McGill University
Faculty of Medicine

Guidelines for the management of data and tissue banks

Modern health research involving genetics, DNA and the use of databanks increases concerns about maintaining the confidentiality of subjects and the protection of their privacy. In December 2000, the Research Ethics Committee of the Faculty of Medicine adopted Guidelines for a consent document for *Genetic Research and DNA Banking* (*Cardinal, Deschênes, Knoppers, Glass)* and in June 2003 extended these principles to apply to both tissue and data banking. The "*Guidelines 2003"* considered individual research projects as well as the establishment of larger, more widely used, data/tissue banks. This current document outlines the principles for the management of multi-user "databanks".

The following procedural guidelines fulfill the minimal requirements to establish, maintain and access data and/or tissue banks. They are meant to be consistent with the "CIHR Best Practices for Protecting Privacy in Health Research" (2005). McGill affiliated hospitals may already have procedures in place or plan to develop procedures in the future, that provide details specific to their needs.

These guidelines apply to all new and existing data repositories and tissue banks to be used for human subjects' research. A databank includes any systematic collection of data or tissues and can include personal and medical data, genetic data, proteomic data, and biological material (cells, tissues, organs, blood, saliva and other substances). While all data or tissues collected or used for research involving human subjects 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 to ensure that the databank has appropriate administration. The administrator (individual or institution) of the data and/or tissue 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 subjects. 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 (eg 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 databanks must be reviewed by a McGill Approved Research Ethics Board (*see Appendix II, Policy on the Ethical Conduct of Research Involving Human Subjects, for list of these REBs*)

2. Collection of data and/or tissue and recruitment of subjects

As part of a research project

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

Data and/or tissue are to be collected with the subjects' consent and the adopted consent guidelines for Genetic Research and DNA Banking are to be consulted when drafting the consent document. These guidelines also contain information that provides for:

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

As part of a retrospective review

- DPS approval is obtained in the case of medical charts/records (LSSS); or
- Subjects' consent to collect health information and REB approval were obtained.

Secondary (research) use of nominal, coded or anonymized data and/or tissue already collected

- REB approval is required for secondary use of existing research data and/or tissue;
- In the case of data and/or tissue collected in the course of patient care, written consent for the proposed research use must have been or must be obtained from the prospective subjects or their legal representatives;
- In the case of data and/or tissue collected in the course of a research project, the consent document must have anticipated the proposed use of the data and/or tissue for research.

Secondary (research) use of tissue and/or data collected anonymously

- The anonymous collection of tissue and/or data must have been authorized by the subject;
- REB review and approval is required.

3. Storage and safekeeping of data and/or tissue

Identification of the data and/or tissue:

The data and/or tissue can either be:

- Nominative - Containing elements that allow for subject'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 and/or tissue will be protected by assigning them a specific code. A code will link the subject 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 and/or tissue will be protected by rendering them anonymous; in other words, after the sample is taken, all identifiers which would allow the subject to be retraced will be deleted. The researcher may decide to include specific information with the sample (such as age, sex, or certain clinical, pathological or demographic data, etc.); this information, however, must not allow the subject to be identified or retraced;
- Anonymous/non-nominative – Data and/or tissue is originally collected without identifiers.

Security of data and/or tissue 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 or tissue are to be implemented (i.e. coding, double-coding, encryption, anonymization, lock and key, etc.)

Length of storage

- Coded data and/or tissue are to be kept for a defined period of time as outlined in the consent document (usually for a period of 25 years), after which they will be destroyed, or anonymized. Coded or linked data and/or tissue cannot be kept indefinitely.

- Anonymized data and/or tissue can be kept for an indefinite period of time, provided that subjects' consent and REB authorization for doing so were obtained at the time of collection;
- Anonymous data and/or tissue can be kept for an indefinite period of time.

4. Access to and use of data and/or tissue

- Any use of data and/or tissue for research is to be approved by an REB.
- Use of data and/or tissue is limited to the purposes originally requested, unless otherwise indicated in the consent document (eg. The consent document discloses the possible future secondary use of data and/or tissue for other purposes).
- Access is restricted to researchers or research teams approved by the administrator as consistent with the original purpose of the databank.

Secondary use of data

- Secondary use of data and/or tissue is to be approved by an 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 and/or tissue 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;

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