

# McGill University - Faculty of Medicine

## General Guidelines for Biobanks and Associated Databases

### 1. Preamble

#### *Introduction*

This document offers general guidance for researchers at the Faculty of Medicine of McGill University and its affiliated institutions that collect and store human biological samples and/or associated data, for the purpose of medical research. These Guidelines lay out general requirements for establishing, maintaining and providing access to biobanks and their associated databases.

Biobanks may include: new collections of samples and data; residual samples and data following the completion of a research project or left over from medical care. All three can serve specific research purposes, or act as a resource. In applying these Guidelines, researchers, managers, and research ethics boards (“REBs”) should carefully consider these three specific contexts.

#### *Scope*

These Guidelines cover research using all new and existing biobanks and associated databases at McGill University and its affiliated institutions. Where the research use of previously approved biobanks is currently impracticable, grandfathering (i.e., allowing a pre-existing practice to continue) may be desirable following REB approval. Although these Guidelines primarily target biobanks and associated databases that are part of observational studies, it should be noted that clinical trials are increasingly adding a biobanking component to the main study. Research projects that involve biobanking, but also interventions (such as study drugs or devices) are subject to additional requirements.

The Guidelines must be interpreted in light of existing national and provincial laws and ethical guidelines, with certain clarifications (See Annex 1: Applicable Norms). Specific policies and/or standard operating procedures (“SOPs”) that address the issues outlined in these Guidelines should be adopted. To ensure the research value and future interoperability of biobanks and associated databases, researchers should also follow international ethical norms and scientific best practices, where possible. McGill researchers who store data and samples in exterior locations or jurisdictions should consult these *General Guidelines for Biobanks and Associated Databases*, as their activities affect McGill University and the medical research community as a whole. Finally, special considerations may apply with respect to data and samples collected from minors, incapable adults and deceased persons.

### 2. Definitions

**Access:** access to Samples and/or Data for approved research purposes.

**Approved User:** a researcher with appropriate institutional and ethics approvals that seeks to access Samples and/or Data.

**Biobank:** an organized collection of searchable Samples and/or associated Data stored for specific or as-of-yet unspecified research purposes.

**Broad Consent:** consent provided for future, unspecified research and subject to ongoing ethics review and governance.

**Confidentiality:** the duty to safeguard information provided in trust.

**Controlled Access Dataset:** composite health data that are associated with a unique, but not directly identified, Participant.

**Data:** information about a Participant provided to a Biobank (usually through questionnaires, linkages to registries, and/or morbidity/administrative Databases), including any medical images or information generated from the analysis of Participant Samples (e.g. personal, medical, genetic, genomic or proteomic information).

**Database:** an organized collection of searchable Data associated with a Biobank and stored for a specific or as-of-yet unspecified research purpose. Databases may be established as part of a research project, or as a resource/infrastructure for access by other researchers. They may contain Data collected directly from Participants, or repurposed from existing research, clinical, or administrative Databases.

**General Research Results:** aggregate results drawn from the analysis of Data and Samples of a group of research Participants.

**Identifiability:** there are five levels of Identifiability of Samples and associated Data:

**Directly identifying information:** information that identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

**Indirectly identifying information:** information that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

**Coded information:** information that has been stripped of direct and indirect identifiers, which have been replaced with a numerical code. A list that links the identifiers to the coded information is retained and is kept secure, to allow re-identification of Participants in certain circumstances.

**Anonymized information:** information that is irrevocably stripped of any direct or indirect identifiers, and for which no code is kept that allows for future re-identification.

**Anonymous information:** information that has never been associated with direct or indirect identifiers (e.g., anonymous surveys).

**Incidental Findings (“IFs”):** findings generated during the course of research that may or may not be clinically significant and/or are medically actionable, but go beyond the aims and objectives of the study.

**Individual Research Results (“IRRs”):** findings generated during the course of research that have potential health importance for a Participant.

**Governance:** policy orientation and management that guides and monitors research activities, ensuring that they respect ethical, legal and scientific norms.

**Manager (of the Biobank):** a person or organization that manages the Biobank and has the overall responsibility for staff, for communicating with researchers, and for reporting to institutions or agencies. The Manager is the custodian of Data and Samples, and is responsible for their security and ethical use throughout the lifecycle of the Biobank.

**Open Access Database:** a Database that usually contains aggregate Data and is publicly accessible.

**Participant:** an individual (patient or healthy volunteer) who contributes Samples and/or Data to a research project and/or study.

**Privacy:** the right of an individual to be free from intrusion or interference by others, or to choose to be identifiable to others.

**Research Ethics Board (“REB”):** an independent body, board or committee constituted of health professionals and non-medical members to review the ethical acceptability of research involving humans conducted within McGill and its affiliated institutions. An REB may be officially recognized by the Quebec Ministry of Health, but need not be.

**Samples:** all human biological materials, including tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other bodily fluids. Biological materials related to human reproduction are subject to additional requirements beyond the scope of these Guidelines.

**Secondary Use:** the use of Samples or Data in a way that differs from the original purpose of their collection.

### **3. Custodianship**

Institutions, researchers and Managers have continuing obligations to ensure, among other things, the long-term physical integrity of Samples; the Privacy and Confidentiality

of Participants; as well as the use, storage, distribution, and disposal of Samples and Data.

#### **4. Governance**

Appropriate Governance reassures Participants that the Biobank and associated Databases have processes in place to protect their interests in the use of their Samples and associated Data.

Governance should be proportionate to the size and purposes of the Biobank and associated Databases, and should be appropriate to their mission and potential benefits and harms. To ensure that they are governed by the overarching principles of transparency and accountability, Biobanks and associated Databases should clearly define their mission, operational scope, Governance structure and managerial responsibilities. This information should be public.

Governance structures should be in place to ensure: management; operations; access to, use of and discontinuation of the Biobank and associated Databases; and continued communication with Participants as well as compliance with legal and ethical principles. Processes should also be in place to review, update and modify Governance policies over time.

In developing and adjudicating Governance, attention should be paid to maximizing the future scientific value of Data and Samples. Biobanks and associated Databases should also prospectively pursue harmonization with national and international governance, policies and procedures that promote the sharing of Samples and Data. There are both external and internal aspects of Governance, as described below:

##### *External Governance / Compliance*

McGill and its affiliated institutions should ensure that the Biobank and associated Databases comply with external sources of Governance, including laws, codes, institutional policies, and funding agency ethics requirements. Such laws include Canadian and provincial legislation and regulations governing the collection, use dissemination, retention and destruction of Samples and Data for research purposes. External accountability factors required by funders or institutions (e.g., annual reporting, creation of advisory boards, etc.) can be incorporated into the internal Governance of the Biobank and associated Databases.

Biobanks and associated Databases should also undergo review and approval by a McGill-approved REB, and must also respect Quebec legislation. A committee (e.g., access committee) should also be in place to, among other roles, adjudicate use of and access to Samples and Data. This includes situations where Broad Consent for future unspecified uses is obtained subject to ethics approval, or where initial consent for research was not obtained or clearly does not cover the research use. For Access, see Section 12.

### *Internal Governance*

McGill and its affiliated institutions are responsible to ensure that the Biobank and its associated Databases have appropriate internal Governance. An internal Governance framework outlines leadership, management of operations, recruitment, re-contact and access processes, and may be subject to review by an REB or other external body. These roles and the individuals or committees who will perform them should be clearly defined. Two particularly important roles are operations management and oversight of access. Operations management establishes and oversees standards for the operations of the Biobank and associated Databases, including standard operating procedures, quality control, quality assurance, and data protection policies used when handling and storing Samples and Data. In turn, access is governed by an access policy and in some cases a separate committee (see Section 12). In some situations, an access agreement may be signed that limits the use of Samples and Data to approved purposes, ensures confidentiality, and clarifies any publication policies and downstream intellectual property rights, etc. Other internal Governance roles include communications and the establishment of ethical/legal, and scientific advisory positions.

## **5. Collection of Samples and Data / Recruitment**

A REB should review and approve the establishment of a Biobank and associated Databases before Participants are recruited. Even where Data alone is collected, and there is little interaction with Participants or risk to their bodily integrity, REB review is required. The REB should ensure that the basic elements of a Governance framework (see Section 4) are in place. The scope of research activities, potential Privacy risks, and future access approval systems should also be put in place before recruitment, so they can be appropriately reflected during the consent process. Biobanks and associated Databases should carefully consider any special issues relating to the participation and inclusion of vulnerable populations. In all cases, the means used to solicit a Participant should not undermine the voluntary quality of consent. Participants should neither be unduly induced nor over-solicited. The REB should keep in mind how the proposed procedures will affect the scientific validity and integrity of the proposed research.

## **6. Residual Samples from Medical Care**

In Quebec, consent is required from the person himself or from a person qualified to give consent on his behalf in order to use a Sample left over after routine medical care for research. An institution's admission consent form may be sufficient if the possibility of research on residual tissue is clearly mentioned and agreed to.

## **7. Secondary Research Use of Samples or Data**

REB approval is required for the use of already existing research Samples and Data in ways that differ from the original purpose of their collection. In addition, re-consent may be required unless waived by the REB. For further discussion, please see TCPS2, Chapters 5 and 12.

## **8. Consent**

Research involving the collection of Samples and Data requires both REB review and the consent of the Participant donating the Samples and Data. Consent should be given in writing, unless the circumstances justify otherwise (e.g., illiteracy; ethics approved electronic format; linguistic issues, etc.). Many normative documents describe the contents of informed consent. These McGill Guidelines cover issues specific to Biobanks and associated Databases. Despite the complex administrative, scientific, and ethical nature of biobanking, care should be taken by Biobanks and associated Databases and REBs to ensure that the consent process is neither incomprehensible nor prohibitively long. Associated standard operating procedures or policies should be reviewed by the REB along with the consent form. (See Annex 2 for a non-exhaustive list of factors that Biobanks and associated Databases should consider communicating (where appropriate) to Participants during the informed consent process at recruitment).

## **9. The Right to Withdraw and its Modalities**

Participants have a right to withdraw from research at any time, even verbally. Researchers should ensure that Participants understand this right, and provide a simple way of exercising it, including control over future use and/or destruction of Samples or Data. This right, procedures for its exercise, and any limitations posed to it by Data aggregation and anonymization or publication, should be clarified in the consent form.

## **10. Confidentiality and Privacy**

Biobanks and associated Databases should ensure that appropriate safeguards (physical, administrative, and technical) are in place to protect the identity of Participants to the degree desired, to clearly identify the individuals authorized to access personal information (including access from outside researchers), and to identify and plan for situations where linkage has been consented to. REBs should ensure that each of these aspects is addressed.

## **11. Storage**

Biobanks and associated Databases “shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards” (art. 12.5a) TCPS2. Security mechanisms that prevent non-authorized persons from accessing Samples and Data are to be implemented (i.e., coding, double-coding, encryption, scrambling, anonymization, lock and key, etc.) The code should only be accessible to authorized individuals, and only in those situations foreseen in the consent.

## **12. Access**

Any access to and use of Samples and Data should be consistent with the Participant’s original consent, or should be foreseen by law. Access procedures should be clearly



described in an access policy. The procedures should be fair and transparent (i.e., publicly available), and should also be approved by an REB. Biobanks and associated Databases planning to share Samples and Data with outside researchers should have an access procedure in place to ensure that such outside researchers have obtained the appropriate ethical approvals from their local REBs or other institutional bodies. These procedures may involve the establishment of a committee or officer in charge of reviewing access requests and verifying researcher bona fides. The responsibilities of outside researchers to limit use to approved purposes, to protect Samples and Data from unauthorized access, and to not attempt re-identification should be outlined in a legally binding access agreement. Access to Biobanks can be either open and/or controlled.

### **13. Commercialization**

The Biobank and associated Databases, Participants, and researchers should all understand who may have rights in any possible, eventual commercial applications or intellectual property (“IP”) generated. Generally, Participants do not receive any eventual intellectual property rights. This should be clearly stipulated in the consent form. Approved Users can develop commercial applications and IP via contractual arrangements. The Biobank should clearly state any limitations or privileges relating to IP as a condition of Access.

### **14. Dissemination**

Participants should not be identified in academic publications stemming from biobanking activities. This should be explained during the consent process, and should be stipulated as a condition for any publications by Approved Users. To ensure proper recognition of funders, Data providers, Managers, procedures and Participants, the Biobank and its associated Databases may also request proper attribution, as a condition of access, in publications by Approved Users.

### **15. Deceased Individuals**

Legal representatives should respect the wishes of deceased individuals, as expressed during their lifetime. If there is no such indication, legal representatives should act in accordance with the interests of deceased individuals. In Quebec, samples removed during routine medical care can be used with the consent of the person who could have given consent to the care required by the state of health of the individual while alive.

### **16. Feedback to Participants**

#### General Research Results

The names of projects and researchers using Samples and Data, along with information in lay language, on the general progress or on aggregate results should be made available to Participants on a publicly accessible website, or by other means and sent to them upon request.

### Individual Research Results and Incidental Findings

The consent form should identify whether or not IRRs and/or IFs will be returned to Participants, and the conditions and procedures for such return. The REB should review the plan for such return. It will depend to a large extent on the purpose, structure, and particular population of the Biobank and its associated Databases. In addition, the research protocol determines what information is collected and how it is analyzed, and therefore determines the likelihood that the research may reasonably generate findings that are scientifically valid and of clinical utility to individuals. Other conditions include their vulnerability and dependence, whether a clinical relationship already exists, the intensity and duration of their interactions, and, the availability of adequate funding, personnel, and validation or re-identification technologies.

If warranted, IRRs and/or IFs concerning Participants who are minors, incapable adults or deceased individuals should be returned to their legal representatives. All decisions concerning medically actionable results should be taken in the best interests of minors and incapable individuals.

## **17. Length of Storage / Closure**

The consent form should define how long Samples and Data will be stored, and specify whether they will be destroyed, transferred or anonymized, unless a REB decides otherwise. Anonymized Samples and Data can be kept for an indefinite period of time with REB authorization.

Biobanks and associated Databases may close for many reasons: the specified time for storage may run its course, the Samples and Data may lose their usefulness for the agreed research purpose, or funding may run out. Biobanks should develop a life-cycle plan, preferably before recruitment. This plan should detail how long Samples and Data will be stored, and procedures for the appropriate transfer, or, destruction of Samples and Data when the Biobank closes. This plan should be mentioned in the consent form, particularly the possibility of transferring Samples and Data to a third party, and the need for REB approval.

The Managers of Biobanks and associated Databases have an ethical duty to consider the possible transfer of Samples and Data to appropriate and purpose-compatible research entities. Managers should ensure that the recipient has in place equivalent policies, Governance structure, equipment and systems, and staff (e.g., equivalent institution – university to university).



**Annex 1: Applicable Norms (as these are updated, the updated versions will apply)**

<b><u>National and Provincial Laws</u></b>	
Quebec	Civil Code of Quebec [CCQ] <i>Loi modifiant le Code civil et d'autres dispositions législatives en matière de recherche</i> (entered into force 14 June, 2013).
<b><u>National and Provincial Guidelines</u></b>	
Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada.	<i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i> (2010) [TCPS2]
National Research Council	<i>Research Integrity Policy</i> (September 2009)
Ministère de la Santé et Services Sociaux - Québec	<i>Guide d'élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche</i> (2012)
Québec Network of Applied Genetic Medicine	<i>RMGA Statement of Principles on the Return of Research Results and Incidental Findings</i> (March 2013)
Fonds de la recherche en santé du Québec	<i>Les Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique</i> (May 2008)
<b><u>Applicable International Policies</u></b>	
Public Population Project in Genomics and Society (P3G)	<i>Generic Access Agreement for Population Genomic Studies</i> (2013) <i>P3G Model Framework for Biobank Access Policy: Core Elements</i> (2013) <i>Model Consent Form; Model Information Pamphlet</i> (2007; update 2014)
Organisation for Economic and Cultural Development (OECD)	<i>Privacy Framework</i> (11 July 2013) <i>Guidelines on Human Biobanks and Genetic Research Databases</i> (2009)
International Society for Biological and Environmental Repositories	<i>Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research</i> (2012)

## Annex 2: Considerations for Informed Consent

The following is a non-exhaustive list of factors that Biobanks and associated Databases should consider communicating (where appropriate) to Participants during the informed consent process at recruitment:

- consent to research procedures or tests that are clearly described and distinguished for the purposes of clinical care;
- the freedom of individuals to withhold consent to research without penalty, and without prejudice to any care they would otherwise receive;
- the type, amount, timing, and manner of acquiring Samples and Data;
- any anticipated linkage of Samples and Data with other information about the Participant;
- the potential research uses of Samples and Data including possible development of intellectual property and commercial uses;
- a list of persons and/or institutions who will have access to identifying information;
- the length, location, security and governance of Samples and Data storage;
- whether or not the Participant will be re-contacted for further information or secondary research;
- the conditions for release of Samples and Data, including the types of users (academic institutions, commercial companies), the requirements of REB approval, and/or review by an access committee;
- the researchers' plan for handling results and findings, including General Research Results, clinically relevant Individual Research Results and Incidental Findings;
- the right to withdraw, and an explanation of what happens to stored Data and/or Samples upon withdrawal;
- the measures employed to protect the Confidentiality of and minimize risks to Participants;
- what happens to Samples and Data should the Biobank close or the project end (and who decides what happens to such Samples and Data);
- an explanation of whom to contact (such as a patient representative or an ombudsperson) in the event that the Participant wishes to express a concern or complaint; and
- any compensation for their time or for inconveniences resulting from their participation.

The signed informed consent form should be filed in the recruitment log along with the following information:

1. The date that informed consent was obtained;
2. Whether a translator or legal representative was used; and
3. The name of the individual who obtained the informed consent.