

Policy for the Creation of a Research Databank and the Management of Research Records at the CRIR Institutions

(If the meaning of the English version differs from the French version, the later will predominate)

Introduction

Measure 1 of the *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (Ministerial action plan on research ethics and scientific integrity) stipulates that the regulatory framework for research activities conducted by a health care or research centre such as the CRIR must set specific standards for the management of databanks. The present policy is intended to fulfill this ministerial requirement and ensure the ethical framework required for the implementation of a databank for researchers, clinical practitioners and students in any of the following situations:

- The individual is a CRIR member;
- The individual, whether a CRIR member or not, wishes to collect research data obtained from users of a CRIR institution.

The present policy is also intended to provide proper management of the research records of CRIR researchers, clinical practitioners, students and members. The present policy does not apply to databases retained by the researchers.

Definition

As used by the ministère de la Santé et des Services sociaux (Minister of Health and Social Services), **data** means information preserved both electronically and on paper (i.e., user records), medical information, including genetic banking, and biological material (cells, tissues, organs and other substances)¹.

A **databank** is an archive of organized information covering a particular knowledge domain and collected on any type of support media. The databank is designated for research purposes.

A **database** retained by a researcher differs from the databank in that it concerns a specific research project and the research subjects have given their informed consent for the data to be retained for purposes of the project.

A **research file** is an archived record of information in connection with a research project, such as consent forms and the researcher's database. It contains, notably, nominative information. This information is collected on a support medium.

In the present document, the term **CRIR member** refers to researchers, clinical practitioners and student members of the CRIR.

A) Databanks: safeguard measures for researchers, clinical practitioners and students wishing to create a databank

Ethical approval

¹ Guidelines for the establishment of standards for databank management [translation], MSSS, Ethics branch, May 12, 2004.

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- 1 All researchers, clinical practitioners and students, whether CRIR members or not, who wish to utilize research data obtained from the clients of any of the CRIR institutions in order to (a) create a databank for research purposes or (b) deposit the data in an existing databank must previously have submitted a request for approval to the REB for the CRIR institutions. Thus, this individual must:
 - a) Submit the protocol establishing the operating rules and procedures for the databank;
 - b) Commit to distributing this protocol to the individuals being recruited (i.e., the research subjects);
 - c) Obtain the informed consent of the individuals being recruited to participate in the databank.

- 2 All CRIR members collecting information from sources other than users of the CRIR institutions (i.e., healthy subjects, clients of other health care institutions, or close relatives of CRIR institution users) and wishing to utilize them to (a) create a databank for research purposes or (b) deposit the data in an existing databank must previously have submitted a request for approval to the REB for the CRIR institutions. Thus, the individual must:
 - a) Submit the protocol establishing the operating rules and procedures for the databank;
 - b) Commit to distributing this protocol to the individuals being recruited (i.e., the research subjects);
 - c) Obtain the informed consent of the individuals being recruited to participate in the databank.

Consent for the databank

- 3 The consent form relating to the databank must be signed by the participants, and must include clauses addressing the following matters:
 - a) Purpose of the databank;
 - b) Type of databank preservation (denominalized or anonymized) and the types of research projects for which the data will be used. **Denominalized data** allows tracking of individuals by means of an identity code. **Anonymized data** is completely disconnected from the individual concerned, since there is no way to connect the data with the individual;
 - c) Anticipated data retention period;
 - d) Possibility of withdrawing consent, and what happens to the data once consent has been withdrawn;
 - e) Possibility of recontacting the individual;
 - f) Data processing procedure in the event of the individual's death.

B) Retention of research data: safeguard measures for research record keeping and management

All CRIR members are responsible for the proper management of their research records.

Utilization of research data

- 1 All CRIR members must ensure that the research data they collect is used solely for the purposes for which it was collected, with the informed consent of the research subjects.
- 2 If a CRIR member wishes to use his or her research data for a purpose other than the original research (secondary use), the researcher must, depending on the case, initially provide for such use in the consent form signed by the research subjects. Otherwise, the researcher must recontact the individuals who participated in the project to obtain their written consent for the new utilization of the research data.
- 3 Since the secondary use of research data would be exceptional, certain further criteria must be met to justify such use. The project for which the secondary use is requested must have received prior approval by the REB for the CRIR institutions. In addition, the new project must be connected to the initial research project, unless the data have been rendered anonymous.

Retention of research records

- 4 The CRIR member must ensure the accuracy of the collected data in the research files.
- 5 The CRIR member must ensure that all active research files are regularly updated.
- 6 The CRIR member must retain in the research file all signed consent forms of the project participants.

Preservation of research records

- 7 The CRIR member must preserve in the research file all information required to complete Form R (annual renewal approval by the Research Ethics Committee).
- 8 The CRIR member must keep his or her research files in a locked cabinet at a secure site (i.e., the member's laboratory or office).
- 9 The CRIR member must ensure that only members of the research team have access to the research file and any data connected with the project.
- 10 The CRIR member must implement appropriate safeguards to protect the confidentiality of the information contained in the research file. For example, all participants could be assigned an identity code prior to participating in the project. The CRIR shall be the sole possessor of the coding key. The CRIR member may also render the research data anonymous.
- 11 The CRIR member must preserve his or her research records for a maximum period of five years following completion of the research project. The CRIR member may request an extension of this retention period with justification.

Destruction of research files / research data

- 12 Unless otherwise specified, all research files must be destroyed at the end of the retention period. The CRIR member must ensure that research files are destroyed with due regard for privacy and confidentiality.

Publication

- 13 The CRIR member must ensure that all publications and communications that make use of the collected data during the course of the research project can in no way identify the participants.

Annual report and report of project completion or abandonment

- 14 The member must submit to the Research Ethics Committee of the CRIR institutions an annual report for each project in progress. Form R, which has been developed to this effect, may replace the annual report the CRIR member is required to prepare for the REC when a project extends beyond one year. The CRIR member must ensure that Form R is duly completed and signed prior to submission to the Research Ethics Coordinator. Failing which, ethical approval may be declined.
- 15 The CRIR member must preserve in his or her files all research data required to complete Form R, notably the number of individuals recruited per CRIR site, number of individuals who actually participated in the project, number of individuals who withdrew from the project, the reasons for such withdrawal, and any adverse incidents that occurred.
- 16 Upon project completion, the CRIR member must submit to the Research Ethics Committee of the CRIR institutions and all participating CRIR institutional sites a project completion report covering the findings and impact of the research project.
- 17 The CRIR member must advise the Research Ethics Committee of the CRIR institutions in the shortest possible delay of any unexpected terminations of a research project that was granted REB approval.