

Policy for the Retention of a List of Research Subjects by the Researcher

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

Introduction

Measure 9 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 the following:

An individual that agrees to participate in a research study must enjoy the same rights as an individual receiving health care or social services. To this end, institutions in the health care and social services network that engage in research activities must apply the following measures:

- 9) Identify individuals that participate in research activities while respecting confidentiality. [translation]

According to a clarification note issued by the MSSS on December 11, 2003, this measure is designed to ensure the protection of research subjects and the transparency of information so as to:

1. Prevent, avoid or reduce harm;
2. Identify potential overutilization of research subjects;
3. Respect the autonomy of research subjects;
4. Provide a record to the appropriate authorities of the number of individuals participating in the institution's research projects for a given period.

According to a second clarification note issued by the MSSS on February 8, 2005, the institutions are responsible for choosing the means necessary to achieve the underlying goals of protection and transparency, as stipulated in Measure 9. To this effect, the MSSS proposes the following two approaches:

1. Establishment of a central inventory;
2. Retention by researchers of lists of research subjects. Institutions must obtain the explicit commitment of the researchers concerned.

In fulfillment of this ministerial requirement, the CRIR institutions have decided to adopt the second option. Nevertheless, each CRIR institution may independently provide for additional measures to complement the above mechanism, such as establishing a central inventory of research subjects.

Researcher commitment

1. All researchers initiating research projects involving human subjects in connection with a CRIR institution must formally commit, by signing Form A (request for REB review of a research proposal), to retain in his or her possession a list of all participants in the project.

Mandatory collected information in the researcher's list

2. The following collected information must be contained in the list of subjects retained by the researcher:
 - Name of individual (research subject) or coding system used;
 - Coordinates to allow participant tracking;
 - Project number;
 - Start and completion dates of project participation.
3. **Research subject** means an individual who has agreed to participate in a research project and has access to the institution's complaints procedure. This includes institution users or their close relatives as well as individuals in a control group.
4. Measure 9 does not apply to the following cases:
 - Users whose files have been consulted for purposes of research without prior obtention of informed consent (files research);
 - Research subjects who have consented to participate in a research project that has undergone a prospective ethics review by the institution's REB in compliance with Article 1.14 of the *Tri-Council Policy Statement*.¹ In effect, this type of project is conducted outside the jurisdiction of the institution and does not involve its users. Nevertheless, given the researcher's affiliation to the institution or the institution's identification with the project, the researcher must submit his or her proposal to the institution's REB.

Research projects involving anonymous subjects

5. In order to prevent certain research subjects from being exposed to significant risks of stigmatization, their anonymity may have to be preserved. In such cases, the information appearing on the list of research subjects retained by the researcher shall be limited to the following: number of individuals participating in the research, project number, and a summary of the reasons for preserving the anonymity of the research subjects.

Retention period

6. The retention period for the collected information in the list is twelve months following project completion. At the end of that time, the information shall be destroyed.

Inventory management

7. The researcher shall have the responsibility to manage the list of research subjects.
8. The researcher must keep the list of research subjects in a locked cabinet at a secure site (i.e., the researcher's laboratory or office).
9. The list may be preserved on the researcher's choice of media.
10. Data processing procedures must be conducted with absolute respect for confidentiality.

¹ Article 1.14 of the *Tri-Council Policy Statement* concerns research to be performed outside the jurisdiction or country of the institution which employs the researcher.

Access and dissemination of information contained in the list of subjects

11. Only the researcher, persons authorized by the institution, the representative of the duly mandated Research Ethics Committee, authorized representatives from the ministre de la Santé et des Services sociaux (Minister of Health and Social Services) and other legally authorized persons may have access to the information contained in the lists retained by the researchers. This must be specified on the consent form signed by the subject. Moreover, the type of information provided to authorized individuals shall depend on the purpose of the request.
12. The researcher's list of subjects must not be used for purposes other than the research itself (secondary use).
13. The collected information in the list may not be disseminated to third parties without prior consent of the user or legal authorization, nor may it be used for a purpose that is incompatible with that for which it was obtained.

Date of coming into force of the present policy

14. The present policy shall enter into force on April 11th, 2005, in replacement of *la Politique portant sur la constitution et la gestion d'un répertoire des sujets de recherche* (Policy for the establishment and management of an inventory of research subjects) [translation].