Centre universitaire de santé McGill | McGill University Health Centre

Policy Title: Policy on Biobanks and Databases (BBDB) for Research Purposes	
Related Procedure: Revision to section 2.1.6 of the 2010 *Regulatory Framework in Health Research at the MUHC*	**Associated SNC-O&M Policy and Procedure** (if applicable): _____
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Policy: ☐ New ■ Revised (changes) ☐ Reviewed (no changes)	**Revision/Review Date:** 2020/06/14 (yyyy / mm / dd)
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Approved by: ☐ Director/Manager ☐ Risk/Ethics ☐ Policy & Procedure Committee ☐ Document Management ☐ Executive Committee ☐ CGAS (comité de gouvernance administration et soutien) ■ Board of Directors **Date:** 2018/06/15 (yyyy / mm / dd)	
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Summary: The "Policy on Biobanks and Databases for Research Purposes" clarifies the roles and responsibilities of the various stakeholders involved in the creation, management, use, support and oversight of biobanks and databases, while ensuring the protection of participants.	

I. Purpose

Considering that medical advances are based on research and that biobanks and databases (BBDB) are an important tool for furthering research, this McGill University Health Centre (MUHC) policy has three main aims:

- Ensuring that the creation, management, use, oversight, and destruction of BBDB under the responsibility of the MUHC promote high quality research, while respecting the fundamental rights and freedoms of participants, notably their autonomy and their rights to privacy and confidentiality of their data and samples.
- Harmonizing BBDB practices across the MUHC in order to ensure consistency and promote interoperability.
- Clarifying the roles and responsibilities of the various stakeholders involved in the creation, management, use, and oversight of BBDB.

II. Persons/Areas Affected

This policy is directed at researchers of the McGill University Health Centre, as defined below. It applies to all BBDBs under the auspices of the MUHC, RI-MUHC, or the MNI/MNH, including collections of biological samples and/or data used for research purposes that were in existence at the time of the implementation of the Policy.

III. References/Definition of terms

BBDB: Acronym used in this Policy to refer to a Biobank and/or a Database, as defined herein.

BBDB Director: One or more MUHC Researcher(s) with adequate training and experience to oversee the operations of a BBDB. Each MUHC BBDB must have at least one designated BBDB Director. Certain responsibilities of the BBDB Director can be shared by more than one person or delegated to a committee (e.g., Access Committee).

BBDB Management Framework: A written document outlining the governance structure and functioning of a BBDB that meets the requirements of the Québec Ministry of Health and Social Services[1]. The management framework of a MUHC BBDB requires approval from the MUHC REB.

Biobank: A systematically organized collection of biological samples and/or associated data collected, stored, and distributed for use in future research. The biological samples forming part of the biobank may be collected specifically for the biobank's purposes or be repurposed from another research project or from clinical use.

Biological Samples: Any specimen obtained from a human being, including tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva, cerebrospinal fluid, and other body fluids. Biological samples related to human reproduction include embryos, fetuses, fetal tissues and human reproductive materials. Derived products, including induced pluripotent stem cell (IPSCs) lines, are also considered biological samples for the purpose of this Policy.

Data: Information about a participant provided to, or obtained by, a BBDB, including but not limited to health and genetic information. Prior to being added into the BBDB, the information may have been contained in the participant's medical record, in administrative databases, in medical images, etc. Alternatively, primary collection may have for research purposes.

Database: A systematically organized collection of searchable data stored for specific, general, or unspecified research purposes. The data forming part of the database may be collected specifically for the databank's purposes or be repurposed from another research project or from clinical care.

Institution: For the purpose of this Policy, Institution refers to 1) the Research Institute of the McGill University Health Centre (RI-MUHC), which has been mandated by the McGill University Health Centre (MUHC) to administer research activities at the MUHC and/or 2) the relevant authority at the Montreal Neurological Institute/Montreal Neurological Hospital (MNI/MNH).

Participant: Any human being, alive or deceased, whose biological sample and/or data is stored in a BBDB. Where relevant, a reference to a "participant" includes any legally authorized representative of the individual whose biological sample

[1] *Guide d'élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche, 2012* [MSSS Guide].

and/or data is stored (e.g. the parent of a minor child or in the case of a deceased individual, the person who was or would have been qualified to consent to care).

"Personne mandatée": The "personne mandatée" is the individual formally appointed by the Board of Directors to authorise research in the institution. The "personne mandatée" can be reached by email at personne.mandatee@muhc.mcgill.ca

Researcher: Any person who can conduct research under the auspices of the MUHC according to the applicable institutional policy. Conducting research under the auspices of the MUHC includes recruiting MUHC patients.

IV. Policy

According to the Québec *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (PAM), health and social services institutions undertaking research activities must adopt specific standards for the management of biobanks and databases as part of the institutional regulatory framework. Consequently, the Board of Directors of the McGill University Health Centre adopts the *Policy on biobanks and databases for research purposes* (the "Policy").

The Policy should be interpreted in light of existing national and provincial laws and ethical guidelines, including the current versions of the *McGill University - Faculty of Medicine General Guidelines for Biobanks and Associated Databases* and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*.

The principles set forth in the Policy are specified and operationalized in the Standard Operating Procedures ("SOPs") of the MUHC Research Ethics Board ("MUHC REB").

1. Guiding principles

The full lifecycle of BBDBs should be guided by a participant-centred approach that strives for balance between:

a) Respect for autonomy,
b) Protection and promotion of participants' interests, and
c) The pursuit of discoveries and new knowledge to improve health, diagnostics and therapeutics.

The management frameworks of individual BBDBs must reflect this balance, particularly in their sections outlining objectives.

In addition to referring to the importance of respecting applicable regulations and policies, the principle of *respect for autonomy* also implies that data and specimens collected from participants for research purposes should, as a matter of principle, be used to their greatest research potential.

Participants can be asked to provide consent to the use of their data or biological samples for a broadly defined research purpose, as long as it is adequately exposed and justified in light of the aims of the BBDB and of the measures in place to ensure protection and promotion of participants' rights and interests.

Before being granted use of biological samples or data stored in an MUHC BBDB, researchers, regardless of affiliation with the MUHC, shall agree to acknowledge the contribution of the MUHC BBDB from which biological samples and/or data were obtained in all related research dissemination activities.

2. Roles and responsibilities

The Institution, the researcher appointed as BBDB Director, and the Research Ethics Board (REB) have roles and responsibilities related to the creation and administration of MUHC BBDBs. The Institution and the BBDB Director shall have joint responsibility for the data and biological samples held in the BBDB. This includes the responsibility to ensure proper handling, security, and use during the full lifecycle of biological samples and data in accordance with the three guiding principles set out above, as well as in accordance with the BBDB management framework and applicable laws, regulations, and policies.

2.1 Institution

The Institution is responsible for overseeing each BBDB operating under its auspices.

The Institution must assess and approve the creation of any BBDB from the perspective of institutional feasibility for its entire life cycle. The “personne mandatée” will be informed of the identity of the persons of each Institution responsible for the feasibility review of BBDB.

The Institution has a leadership role to play to ensure the sustainability of BBDBs, as well as efficient procurement pathways from participants to BBDBs.

The Institution, after consulting the MUHC REB, must approve the transfer, and/or relocation of a BBDB (whether complete or partial), as well as any other major change in status. In providing such approval, the MUHC REB and the Institution must be satisfied that the rights and interests of participants are duly respected. If the parties cannot come to an agreement, the Institution will retain ownership over the biological samples and/or data.

2.2 BBDB Director

The researcher who acts as a BBDB Director is vested with custodian-like roles and responsibilities, as defined below:

- Ensuring the protection of the rights and interests of a BBDB’s participants;
- Ensuring the good functioning of the BBDB, in keeping with its stated aims and purposes;
- Ensuring that the BBDB personnel receives adequate and continuous training on relevant scientific and technological advancements; safety; and relevant ethical and legal developments;
- Ensuring that the aims and purposes of the BBDB are furthered through a transparent and equitable access policy;
- Ensuring that every researcher using a MUHC BBDB signs and abides by all applicable required agreements and undertakings (e.g., confidentiality agreement, material transfer agreement, data sharing agreement);
- Ensuring that if, and when, left-over data and biological samples must be destroyed, the destruction is done in accordance with the applicable MUHC policy;
- Ensuring, once the BBDB is approved, that the MUHC REB is promptly informed of any change to the BBDB;
- Ensuring that procedures for specimen retrieval, processing, storage, transportation, and distribution maximize the value of the specimens;
- Ensuring the applicable policies and guidelines are met.

2.3 Research Ethics Board

The MUHC REB is responsible for the ethics review, approval, and continuing oversight of all MUHC BBDBs. This includes any consideration of transfers, relocations**,** premature destruction, and other major events.

The MUHC REB will provide ethics oversight according to its SOPs and applicable regulations and policies. It provides information on the science and ethics review process.

3. Required Approvals

3.1 Creation of BBDBs

The constitution of a new MUHC BBDB must receive science, ethics, and institutional feasibility review and approval, followed by institutional approval from the "personne mandatée". To that effect, a management framework specific to the proposed BBDB, as well as any other required document (as described in the MUHC REB SOPs) must be submitted.

3.2 Projects accessing stored specimens/data

Access to biological samples and/or data stored in an MUHC BBDB will only be allowed for projects supported by a protocol that has received science and ethics review and approval by a competent REB (normally the REB of the institution under the auspices of which the analysis will be conducted). The BBDB management framework may also specify further requirements, such as approval by an access committee.

3.3 Registry of BBDB

The Institution is responsible for maintaining a registry of all the BBDBs under its auspices. These may be held by MUHC researchers or containing biological samples and/or data that were obtained from MUHC participants.

3.4 Ongoing compliance and renewal of approvals

Any approval from the MUHC REB must be renewed at least annually upon submission of an annual report. In addition, in order to ensure all documents of a BBDB remain compliant with current versions of policies and regulations, full-board REB review of existing BBDBs must occur on a regular basis, as defined in the REB SOPs.

Given the inherent long-term nature of BBDBs, researchers responsible for collections of biological samples and/or data already in existence at the time of implementation of this Policy must ensure that those collections complied with the ethical norms that were applicable at the time the biological samples and/or data were collected. In addition, as far as possible, they must ensure compatibility with currently applicable norms, including the present Policy. If compliance is not possible, REB approval is required for further use of the biological samples and/or data.

3.5 Special case

3.5.1 Dual purpose BBDBs

BBDBs constituted from the outset for a dual purpose (clinical and research) are not exempt from science, ethics, and institutional feasibility review and approval. The science, ethics, and feasibility review of a bank that is constituted with a dual clinical and research purpose can help reduce redundancies (by confirming that the data are not already captured elsewhere), increase access to researchers across the institution (by ensuring registration in the list of active BBDBs), and put in place data capturing mechanisms that maximise protection of participants.

3.5.2 Pre-existing collections

Researchers who, prior to the adoption of this Policy, constituted collections of biological samples and/or data meeting the definition of BBDB have the duty to ensure that such activities are disclosed to the Institution and undergo proper review and approval. If an existing collection of biological samples and/or data that meets the definition of a BBDB has not undergone science, ethics, and institutional feasibility review and/or has not been

authorised by the "personne mandatée" at the time of the coming into force of the Policy, a submission for research review of the project must be made within twelve months. The submission must follow the procedures applicable to new BBDBs.

If recent policies and guidelines were to be strictly applied, it may be impossible for certain existing collections of biological samples and/or data to continue to be used for research. For example, in older collections, consent may not have been obtained for the banking of residual tissue (either collected as part of care or for a primary research purpose). Such situations should be disclosed to the REB at time of submission for ethics review and a rationale provided to justify why a pre-existing, but non-compliant practice, should continue. The MUHC REB may exercise its discretion to authorize the continued use of pre-existing collections and/or require any additional measures deemed necessary to ensure the protection of participants.

4. Non-compliance with the Policy

Non-compliance with the Policy may warrant suspension of ethics approval, suspension of funding, revocation of research privileges, and/or other disciplinary measures.

5. Administration of the Policy

The Board of Directors mandates the McGill University Health Centre Research Ethics Board, the Research Institute of the McGill University Health Centre, and the relevant authority at the Montreal Neurological Institute/Montreal Neurological Hospital to apply and administer the Policy.

V. Special Considerations

1. Clinical databases

The secondary use of clinical databases for research purposes falls outside the scope of this Policy. Other relevant provisions apply to secondary data use (e.g., *Loi sur les services de santé et les services sociaux* (Article 19.2), *Tri-Council Policy Statement* (Articles 5.5A and 5.5B)).

VI. Relevant Forms

1. Biobank Management Framework template: https://muhc.ca/cae/page/templates-consent-forms
2. Information and consent form templates: https://muhc.ca/cae/page/templates-consent-forms

DELETION

☐ Replaced by #: _____ Name: _____

☐ No longer in effect ☐ Other: _____

Authorized by:

Name (please print): _____

Signature: _____Date:_____

Approved by the Policies and Procedures task force committee:

☐ Yes ☐ No

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