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# Guidelines for Databank Management

These guidelines apply to all new and existing data repositories to be used for human participant research. A data bank includes any systematic collection of data and can include personal and medical data, genetic data as well as biological material (cells, tissues, organs, blood, saliva and other substances). While all data collected or used for research involving human participants potentially constitute a databank, these guidelines are intended primarily for management of those banks and repositories that serve the needs of multiple research projects and/or multiple research groups.

## 1. Management

The holder of the bank refers to the individuals, groups, and institutions that created the bank. The institution is responsible for ensuring that the databank has appropriate administration. The administrator (individual or institution) of the data bank is responsible for its operation according to this policy, and includes privacy, confidentiality and appropriate access by users.

Researchers have access to the bank as limited by the nature of the consent given by participants.

As governed by this policy, researchers are responsible to the Research Ethics Board (REB), to the Institution and to the Administrator with whom they will sign an agreement establishing, for example, the type of access (e.g. user or user/contributor), as well as ensuring confidentiality and clarifying any potential intellectual property rights.

Researchers, institutions and sponsors can acquire intellectual property rights over inventions derived from the use of the databank.

The creation and/or use of data banks must be reviewed by a McGill recognized Research Ethics Board.

## 2. Collection of data and recruitment of participants

***As part of a research project***
A REB with authority in the McGill jurisdiction is to review and approve the creation and use of the data bank before collection begins. Unless specifically provided for in the consent document, data collected are not to be used for purposes other than for those initially requested. Only the data directly pertaining to the study are to be collected and stored. Data are to be collected legally and in good faith.

Data are to be collected with the participants' consent. The consent form should contain information addressing the following:

- Informing the participant of the use and lifetime of the bank;
- Identifying information and its potential traceability;
- Length of storage and disposition of data;
- Requesting whether or not the participant may be contacted again for further research;
- What happens to data at the end of the project (i.e. coded data; destroyed or rendered anonymous so that all identifiers which would allow the participant to be retraced are deleted);
- The possibility or not for the participant to withdraw consent and an explanation of what happens to the stored data once consent has been withdrawn;
- Describing the potential benefits or lack of benefits for the participants;
- Describing the possible risks for the participants;
- Disclosing incidental findings that could affect the well-being of the participants or their relatives, particularly while the research findings are linkable with the participants' identity;

- Describing confidentiality, and how it will be maintained (e.g. who has key code to data; where the data will be stored; and type of security measures taken);
- Restricting access to researchers or research teams involved in the study and conditional to approval by the administrator;
- Keeping data confidential within the limits of the law or within the limits set by the consent of the participant;
- The potential uses for the data including potential development of intellectual property and commercial uses.

***Secondary (research) use of nominal, coded or anonymized data already collected***

- REB approval is required for secondary use of existing research data or for the use of data collected for other purposes (e.g. school records). Participant consent for use of secondary data is subject to the rules and regulations of the REB, the McGill *Policy on the Ethical Conduct of Research Involving Human Participants*, the Tri-Council Policy Statement and the requirements of any other relevant agency.

**3. Storage and safekeeping of data**

***Identification of the data:***
The data can either be:

- Nominative - Containing elements that allow for a participant's identification, either by name, or by identifiers, or can reasonably be deducted from a combination of identifiers. Secondary code lists cannot be created;
- Coded - The confidentiality of the data will be protected by assigning them a specific code. A code will link the participant to the sample. Decoding can only be performed by the principal researcher or an individual authorized by the former; or
- Anonymized - The confidentiality of the data will be protected by rendering them anonymous; in other words, after the sample is taken, all identifiers which would allow the participant to be retraced will be deleted. The researcher may decide to include specific information with the sample (such as age, sex, demographic data, etc.); this information, however, must not allow the participant to be identified or retraced;
- Anonymous/non-nominative – Data is originally collected without identifiers.

***Security of data bank***

- A list of all internal users (members of the research team) and all external users (persons or organizations) is to be kept and the criteria for accessing the data are to be defined. This is to be overseen by the Administrator.
- Security mechanisms that prevent non-authorized persons from accessing data are to be implemented (i.e. coding, double-coding, encryption, anonymization, lock and key, etc.)

***Length of storage***

- All data are to be kept for the defined period of time as outlined in the consent document. Nominative/coded data should only be retained as long as is necessary to fulfill the research purposes after which they which they will be destroyed, or rendered anonymous.
- Anonymous data can be kept for an indefinite period of time.

**4. Access to and use of data**

- Any use of data for research is to be approved by a REB.

- Use of data is limited to the purposes originally requested, unless otherwise indicated in the consent document (e.g. The consent document discloses the possible future secondary use of data for other purposes).
- Access is restricted to researchers or research teams approved by the administrator as consistent with the original purpose of the data bank.

***Secondary use of data***

- Secondary use of data is to be approved by a REB.

***Third party access***

- If the personal data is coded, it is not to be made available to third parties such as employers, governmental organizations, insurance companies or educational institutions. However, for research monitoring and regulatory purposes, members of REBs, government officials, or other legally authorized parties may consult the data.

- If the personal information is rendered anonymous (i.e. stripped of all identifiers), third party access to the data is generally acceptable in accordance with the provisions of this policy and may be obtained through REB approval.

**5. Commercialization**

- The consent document must indicate that intellectual property might derive from the use of the bank with potential commercialization of results by researchers and institutions;
- Agreement as how to share any intellectual property rights must be part of the agreement signed by users;