

Comité d'éthique de la recherche
des établissements du CRIR



**REGULATIONS CONCERNING THE CREATION AND OPERATION
OF THE RESEARCH ETHICS BOARD FOR THE CRIR
INSTITUTIONS**

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

Updated November, 2007

TABLE OF CONTENTS

Introduction.....	3
1. Mandate and Jurisdiction.....	5
2. Succession.....	6
3. Composition and Appointment of Members	6
4. Research Ethics Coordinator.....	7
5. Drafting of the Regulations for Internal Management.....	8
6. Meeting Procedures	8
7. Review Process.....	9
8. Scientific Assessment.....	11
9. Assessment of Institutional Suitability.....	12
10. Annual Report	12
11. Access to REB Documents.....	13
12. Administrative and Financial Support	13
13. Continuing Education	13
14. Operational Assessment.....	14
15. Date of Coming into Force of the Regulations	14

Regulations Concerning the Creation and Operation of the Research Ethics Board for the CRIR Institutions

Introduction

The institutions of the Centre de recherche interdisciplinaire en réadaptation du Montréal métropolitain (CRIR) (Greater Montreal Interdisciplinary Rehabilitation Research Centre) hereby express their intention to establish a common Research Ethics Board (REB). This intention arose from the ever-increasing development of research activities in the CRIR institutions. The identification and utilization of ethical safeguards constitutes added value to the benefit of all the CRIR institutions.

An essential element of the CRIR's mandate is to promote joint action and accountability for research activities by the rehabilitation institutions, universities and funding bodies. Thus, the CRIR institutions acknowledge that such partnership can be accomplished through scientific excellence and the ethical conduct of research. Moreover, it is vital to the credibility of the entire CRIR organization that the research conducted in any of its institutions be of equal quality to that conducted in other institutions, in terms of both science and ethics.

The CRIR institutions view the creation of a common REB as the preferred means to achieve the following objectives: effective protection of research subjects, the establishment of a highly qualified ethics board, and a simple and faster ethics review process for research projects carried out in more than one CRIR institution.

Like all research involving human subjects, rehabilitation research must be conducted in accordance with the legal and ethical norms in force. It is now widely recognized that the scientific quality of research is inseparable from its ethical quality. The norms contained in the *Standards du FRSQ en éthique de la recherche et en intégrité scientifique* (Research Ethics and Scientific Integrity Guidelines) published by the *Fonds de la recherche en santé du Québec* (FRSQ) state that the quality of health care research shall be assessed on the basis of scientific and ethical standards as follows:

"The expectations of the FRSQ greatly exceed the aspect of scientific validity, and encompass the protection of the dignity of persons who agree to participate as subjects, respect for persons involved with research implementation, and good governance of all resources utilized. In sum, the overall quality of health care research shall be assessed in terms of two categories of standards: scientific standards as well as standards for ethics and research integrity. The FRSQ adheres to the principles stated in diverse international documents such as the **Nuremburg Code** and the **Declaration of Helsinki**. We also recognize the general principles contained in the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, published in 1998 and revised in 2003**".¹ (free translation)

¹ Fonds de la recherche en santé du Québec. *Les Standards du FRSQ sur l'éthique de la recherche et l'intégrité scientifique*. December 2000, revised April 2001, section P.1, page 6. August 2003.

The CRIR institutions consider that their common REB should render decisions based on the standards and principles stated in internationally recognized documents such as the *Nuremberg Code* and the *Declaration of Helsinki*.

In June 1998, the Quebec's government issued a *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (Ministerial Action Plan on Research Ethics and Scientific Integrity (the Action Plan)). The Action Plan stipulates the various requirements and responsibilities for participation in health research activities, including the institutions that engage in research projects.

The Action Plan begins by reminding all boards of directors of their legal and moral duties with regard to research conducted in the institution under their charge. It next calls upon the institutions to adopt a regulatory framework for their research activities. The Action Plan then sets out very specific measures for management and supervision as follows:

“The institutions and bodies in the health and social services network that engage in research activities must adopt a framework of regulations for research activities. This framework should establish explicit responsibilities as well as fair and transparent operating procedures.

As a point of reference, the framework should be harmonized with the guidelines set forth by Quebec's funding bodies and the *Tri-Council Policy Statement* issued by the three Canadian research councils. At a minimum, this framework should contain standards for the following:

- Protection of human subjects
- Mandatory declaration of research activities
- Handling cases of scientific misconduct and ethical lapses
- Management of conflicts of interest, double remuneration and researchers' business activities
- Financial management and the cost of research projects
- Management of data banks and research records
- Control of experimental medication
- Operation of the research ethics committees”.² (Free translation).

The present Regulations addresses the need to protect the dignity, wellbeing and rights of human research subjects. Thus, it provides for the creation and operation of a common REB for the CRIR institutions.

Beyond respecting the applicable laws of Quebec, the REB shall conduct all its activities such that reviews of research projects are undertaken in accordance with the *Tri-Council Policy Statement* published in Ottawa in 1998 and revised in 2003. Moreover, the CRIR institutions shall strive to ensure that research projects under their direction are undertaken in compliance with the guiding principles of bioethics, namely autonomy, fairness and justice, and non-maleficence.

² Ministère de la Santé et des Services du Québec. *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*. Québec, 1998, p. 11. Les Standards du FRSQ sur l'éthique de la recherche et d'intégrité scientifique, Montréal, Fonds de la recherche en santé du Québec, August 2003.

The CRIR institutions wish to support research projects involving minors and legally aged persons unable to give consent without having to go through the Central Committee appointed by the Minister. The CRIR institutions have agreed to apply for a common REB to be designated by the Minister by virtue of Section 21 of the *Code civil du Québec* (Civil Code of Quebec).

All institutions providing health care and social services bear legal and ethical responsibility for what transpires within the institution as well as inside its legal entity. This institutional responsibility extends to research activities. This responsibility is one of the reasons that the local REB must report directly to the board of directors of the institution. In addition, the board of directors shall appoint members to the REB.

The creation of a common REB for the CRIR institutions does not release any of the institutions from its legal or ethical responsibilities for what transpires within the institution's legal entity. Respect for the standards in force and the statement of autonomy of the REB require that the common REB report directly to the boards of directors of each CRIR institution, and that its members be appointed by the board of directors of each institution.

1. Mandate and Jurisdiction

1.1

The REB's mandate is three-fold, as follows: assessment of research projects, continuing ethics review of ongoing projects, and ethics training for the staff of the CRIR institutions.

The REB's mandate extends to research projects involving minors and disabled person.

1.2

The REB undertakes to assess and monitor all research projects conducted in their entirety or in part in one or more of the CRIR institutions. The REB has the authority to approve, modify, terminate or reject all research projects.

1.3

By virtue of its authority, the REB has the right and duty to make decisions on research projects involving human subjects. The REB shall examine all research projects involving humans and having at least one of the following characteristics in connection with a CRIR institution:

- The project is at least partially conducted in the institution
- Subjects are to be recruited from the users served by the institution or from files retained by the institution
- Project proponents or researchers confirm or imply the participation of the institution
- Proponents or researchers confirm or imply their affiliation to the institution
- The project makes use of human resources, materials or funding from the institution
- The project makes use of personal information contained in the files retained by the institution.

The REB shall fulfill its obligation for providing ethics training jointly with the Research Ethics Coordinator of the CRIR institutions and the administrative officers of each institution. Ethics training activities shall be provided to all institutional staff and management, but shall also provide greater support to researchers.

2. Succession

Upon taking up its duties, the REB shall assume the mandates of the existing research ethic committees in the CRIR institutions. As of that time, the REB undertakes to manage and supervise all ongoing research projects.

3. Composition and Appointment of Members

3.1

The REB shall be composed as follows:

- One person with expertise in psychosocial rehabilitation
- One person with expertise in biomedical rehabilitation
- One clinical practitioner with expertise in auditory or visual sensory impairment
- One clinical practitioner with expertise in motor or neurological impairment
- One ethics specialist
- One legal expert
- One person not affiliated with a CRIR member institution and representing the clientele of legally age persons with full decision making capacity
- One person not affiliated with a CRIR member institution and representing the clientele of minors or persons unable to give consent
- One person representing the general public, who may also be a user of the institution's services
- One representative from Université de Montréal
- One representative from McGill University
- One representative from Université du Québec à Montréal
- The Research Ethics Coordinator, with no voting rights.

The REB shall be composed of at least one person with expertise in each of the following areas: motor impairment, visual impairment, auditory impairment, and language and communication impairment.

Representatives of the general public shall constitute at least 20% of the REB membership at all times. For purposes of this provision, non-affiliated clients shall be considered as representatives of the general public.

3.2

In order to fill vacancies, the REB shall have recourse to a pool of human resources. The President of the REB may request the collaboration of said persons. The CRIR institutions shall constitute the bank by providing the names of persons belonging to the three following groups: clinical practitioners, researchers and the community served by the institution.

3.3

REB members, including the President, are appointed by the board of directors of each CRIR affiliated universitie, on the recommendation of the CRIR Board of Directors.

A member's mandate may only be revoked by the same process.

Moreover, each affiliated university shall designate only one representative.

3.4

REB members shall be mandated for a two-year term, renewable indefinitely. However, half the members in the first appointed group shall be chosen at random to serve an initial three-year mandate.

3.5

Members and substitute members who withdraw or are unable to perform their duties shall be replaced for the duration of their term by a person appointed by the CRIR Board of Directors.

3.6

Members of the boards of directors' concerned, directors-general and any other directors of the CRIR institutions, and legal advisors for any of the institutions are prohibited from serving on the REB in whatever capacity.

3.7

Any changes in the composition of the REB shall be notified to the Minister as they occur. Such notice shall be accompanied by the curriculum vitae of the new member and a document attesting to his or her appointment by the CRIR Board of Directors or by the boards of directors of the institutions, as the case may be.

4. Research Ethics Coordinator

4.1

The Research Ethics Coordinator is mandated to carry out the following duties:

- Receive research projects for REB review
- Ensure that the examination of the scientific quality and of the institutional suitability of the project were done
- Draw up, jointly with the parties concerned, the required procedures and forms for REB approval
- Maintain and update the REB human resources pool
- Coordinate research project monitoring
- Share pertinent information with the CRIR and the university authorities
- Implement training activities for research ethics within the CRIR institutions.

4.2

The CRIR Research Ethics Coordinator shall be appointed by the CRIR Board of Directors, and shall report directly to the Board. The Research Ethics Coordinator shall participate at REB meetings in a secretarial and support role for the work of the Committee.

4.3

The appointed Research Ethics Coordinator must have relevant expertise in legal and ethical matters.

5. Drafting of the Regulations for Internal Management

Except as provided for under the present Regulations, the REB shall have the authority to establish procedures for the following:

- REB operations, notices of meetings, minutes, meeting schedule and work plans
- Management of conflicts of interest among the REB membership
- Nature and content of mandatory documentation that research project heads are required to submit prior to REB review
- Constituent components of the research project review process
- Constituent elements of the research project, including the mandatory disclosure of information by the researcher to the REB
- Expedited ethics review for certain projects.

6. Meeting Procedures

6.1

The REB shall meet on a regular basis. REB activities shall include training sessions for its members.

6.2

The President shall oversee the work of the REB and preside over its meetings. The President shall also represent the REB to all concerned parties.

6.3

The quorum for meetings is seven members.

The quorum for a full ethics review for research projects is seven members, to include the five following persons at a minimum:

- Two persons with knowledge of the research methods and disciplines practiced at the CRIR institutions
- One ethics specialist
- One legal expert
- One client or representative of the general public who is non-affiliated with the institution.

6.4

Any person who has participated in the scientific assessment of a research project may not participate in the REB project review.

6.5

The REB is at liberty to consult with the research project heads.

6.6

Any member in a conflict of interest situation, or who foresees being in such a situation, in connection with an REB review of a research project must disclose the conflict to the other REB members and withdraw from the review process.

6.7

The Committee forms decisions on research projects by consensus arising from discussion. If consensus proves unattainable, the Committee shall proceed to a vote, with the President casting the deciding vote.

6.8

All Committee members must undertake to scrupulously respect the confidentiality of REB deliberations and documents. All members shall sign an agreement to this effect.

7. Review Process

7.1

The essential mandate of the REB is to protect the dignity, well-being and rights of human research subjects. REB approval and follow-up of research projects must constitute a public guarantee of safety for the subjects who participate.

The REB must ensure the scientific validity, institutional suitability and ethical compliance of the research projects submitted for review.

7.2

The REB has a legal and moral obligation to provide itself with the mechanisms required to fulfill its mandate. Thus, the REB undertakes to review research projects in conjunction with the applicable laws and regulations as well as international, Canadian and Quebec prescriptive documents. Among the prescriptive documents, the REB must pay particular attention to the Tri-Council Policy Statement and the FRSQ norms.

As part of its research project review, the REB must, at a minimum:

- a) Ensure the scientific validity and relevance of the study as well as the qualifications of the researchers
- b) Determine whether there is an adequate balance and distribution of harms and benefits for research subjects and, where appropriate, determine the potential impact of the project on the health of persons presenting the same characteristics (age, disease or handicap) to the experimental subjects
- c) Examine the subject recruitment method and assess the informed consent process
- d) Pay particular attention to confidentiality; in addition, special attention should be paid to the consequences for the participants of the introduction of new medications as part of therapy, where applicable.

7.3

The REB may perform an expedited ethics review in the following three situations:

- a) Research protocols involve no more than minimal risk for voluntary subjects
- b) The researcher proposes a minor modification to a research project that the REB has previously approved
- c) Annual renewals of ongoing projects.

The expedited review does not apply to initial ethics assessments of research projects involving disabled or minor subjects.

The President and one other REB member may conduct an expedited ethics review.

7.4

The REB shall make a motivated decision, and must present a report to the researchers with justifications.

A decision in writing is sent to the researcher, as far as possible within two weeks following the date of the meeting at which the project was reviewed. This letter shall include the following elements:

- a) Title of research project reviewed
- b) Clear identification of the research project or proposed amendment, date and version number, as the case may be
- c) Name and identification numbers of documents examined, including the briefing note and proposed participant consent form
- d) Name and status of researcher
- e) Designated research site(s)
- f) Place and date of decision
- g) REB decision
- h) Clear description of the decision
- i) Any further recommendations by the REB
- j) In case of a conditional decision, a description of all requirements imposed by the REB along with suggestions for review and the procedures for proposal reassessment
- k) In case of approval, a statement of the proponent's responsibilities, e.g., confirmation of the acceptance of the requirements imposed by the REB, submission of research progress reports, requirement to advise the REB of any changes in protocol (other than modifications involving solely administrative or research logistics aspects), requirement to advise the REB of any modifications involving recruiting conditions, data on potential participants or the informed consent form, requirement to record all serious adverse and unforeseeable incidents in connection with the research undertaking, requirement to record unexpected circumstances, termination or suspension of the research or other significant decisions made by the REB, information requested by the REB in order to proceed with the review in progress, and final summary or final report
- l) REB review plan or schedule
- m) In case of denial, clearly stated justifications for the decision
- n) Dated signature of the President of the REB or other duly authorized person.

The section dealing with ethics monitoring stipulates the obligation of the researcher to advise the REB in the following cases:

- a) Any new information liable to change the harm/benefit balance of the research
- b) Premature termination of the project
- c) Project completion
- d) Any issues noted by a third party in the course of follow-up (internal or external audits), and any suspension or withholding of approval in connection with the project by a funding body or regulatory agency.

7.5

Researchers have the right to request that the REB reconsider its decision for approval of the research project in its entirety or in part.

7.6

The REB's decision on total or partial approval of a research project may be reviewed by an appeal board.

The appeal is heard by the research ethics committee to which the researcher would normally appeal if he or she sought to obtain the approval of the appropriate authority within his or her university of affiliation.

7.7

An ethics review decision that rejects a research project may not be overturned by an institution.

7.8

Assessment fees are charged for ethics reviews of research projects submitted and funded by private companies (e.g., pharmaceutical, biotechnical, or orthotics/protheses companies).

For purposes of this provision, the term "ethics review" shall encompass three stages of the ethics review process as implemented in the CRIR: scientific assessment, examination of institutional appropriateness and the ethics review itself.

Upon receiving a private proposal, the Research Ethics Coordinator shall bill the company submitting the proposal. This bill must be paid before the REB is called upon to make a decision on the ethics of the project; otherwise the ethical review shall be deferred to a later date.

8. Scientific Assessment

8.1

Scientific evaluation is conducted by a scientific evaluation committee (the Committee) responsible for reviewing research projects. The Committee is in charge of the preliminary scientific evaluation of all research projects submitted to the REB, except those that have already been examined for quality and scientific relevance by a recognized peer review committee.

A recognized peer review committee can be one of the following:

1. A scientific committee of an institution that has a research centre subsidized by a Quebec or Federal funding organization
2. A scientific committee of a funding organization recognized by the Fonds de la recherche en santé du Québec (FRSQ)
3. A scientific committee of a university
4. A scientific committee of a recognized organization located in a country that is a member of the Organisation for Economic Co-operation and Development (OECD) (e.g., INSERM, NIH).

The President of the Committee may also recognize any other external scientific evaluation of a research project, provided that the evaluation was carried out according to criteria similar to those used by the Committee.

8.2

The Committee is composed of a President, four biomedical researchers and four psychosocial researchers. The President and other members are mandated for a period of two years, renewable indefinitely.

8.3

The CRIR's Scientific Directors are responsible for establishing the Committee by appointing the members and supervising its proper conduct.

8.4

The President receives research projects submitted for review. The President assigns two Committee members to assess each research project. All research projects must be approved by the President and the two assigned members in accordance with the review criteria in force.

The President may seek the advice of an expert who is not a member of the Committee, if appropriate.

8.5

The findings of the scientific evaluation are sent in writing to the Research Ethics Coordinator.

9. Assessment of Institutional Suitability

9.1

Institutional suitability means the appropriateness of the implementation of the project in a particular institution. Each institution that supports a research project, even partially, must assess the three following aspects:

- Linkage potential between the project and institutional directions
- Practical capacity of the institution to support the project (e.g., qualified staff, adequate equipment)
- Potential for certain targeted subjects to be inappropriately or unfairly recruited, which is incompatible with the justice principle.

The institutional suitability committee must also ensure that the financial evaluation and financial management have been performed by the institution.

9.2

The CRIR institutions shall appoint a person or committee to oversee the examination of institutional suitability.

9.3

The findings of the institutional suitability examination shall be sent in writing to the Research Ethics Coordinator.

10. Annual Report

The President of the REB shall submit an annual report to the CRIR Board of Directors, the boards of directors of each CRIR institution, the authorities of the universities represented on the REB and the ministre de la Santé et des Services sociaux (Minister of Health and Social Services (the Minister)).

The annual report shall encompass the following items:

- A list of the members and their qualifications
- The number of meetings held by the Committee during the year
- All rules and procedures adopted during the year
- A list of projects that have been submitted for review, each accompanied by the name of the researcher, project summary, funding sources and the Committee's decision
- A general description of all ethics follow-up activities undertaken by the Committee
- A description of the ethics training activities carried out
- Any other items that the REB deems relevant for the information of the CRIR Board of Directors, the boards of directors of the CRIR institutions, the authorities of the universities represented on the REB or the Minister.

11. Access to REB Documents

REB documents shall be retained for a period of five years at the Research Ethics Office and kept in a locked file. The CRIR Research Ethics Coordinator shall grant access to the operating rules of the REB to all persons who so request, as well as any other document establishing standard operating procedures (including researcher guidelines for proposal preparation and procedures for proposal submission).

Researchers shall have access to the REB's list of members and their qualifications (profession and affiliation) and role on the REB, and may obtain copies of extracts of the minutes of REB meetings that detail consideration of their proposal.

An updated list of REB members, including their qualifications and roles on the REB, shall be provided to the Minister's representative, the promoter, the funding body and the regulatory agency. All REB records shall be made available, for audit and monitoring purposes, to the representative of the CRIR Board of Directors and to all the institutions, the Minister, the funding bodies and the regulatory agencies.

12. Administrative and Financial Support

The boards of directors of the CRIR institutions have an obligation to provide the REB with the means necessary to fulfill its mandate in terms of administrative and financial support.

13. Continuing Education

The boards of directors of the CRIR institutions have an obligation to provide support in the form of continuing education to the REB members as well as the researchers, clinical practitioners and students, and CRIR

Continuing education may consist of attendance at courses, conferences and symposiums addressing research ethics issues.

14. Operational Assessment

The CRIR Board of Directors shall undertake an operational assessment of the REB every two years. This assessment shall include consultation with the administrative officers of the institutions, the researchers, REB members and any other parties or authorities concerned.

An Operational Assessment Report shall be submitted to the CRIR Board of Directors, the board of directors of each CRIR institution and the authorities of the universities represented on the REB.

15. Date of Coming into Force of the Regulations

The present Regulations shall enter into force on the fourth day of September, 2002.