

*Comité d'éthique de la recherche
des établissements du CRIR*



REB INTERNAL MANAGEMENT RULES AND REGULATIONS

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

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PREAMBLE

- WHEREAS** The Research Ethics Board's mandate is to ensure that all research involving humans takes place in accordance with ethical principles in place such as *Standards du FRSQ en éthique de la recherche et en intégrité scientifique* and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
- WHEREAS** The Research Ethics Board is also responsible for ensuring a preliminary, independent and multidisciplinary review of all projects taking place at a CRIR's institution or in one of its regional partners;
- WHEREAS** Section 5 of the *Règlement portant sur la création et le fonctionnement du 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) (hereinafter the Regulations) stipulates that the Research Ethics Board has the authority to establish its operating procedures.

THE RESEARCH ETHICS BOARD FOR THE CRIR INSTITUTIONS (HEREINAFTER THE REB) PROPOSES AND ADOPTS THE FOLLOWING RULES AND REGULATIONS FOR IT'S INTERNAL MANAGEMENT.

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SECTION 1 — GENERAL PROVISIONS

1. SCOPE AND PURPOSE

The purpose of the present REB Internal Management Rules and Regulations (here after RIM) is to define the mandate, composition and operating rules of the Research Ethics Board (REB) for the Institutions of the Centre de recherche interdisciplinaire en réadaptation du Montréal métropolitain (CRIR).

2. PREAMBLE

The preamble is an integral part of these regulations.

3. DEFINITIONS

In the present regulations, unless otherwise indicated by the context in which it is used, the expressions and terms below shall have the following meanings:

a) Investigator

Any person who initiates a research project.

b) Conflicts of interest

In the present regulations, a *conflict of interest* means any situation where a member has, or appears to have, private, personal, professional or institutional interests such that his or her objective judgement in the exercise of official duties may be influenced or appear to be influenced.

c) Board of Directors

The board of directors for each of the CRIR institutions.

d) Institution

Any of the CRIR institutions.

e) Research ethics

A set of guidelines for conduct designed to regulate research such that the subject's dignity and integrity are preserved.

f) Research project

For purposes of these RIM, a *research project* means any investigation carried out in one or more of the institutions, structured in several stages and following a logical order, and intended to establish facts, principles or generalizable knowledge. Research projects may be funded or non-funded.

4. GUIDING ETHICAL PRINCIPLES¹

The cardinal principle of modern research ethics is **Respect for Human Dignity**. This principle, which aspires to protecting the multiple and interdependent interests of the person—from bodily to psychological to cultural integrity—forms the basis of the following ethical obligations:

- a) Respect for Free and Informed Consent
- b) Respect for Vulnerable Persons
- c) Respect for Privacy and Confidentiality
- d) Respect for Justice and Inclusiveness
- e) Balancing Harms and Benefits
- f) Minimizing Harm
- g) Maximizing Benefit.

As part of any ethics review, the REB shall take into account these guiding principles.

SECTION 2 — MANDATE AND JURISDICTION

5. MANDATE

As specified in Section 1 of the Regulations, the REB's mandate is three-fold, as follows:

1. Ethics assessment of research projects
2. Continuing ethics review of ongoing projects
3. Ethics training.

The REB's mandate extends to research projects involving minors and legally incompetent persons.

6. POWERS AND DUTIES

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.

7. AUTHORITY

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:

¹ **Tri-Council Policy Statement**. See note (1).

- 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.

SECTION 3 — COMPOSITION

8. COMPOSITION

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 legal aged persons unable to give consent (incompetent)
- One person representing the general public, who may also be a user of the institution's services
- One representative from the University of Montreal
- One representative from McGill University
- One representative from the 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.

8.1 RESTRICTIONS ON MEMBERSHIP

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

9. APPOINTMENT OF MEMBERS

REB members, other than university representatives, are appointed by the boards of directors of each CRIR institution, on the recommendation of the CRIR Board of Directors.

University representatives, for their part, are appointed by their respective universities for a two-year term.

9.1 CHANGES IN COMPOSITION

Any changes in the composition of the REB shall be notified to the "Ministre de la Santé et des Services sociaux" (Minister of Health and Social Services (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 and by the Boards of Directors of each CRIR's institution, as the case may be.

10. TERMS OF OFFICE

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.

SECTION 4 — OFFICERS

11. EXECUTIVE COMMITTEE

The REB shall be headed by an Executive Committee composed of a President, a Vice President and a Secretary.

12. PRESIDENT

The President of the REB is also the Chief Executive Officer of the Board, and represents the REB to all concerned parties.

The President shall carry out the following duties:

- Chair Board meetings
- Oversee the work of the Board
- Sign the Board's official records, minutes, reports and documents
- Participate in expedited REB reviews, as required

- Jointly with the Research Ethics Coordinator, ensure follow-up on Committee decisions
- Represent the Committee to institutions and bodies involved in the research projects
- Prepare annual reports for submission to the CRIR Board of Directors
- Carry out any other duties that may be assigned by the Committee.

13. VICE PRESIDENT

In the absence of the President or when the President is prevented from acting, the Vice President shall assume the President's functions.

14. SECRETARY

According to Section 4.2 of the *Regulations concerning the Creation and Operation of the Research Ethics Board for the CRIR Institutions* (Règlement portant sur la création et le fonctionnement du CÉR des établissements du CRIR), the Research Ethics Coordinator for the CRIR institutions shall participate at REB meetings as the secretary of the Committee. Also, the Research Ethics Coordinator shall support the work of the REB.

The Secretary shall prepare the notices of meetings and the agendas for Committee meetings. The Secretary shall also draft the minutes of the meetings and submit them for approval by the Committee members.

15. ELECTION OF THE PRESIDENT AND VICE PRESIDENT

Committee members shall recommend to the CRIR's Board of Director by a simple majority the President and Vice President of the REB from among the membership.

Elections of the President and Vice President shall be held during the September meeting.

16. DURATION OF MANDATES

The mandates of the President and Vice President of the REB shall be for a two-year term, renewable indefinitely.

SECTION 5 — TERMINATION OF MANDATES

17. VACANCIES

An REB member ceases to be a member of the Committee upon the following circumstances:

- The member submits a written resignation to the President
- The member becomes incapacitated
- The member ceases to qualify for membership

- The member's mandate is revoked in the manner provided for in the Regulations.

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.

18. REVOCATION OF MANDATE

The mandate of an REB member may be revoked by a board resolution if the member's conduct would prejudicially affect the duties assigned to him or her by the Boards of Directors.

SECTION 6 – MEETING PROCEDURES

19. FREQUENCY OF MEETINGS

The REB shall meet once a month between September and June of each year, on predetermined dates. However, the REB may be called to meet during the summer holidays when the workload warrants.

Aside from regular meetings, the REB may also meet on an ad hoc basis to attend to business.

20. PLACE OF MEETING

The REB meetings shall take place at a site named in the notice of meeting.

21. NOTICE OF MEETING

A notice of meeting shall be sent to each REB member by the Committee Secretary at least five working days prior to the predetermined meeting date. This notice shall be accompanied by the meeting agenda and the minutes of the last meeting, if possible.

22. MINUTES

The minutes of every meeting are taken by the REB secretary. The minutes must contain the following information:

- The names of the REB members in attendance who participated in the discussions and, if applicable, the names of resource people and invited speakers
- Whether the request is being submitted for a full-board or an expedited evaluation

- The name and position of the principal investigator
- The exact title of the research project being reviewed
- Clear identification of the proposed research protocol or amendment, with the date and version number if applicable
- Names and (if possible) specific identification numbers (version number/date) of the documents being reviewed, including the information sheet and consent form
- Identification of the research sites (in the case of multicenter projects)
- Origin of the project's funding
- Project summary (e.g., objectives, profile of potential research subjects, expected duration, the type of procedures being conducted, the nature of the research subjects' involvement)
- Summary of the discussions held, highlighting the opinions, the points of contention and the ethically-justified conclusion at which the REB arrived, as well as the position of the minority (names of the dissidents and abstainers) and the disagreements with supporting justifications
- The decision that was reached (e.g., approval, conditional approval, deferred approval, refusal), including (if applicable) a description of all requirements imposed by the REB and the justifications given, as well as any suggestions offered by the REB to the investigator
- Procedures for reviewing documents or re-examining requests (if applicable).

After the minutes have been drafted, they shall be sent to all Board members for verification and consequent adoption, with or without modifications, at the next meeting. The minutes shall be signed by the REB President and Secretary.

23. CONFIDENTIALITY

All Committee members must undertake to scrupulously respect the confidentiality of the information transmitted and discussed in the Committee. All members shall sign an agreement to this effect.

At the end of all meetings, the members shall hand over their copies of project assessments to the Secretary of the CRIR Research Ethics Board for destruction.

24. QUORUM

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.

25. CONFLICT OF INTEREST

All Committee members must avoid getting into conflicts of interest that might interfere with the proper performance of their duties. Thus, all REB members associated with a research project or potentially in a position of conflict of interest in connection with a research project being reviewed by the Committee must advise the other members. The member must then withdraw from the Committee for the duration of the review, either on his or her own initiative or at the Committee's request. However, the member has the right to appeal the decision.

Any member placed in any other situation that may compromise his or her objectivity must disclose this situation to the Committee and, if warranted, withdraw from the review process.

SECTION 7 — SUBSTITUTION AND REPLACEMENT PROCEDURE

26. REPLACEMENT

When a member is absent from a meeting, that member may be replaced by a substitute. In this case, the substitute performs the same functions and has the same rights and obligations as the member being replaced.

27. NOTICE OF ABSENCE

If possible, members should strive to notify the REB Secretary in advance of any foreseeable absences from scheduled REB meetings. The Secretary then contacts the substitute to ensure replacement of the absent member.

28. TRANSMITTING RESEARCH PROJECTS TO SUBSTITUTES

When a regular member is replaced, the substitute shall receive a copy of the research project under review so that he or she can participate in the assessment of the project equally with the other Committee members.

29. MEETING ATTENDANCE

The substitute may attend all REB meetings if so desired. To do so, he or she must inform the REB Secretary so that the relevant documentation may be sent. In such case, the substitute may participate in the review process, but does not have voting rights.

SECTION 8 —REVIEW PROCESS

30. SUBMISSION OF RESEARCH PROJECTS FOR ETHICS REVIEW

Project shall be submitted in accordance with the prescribed procedures.

31. FORMS A, M, R AND END OF RESEARCH PROJECT REPORT

Appropriate forms have been developed to facilitate submission requests, and these must be duly completed.

Form A: Form A must be completed when the researcher wishes to submit a new proposal for an ethics review.

Form M: Form M must be completed when the researcher wishes to make one or more modifications to an ongoing project.

Form R: All researchers whose projects continue longer than one year must request annual renewals of approval by completing Form R.

Form End of Research Project Report: A research project is considered finished when the recruitment is done and data have been collected and analyzed in order to present to the REB preliminary results. Then, the researcher must complete this form.

32. REVIEW PROCEDURE: PROPORTIONATE ETHICS REVIEW

The REB uses a proportionate approach to the ethics review based on the general principle that the more invasive or harmful the research to the participant, the greater should be the care in the ethics review.

The concept of minimal risk provides a foundation for proportionate review. The proportionate review encompasses the following levels: full Board review and expedited review by a member or several members of the REB.

33. EXPEDITED ETHICS REVIEW

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 investigator 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 minor subjects or legally age subjects but who are unable to give consent (incompetent).

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

34. FULL BOARD ETHICS REVIEW

A full Board review must be undertaken for all research projects involving human subjects that do not meet the criteria for an expedited ethics review. Moreover, this applies out of hand to all projects involving minors or disabled persons.

34.1

In cases of a full-board (e.g., complete) evaluation, the following represents the minimum documentation set to be distributed to all REB members within a reasonable timeframe:

- Evaluation submission form
- Summary of the projected research activity expressed in clear, non-technical terms
- Proposed research protocol, including supporting documents and appendices
- Questionnaires and other documents for potential subjects or authorized third parties to be completed or used during the project
- Documents used for recruiting subjects (e.g., classified ads, Internet advertisements), including those that specify reimbursement of incurred expenses or access to care and services
- A description of the ethical issues raised by the project, if not already included in the protocol
- Methods of compensation in the event of an injury, as well as liability insurance, if not already included in the protocol
- Information sheet, as well as any information for potential subjects
- Informed consent form
- A list of all initiatives undertaken by other REBs to approve the submitted project, as well as all previous major decisions (e.g., unfavorable decisions or protocol modification requests) made by other REBs or regulatory authorities regarding this same project and the changes applied to the research project subsequent to these decisions
- A list of the proposed methods for continued follow-up, if not already included in the protocol.

Provided there are no objections from REB members, the following documents may be distributed in a limited capacity based on the following conditions:

- Approval from the scientific committee, provided that this document has been reviewed by at least two REB members
- Whenever applicable (e.g., in the case of a clinical trial), a summary of all tolerability, pharmacological, pharmaceutical and toxicology data published on the product being evaluated, as well as a summary of the clinical experience acquired to date relative to this product (e.g., recent investigator's brochure, non-objection letter from Health Canada), provided that this document has been reviewed by at least two scientific members of the REB and the REB chair (if the chair is not a scientific member) and that these individuals have been granted access to a pharmacist
- A document attesting the competency of the investigators and research team to properly conduct the project (e.g., CV reviewed and deemed adequate, privileges or area of research practice in good standing)
- A list of all research activities being conducted by the investigator in charge of the project at the institution, whether or not these research activities are being carried out internally or outside the said institution

- Relevant excerpts of the budget and sponsor/institution/investigator agreement likely to affect the integrity and ethics of the research (e.g., excerpts that will assist in examining the existence, real or potential, of situations of institutional or individual conflict of interest, as well as excerpts that provide instructions for the investigator regarding the freedom to distribute results), provided that these excerpts were examined by at least three REB members.

These documents must be made available for on-site consultation by committee members who did not receive them.

The individual(s) reviewing one or more of the above documents will be required to summarize them to the other REB members at the REB meeting. The individual(s)' name(s), as well as the nature of the information communicated to the REB, must also appear in the REB minutes.

34.2

Whenever a project undergoes an expedited evaluation (e.g., an accelerated ethics evaluation), all designated members of the expedited evaluation committee must receive all documents. Limited distribution is not allowed.

35. CONSULTATION WITH INVESTIGATORS

The REB may consult or meet with the research project leaders to obtain further information or to better understand certain aspects of the research protocol.

36. DECISION MAKING

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.

37. MOTIVATED DECISION

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 provided 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 a favourable decision, 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 an unfavourable decision, the reasons 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 and of the participant initial consent
- b) Premature termination of the project
- c) Project completion
- d) Any issues noted by a third party during monitoring (internal or external audits), and any suspension or withholding of approval in connection with the project by a funding body or regulatory agency.

SECTION 9 – ETHICS MONITORING

38. RESEARCH PROGRESS

All research projects must be conducted in accordance with the protocol approved by the REB.

39. REQUESTS FOR MODIFICATION

Before bringing any modifications to the research protocol or associated documents, the researcher must advise the REB, who must approve those changes.

40. IMMEDIATE THREATS TO PARTICIPANTS

Nevertheless, changes to the protocol may be made without prior approval by the REB if they are required to prevent an immediate threat to the health of the participants.

If such occasion arises, the researcher must advise the REB in the shortest possible delay of any modifications brought prior to REB consent. Thereafter, the REB shall render a decision on ethical approval.

41. ADMINISTRATIVE AND TYPOGRAPHIC MODIFICATIONS

When the proposed modification consists of an editorial change or correction of a logistics or administrative error (e.g., telephone number, typing error), the researcher is not obliged to advise the REB beforehand.

42. MONITORING MECHANISM

a) Submission of annual report by the researcher

All projects in progress shall be followed up on an annual basis. Thus, thirty days before the end of the annual approval, the researcher must submit an annual report to the REB, including the following information:

- Actual start date
- Progress (stage) and conduct
- Number of subjects initially approached and number of subjects recruited to date
- Number of subjects who withdrew during the course of the project and the reasons, if known
- Occurrences of adverse reactions and other incidents during the year and description of the means implemented to remedy the effects on the subjects
- Anticipated date of project completion
- Any other items identified by the REB in their ethics review.

An appropriate form has been developed to account for the above items, and may be used in place of the annual report that researchers are required to submit to the REB when projects continue longer than one year.

b) Mandatory reporting

Researchers are under obligation to report any and all harm or serious incidences, foreseeable and unforeseeable, during the course of the research.

In light of such information, the Committee reserves the right to terminate the project.

c) More careful Monitoring

In cases of research protocols involving possible **harms above the threshold of minimal risk**, the REB reserves the right to require those in charge of the project to conduct the monitoring with greater care.

43. RECORD KEEPING

All copies of research projects submitted to REB members for ethics review must be destroyed once the REB has rendered its decision on the project. All REB documentation shall be kept at the Research Ethics Office in a locked file for a period of five years following completion of the project.

43.1 ACCESS TO REB DOCUMENTS

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 documents 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 body and the regulatory agency.

44. RESEARCH FILES

The research files shall include: relevant information and documentation retained on all research projects submitted to the Committee. More specifically, these files shall contain the research protocols and any subsequent modifications, consent forms approved by the REB, requests for Committee approval, all correspondence between the Committee and the project head, and all forms used by the Committee following project approval (approval, annual renewal, project modification, notice to Committee, notice of project termination).

Likewise, all documents to be submitted to the Board of Directors, annual reports, project registry and any other relevant Committee documentation must be retained. Files are kept in a locked file at the research ethics office of the CRIR institutions.

45. ANNUAL REPORT

On March 31 of each year, the President of the REB shall submit an annual report to the ministère de la Santé et des Services sociaux, the Board of Directors of the CRIR, the boards of directors of each CRIR institution and the authorities of the universities represented on the REB.

The Annual Report shall encompass the following items:

- a) A list of the members and their qualifications

- b) The number of meetings held by the Committee during the year, including training sessions
- c) A list of projects that have been submitted for review, each accompanied by the name of the researcher, funding sources, project summary and the Committee's decision
- d) All monitoring activities undertaken by the Committee
- e) Any other items that the Committee deems relevant for the information of the Board of Directors.

SECTION 10 — REIMBURSEMENT OF REB MEMBERS

46. REGULAR MEMBERS

Regular members shall be reimbursed for the performance of their duties according to a scale set by the CRIR Board of Directors, e.g. four hours to attend monthly meetings and one hour of review for each research project submitted to the REB.

Prior to each meeting, a timesheet itemizing the titles of projects to be reviewed shall be sent to all REB members so that they may estimate the number of hours required to read the projects.

47. SUBSTITUTES

Substitutes are only paid for acting as official replacements for absent members. This includes time spent attending monthly meetings and one hour of review for each project submitted to the REB.

48. TRAINING SESSIONS

Regular members as well as substitutes will not be paid for attending training sessions.