

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



**PROCEDURE FOR EVALUATION OF A RESEARCH PROTOCOL
SUBMITTED TO THE RESEARCH ETHICS BOARD (REB) OF THE
CRIR INSTITUTIONS**

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

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SECTION I – GUIDELINES FOR SUBMISSION

1. Mandate of the REB of the CRIR institutions

The REB is to examine each research study with human subjects involving a CRIR institution or one of its regional partners, which is characterised by one or more of the following:

- 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.

Reference: Article 1.3 of *Règlement portant sur la création et le fonctionnement du comité d'éthique de la recherche des établissements du CRIR.*

2. Request for evaluation by the REB

Any person who wishes to conduct a research study that meets at least one of the above criteria must obtain an ethics certificate from the REB of the CRIR institutions. For this purpose, the researcher must submit a written request to the CRIR's Research Ethics Coordinator that the study be evaluated under the tripartite evaluation procedure: scientific evaluation, examination of institutional suitability and ethical evaluation.

3. Documents to include in the evaluation request

The request for ethical approval of a study must include the following documents:

3.1

New study submission Form (A) completed and **signed** by the principal investigator.

3.2

A cover letter outlining succinctly the nature and goals of the research study including the expected contribution of the institution(s) involved.

3.3

- Letter of proof for studies **subsidized by a granting agency**

- Letter from the committee with the evaluation and the criteria upon which it was based for studies that have been **evaluated by a scientific committee**.

3.4

The full research protocol. A summary of the research protocol understandable in lay terms is also to be included. The protocol may be submitted in either French or English.

3.5

The complete bibliography of all studies referenced in the protocol.

3.6

Consent Form(s) used in the research study. If both French and English-speaking subjects are included in the research study, copies of the Consent Form in both languages are to be submitted.

Moreover, if the researcher recruits subjects with visual impairment, the Consent Form may need to be printed with large letters or translated into Braille (submit a letter of collaboration from an official translator).

3.7

All documents used for the recruitment of research subjects: publicity, announcements, posters, letters of recruitment.

3.8

Questionnaires, forms or other documents administered to the subjects.

3.9

If appropriate, the Investigator's Brochure.

3.10

A statement by the investigator that a list of research participants (see Form A) will be maintained.

3.11

A commitment on the part of the researcher to respect the ethical requirements of the REB which is based on the following documents: Canadian Tri-Councils' Policy Statement on Ethical Conduct for Research Involving Humans, and the FRSQ standards of research ethics and scientific integrity.

3.12

An up to date curriculum vitae and other documents which attest to the competence of the principal investigator(s) and collaborators who are not members of CRIR.

3.13

A detailed budget of the research study.

3.14

Any other documents judged pertinent by the researcher.

4. Timeline

The REB establishes an annual calendar with specified monthly deadline dates for receipt of submissions of research protocols for evaluation.

In order that the protocol be evaluated within the 7 to 8 week timeframe, the researcher must respect the deadline dates. If the date is missed, the protocol will be evaluated within the next evaluation period.

5. Modality of submission

The submission to the coordinator of the Research Ethics Board must be in two modalities:

- By e-mail (Word, Word Perfect, Acrobat Reader – PDF)
- By post

6. Registration of study by the REB

Any protocol whose request was considered to be admissible by the CRIR's research ethics coordinator will be considered officially registered. The registration date is the date that the research protocol was first received by the REB, whether in electronic or paper form. An identification number will then be allotted to the research project.

7. Transmission to the Scientific Committee and the Committee of Institutional Suitability

Once the study has been registered, the coordinator of the REB forwards, **simultaneously**, the request for evaluation to (1) the Chair of the Scientific Committee and (2) the Committee of Institutional Suitability of the CRIR institution(s) in which the study is to be carried out.

SECTION II – SCIENTIFIC EVALUATION

8. Scientific evaluation

In accordance with article 8.1 of *Règlement portant sur la création et le fonctionnement du Comité d'éthique de la recherche des établissements du CRIR*, the Scientific Committee of CRIR carries out the scientific evaluation of research studies submitted to the REB, except those that have already been examined for quality and scientific relevance by a recognized peer review committee.

The Chair of the CRIR's Scientific Committee has also the power to recognize the validity of other external scientific evaluations.

The evaluation of any research protocol by the Scientific Committee is done in accordance with article 8 of the "*Règlement portant sur la création et le fonctionnement du Comité d'éthique de la recherche des établissements du CRIR*", as well as the procedure of scientific evaluation adopted by the Scientific Directors of CRIR.

9. Timeframe

In accordance with the submission deadlines of the REB, the Scientific Committee has three weeks to carry out the scientific evaluation of the research protocol, to contact the researcher and request modifications, if any, to the research protocol. The researcher will have, thereafter, a week to carry out the modifications and have them approved by the president of the Scientific Committee prior to its transmission to the CRIR's Research Ethics Coordinator.

10. Decision

Following its evaluation on the validity and scientific rigour of a research study, the Scientific Committee can accept or refuse that the protocol be further evaluated by the REB. It can also request that the research protocol be modified in order to meet acceptable scientific standards.

Decisions of the Scientific Committee must be justified and the justifications given.

11. Transmission of the decision

The decision of the scientific evaluation is transmitted to the CRIR's Research Ethics Coordinator in writing.

SECTION III – DETERMINATION OF INSTITUTIONAL SUITABILITY

12. Institutional suitability

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.

13. Determination of institutional suitability

Institutional suitability is determined in any/all institution(s) of CRIR in which the research study is carried out, in accordance with article 9 of *Règlement portant sur la création et le fonctionnement du Comité d'éthique de la recherche des établissements du CRIR*.

Each CRIR institution appoints a person or forms a committee that carries out the determination of institutional suitability and transmits the information to the CRIR's Research Ethics Coordinator of the REB.

14. Timeframe

In accordance with the submission deadlines of the REB, the Committee or person responsible for determining institutional suitability has three weeks to carry out the assessment and then forwards the decision to the CRIR's research ethics coordinator.

15. Decision

Following the determination of institutional suitability, the institution can accept or refuse that the research project be carried out within its walls. It can also ask that the research protocol be modified in order to meet certain institutional requirements.

The decisions of the institution must be justified and the justifications given. Moreover, decisions on the suitability of the institution to carry out a research study are final and without appeal.

16. Transmission of the decision

The decision of institutional suitability is transmitted to the CRIR's Research Ethics Coordinator in writing.

SECTION IV – ETHICAL EVALUATION BY THE MEMBERS OF THE REB

17. Transmission to the REB

Only research protocols meeting favourable scientific evaluation and institutional suitability are evaluated by the REB.

18. Evaluation

The evaluation of any research protocol by the REB is done in accordance with the *Règlement sur la création et le fonctionnement du comité d'éthique de la recherche des établissements du CRIR* and with the procedures adopted for this purpose.

19. Timeframe

In accordance with the submission deadlines of the REB, the board members have three weeks to read and assess research protocols that are evaluated during monthly meetings.

20. Decision

Following evaluation of the research protocol, the REB can grant or withhold the ethics certificate. It can also request that the research protocol be modified in order to meet current ethical standards.

The decision of the REB must be justified and the justifications given.

The decision of the REB whether a research project is fully or partially approved, is subject to appeal. The appeal is heard by the Research Ethics Board of the university to which the researcher is affiliated.

The ethical evaluation of a research study whose decision is unfavourable cannot be reversed by an institution.

SECTION V: REQUEST FOR EXPEDITED REVIEW

21. Application

The expedited review is an ethical evaluation mode to which the REB of the institutions of CRIR can have recourse under the following three conditions, according to article 7.3 *Règlement portant sur la création et le fonctionnement du Comité d'éthique de la recherche des établissements du CRIR*:

- a) When a research study falls below the threshold of minimal risk for subjects (Form A)

- b) When the researcher proposes a minor modification of a research study that the REB of the CRIR institutions has already approved (Form M)
- c) The annual renewal of an on-going study in one of the institutions of CRIR (Form R)

The expedited review does not apply to initial ethics assessments of research projects involving minor subjects or legally age subjects unable to give consent (incompetent).

22. Documents to submit

In order to obtain a certificate of approval from the REB through expedited review, the following documents must be submitted to the secretariat of CRIR:

- The appropriate form duly completed and signed by the principal investigator, accompanied by the documents which are mentioned herein
- If appropriate, modified pages of the project previously submitted to the REB
- If appropriate, the new consent form or the modified consent form (specifically indicating all the changes to the version that the REB had already approved)
- If appropriate, the research protocol, as well as documents intended to be given to the research subjects
- Any other document considered relevant by the researcher.

23. Timeframe for expedited ethical review

If, following a preliminary evaluation of the research study, the CRIR's Research Ethics Coordinator determines that the protocol meets one of the conditions of article 20 (above), it can be sent to the Chair of the REB who, along with at least one other board member, will proceed with the evaluation of the study within, approximately, two weeks starting from the date of reception.

24. Decision

Following their evaluation of the research study, the sub-committee of the REB that carried out the expedited review can either grant or withhold the ethical certification of the project. The sub-committee can also request modification to the study in order to meet current ethical standards. The decision of the sub-committee is made in the name of the REB of the CRIR institutions.

25. Justification of the decision

The decision of the expedited review must be justified and the justifications given to the researchers.

26. Transmission of the decision to the REB

All decisions taken under expedited review are transmitted as quickly as possible to the members of the REB in order that they can continue to control decisions taken on their behalf.

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