conduct of the Biobank Project.

Joint Invention: An invention, as defined according to the Canadian Patent Act, created jointly by the Provider and the Applicant.

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 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 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.

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.

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.

Participants: Parents and their infants who participated in the IMPACT Study.

Parties: the Parties to the IMPACT Biobank Access and Utilization Agreement, including the Applicant, the Provider, the Institution.

Provider: Queen's University, who is the coordinating center and custodian of the Material.

Third Party: Any individual or institution who is not a party to the Agreement, but has an involvement (e.g. a laboratory that conducts analysis). Individuals under the responsibility of the Applicant are not Third Parties.

3.0 Application Process

No one may access the IMPACT Biobank and conduct Biobank Projects unless they have first obtained the approval of the IBMC and of all REBs with jurisdiction over the Project in question and signed an IMPACT Biobank Access and Utilization Agreement. The detailed steps to obtain access are outlined in the *Application Form for Access to IMPACT Biobank*.

4.0 IMPACT Biobank Access and Utilization Conditions

Before the Material is made available to the Applicant, he/she must confirm the following:

4.1 The Applicant agrees to use, share or disclose the Material in compliance with:

a) All applicable laws, regulations, and guidelines, including the "*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*";
b) Generally recognised principles of good clinical practice;
c) The IMPACT Biobank Management Policy;
d) The Protocol and description of the approved Biobank Project, as detailed in the Application Form;

4.2 The Applicant must specify to the Provider if a Third Party requires access. The terms of access will be detailed in the Agreement.

4.3 The Applicant is responsible for fully informing each individual who obtains access to the Material of the conditions contained herein. All these individuals, including Third Parties, must be listed in the End-User Acknowledgement.

4.4 Material transferred to a Third Party may require a sub-agreement.

4.5 Queen's University will transfer coded Material. The Applicant must not use the Material to attempt to identify the Participants from whom it was obtained.

4.6 The Institution and the Applicant must protect the Material against loss, theft and unauthorized access, modification, or disclosure.

4.7 Handling of the specimens must be done in accordance with the approved research protocol to preserve the integrity and volume of the sample.

4.8 If the Material is lost, stolen, accessed, modified or shared without authorization, the Applicant must promptly inform the Biobank Manager, who will agree with the Parties on the appropriate action required to address the situation.

4.9 It is the responsibility of the Applicant to ensure that Designated Sensitive Information does not leave Canada.

5.0 Compliance with Ethics Requirements

5.1 The Provider will not transfer the Material to the Applicant or the Institution before the Biobank Project is approved by the REBs of Health Canada and of his/her Institution (collectively, the "**REB Approvals**"). The Applicant must send a copy of the REB Approvals to the Biobank Manager promptly once obtained.

5.2 The Applicant must maintain the REB Approvals and provide the annual confirmation of REB renewal to the Biobank Manager. The Provider may require that the Material be returned or destroyed if any of the REB Approvals are not renewed, or are suspended or revoked.

5.3 The Applicant must conduct the Biobank Project in compliance with the REB requirements.

5.4 The Applicant must submit any changes to the approved Biobank Project as an amendment to the IMBC. The Applicant must not implement any changes until they are approved by the IMBC. REB approval from his/her Institution may also be required.

6.0 Access Fees

6.1 Access and per specimen fees may be determined on a case-by-case basis, depending partly on the scarcity of the specimens, 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). Estimated access fees will be provided along with the IMBC approval of the Biobank Project, and confirmed in the Agreement. The shipping of the specimens from their storage location 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.

7.0 Reporting to the IMBC

7. The Applicant must submit the *Annual Report to IMPACT Biobank* form each year. At the completion of the Biobank Project, he/she submits a final Report, along with the IMPACT Biobank Project Completion Certificate. The Biobank Manager will confirm the duly completed work.

8.0 Auditing

8.1 The Provider may audit the Institution's facilities, with reasonable advance notice, and during normal business hours to verify its compliance with these terms. The Institution and the Applicant must collaborate with such audits and allow representatives of the Provider to access all records and facilities that could be relevant to such an audit.

9.0 Ownership of the Material and Inventions

9.1 Neither the Institution nor the Applicant is granted any ownership rights in the Material. Queen's University retains all rights and titles in the Material already in the IMPACT Biobank. New Data and Specimens generated from the Material will belong to the IMPACT Biobank upon coming into existence.

9.2 Queen's University hereby grants the Applicant and Institution a non-exclusive licence to use the Material and any new Data or Specimens solely for the purposes of conducting the Biobank Project, subject to the conditions provided for in the Agreement.

9.3 If an invention arises from the Biobank Project, the inventing party will own it. In the case of a Joint Invention, it will be jointly owned by the Parties, in proportion to their intellectual contribution to its development. The Parties must negotiate an agreement regarding the protection and exploitation of the Joint Invention in good faith. This subsection does not supersede any pre-existing intellectual property agreements between Queen's University and the Applicant, or between the Institution and the Applicant.

10.0 Publications

10.1 The rules for publishing or disclosing the results of the Biobank Project or any information from the IMPACT Biobank are detailed in the IMPACT Biobank Management Policy. That Policy also describes how the IMPACT Biobank should be recognized in any publications or presentations.

11.0 No Obligation to Transfer

11.1 The Provider may refuse to transfer the Material to the Applicant. The Provider will not be liable for any damages the Applicant suffers as a result of this refusal.

12.0 Confidential Information

12.1. In the course of the Biobank Project, the Parties might disclose **Confidential Information** to one another. Defined as communications, documents or information related to the Biobank Project **that are not IMPACT Data** and that originate in a confidence that they will not be disclosed, and if disclosed, would result in harm or damage for one of the Parties. For example, the Application Form for Access to IMPACT Biobank is considered Confidential Information, except the title, the name of the Applicant and the lay summary. Such information disclosed by one party (the "**Disclosing Party**") to another party (the "**Receiving Party**") is not considered Confidential Information if:

a) It is in the public domain at the time of disclosure, or becomes part of the public domain after disclosure through no fault of the Receiving Party;

b) It is obtained from a Third Party, provided that the Third Party was not bound by any obligation of confidentiality to the Disclosing Party at the time of disclosure.

12.2 The Receiving Party must use reasonable measures to protect the Confidential Information against loss, theft, and unauthorized use, access, copying, or modification.

12.3 The Receiving Party must not use or disclose Confidential Information except for the purposes of the Biobank Project and in accordance with the terms of the Agreement, unless pursuant to a judicial order or for regulatory requirement. In such a case, the Receiving Party must promptly notify the Disclosing Party and allow the Disclosing Party to intervene to prevent or limit such disclosure.

12.4 Disclosure of Confidential Information is limited to those persons that have a legitimate need to access it for the purposes of the Biobank Project.

12.5 The Parties must notify one another at the first reasonable opportunity if Confidential Information is stolen, lost, or used, accessed, copied or modified in violation of the Agreement. In any of these events, the Parties must collaborate to rectify the situation.

13.0 Indemnification and Exclusion of Warranty

13.1 The Applicant assumes the risk of any damage, loss, or expense that might arise from his/her conduct of the Biobank Project or its use, handling, return, or disposal of the Material from his/her first receiving it (or received by a Third Party) until the duly disposal or return to the Provider.

13.2 In the event of a claim made by a Third Party arising from the Applicant's conduct of the Biobank Project, he/she must indemnify, defend, and hold harmless the Provider and its officers, directors, employees, and agents from any loss, liability, damage, or expense, including reasonable attorney's fees and legal costs arising from the claim. The Applicant is not required to indemnify, defend, or hold harmless the Provider if the claim is a direct result of the Provider's negligence or wilful misconduct, or if it arises from the Provider's infringement or violation of any patent, copyright, or other intellectual property right of a Third Party.

13.3 If the Provider becomes aware of a claim likely to lead to a request for indemnification, it must promptly notify and provide the Applicant with any pertinent information. The Provider must cooperate with the Applicant in the defence of the claim. The Provider may elect to assume control of the defense of the claim, in which case, the Applicant is not required to defend or indemnify the Provider.

13.4 The Material is experimental in nature and may have unknown characteristics, may carry infectious agents, or may be otherwise hazardous. THE MATERIAL IS PROVIDED "AS IS" AND THE PROVIDER MAKES NO WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIAL, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT, COPYRIGHT, OR OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY. Further, the Provider makes no warranty as to the identity, purity, safety, or activity of the Material.

14.0 Duration of Access

14.1 The duration of the access granted to an Applicant, and therefore the duration of the Access Agreement, will be based on the planned duration of the approved Biobank Project. It will thereby vary depending on each Biobank Project.

15.0 Completion of a Biobank Project

15.1 A Biobank Project is considered completed when the left over specimens are returned to the Biobank, all new data are transferred, including results from laboratory analysis, derived variables and created variables from linkage with non-IMPACT datasets, and all planned publications have been released. One copy of the full dataset from the Biobank Project must be kept by the Applicant for five years after the last publication. All dataset duplicates must be destroyed after the last planned publication. The *IMPACT Biobank Project Completion Certificate* must be signed by the Applicant and Biobank Manager.

16.0 Contact Information

16.1 For any questions on this Policy, you can contact 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