



Policy on the Research Ethics Board of the McGill University Health Centre (MUHC REB) ¹	
Related Procedure: MUHC REB Standard Operating Procedures (REB SOP)	Associated SNC-O&M Policy and Procedure (if applicable):
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Summary: In accordance with the <i>Cadre de référence ministériel pour la recherche avec des participants humains</i> (hereinafter called <i>Cadre de référence ministériel</i>), the institution must be able to build and maintain an organizational culture that values research, ethics, and the responsible conduct of research. Therefore, it must implement a regulatory framework for its research activities, including a policy on the institution's responsibilities regarding the research ethics board (REB) and the rules governing its operations.	

(Refer to MUHC Policies and Procedures Manual)

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¹ This policy addresses the following *Cadre de référence ministériel* standards: Standard 2, section 2.3.3 (“Student Projects”), Standard 4 (“Responsibilities of the Board of Directors”) and Standard 5 (“REB Operational Rules”).



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I. Purpose

The purpose of this policy is to describe:

- the responsibilities of the Board of Directors in regard to the Research Ethics Board of the MUHC (MUHC REB);
- the responsibilities of the MUHC leadership in regard to the REB;
- the REB's mandate and the rules governing its operations.

II. Persons/Areas Affected

2.1 Scope

This policy applies to:

- The Board of Directors;
- The MUHC leadership;
- The REB, its members, and its support staff;
- Department heads and scientific directors.

2.2 Responsibilities

In accordance with the *Cadre de référence ministériel pour la recherche avec des participants humains* (hereinafter called *Cadre de référence ministériel*), the institution must be able to build and maintain an organizational culture that values research, ethics, and the responsible conduct of research. Therefore, it must implement a regulatory framework for its research activities.²

The Board of Directors³ must:

- Make sure the REB's membership, mandate, and authority, as well as its terms of operation, meet generally recognized existing ethical standards;
- Make sure that the REB operates under circumstances, namely administrative and financial ones, that are proper to the execution of its mandate in a manner that ensures its independence. It must therefore make sure that the REB:
 - Benefits from sufficient support from support staff;
 - Has an operational budget that allows it to carry out fully its mandate. REB operation costs must be part of the budget related to the primary activities of the institution;⁴

² *Cadre de référence ministériel pour la recherche avec des participants humains*, Government of Québec, Ministère de la Santé et des Services sociaux, October 2020, p. 1 and standard 1, hereinafter called "*Cadre de référence ministériel*".

³ *Cadre de référence ministériel*, standard 4.

⁴ According to chapter 1, appendix 1H and the 024 status update letter from the *Manuel de gestion financière*, the REB's activities are a part of the institution's primary activities (administrative services). Costs associated with REB



- Receive an annual report from the REB, acknowledge receipt of it, and, if necessary, make sure that a copy is forwarded to the MSSS within the specified timelines;
- Make sure the REB meets the generally recognized REB standards, including the *Cadre de référence ministériel* and the terms of operation (“conditions de fonctionnement”) set by the Minister.

The Board of Directors and MUHC leadership must⁵:

- Make sure that the REB has the resources and independence to properly function;
- Make sure members have the required skills to perform their tasks;
- Make sure that REB members and, if necessary, REB support staff have regular access to training in research ethics;
- Make sure that the REB is protected from undue influence.

The REB must:

- Carry out its mandate, which consists in protecting the dignity, safety, well-being, and rights of human participants in research and supporting high-quality research, in accordance with MUHC REB SOPs.

The Centre for Applied Ethics (CAE) is responsible for ensuring:

- The upkeep, update, and availability of operational rules in the form of REB standard operating procedures (SOPs), striving when possible to harmonize with the SOPs of other university health centers (CHUs) of the *Réseau de la santé et des services sociaux* (RSSS);
- The oversight, organization, and maintenance of REB support staff’s skills.

Department heads and scientific directors must:

- Make sure the REB receives candidacies from members with scientific expertise.

III. References/Definition of terms

Provincial:

- *Civil Code of Québec*, CQLR, c. CCQ-1991
 - *Avis sur les conditions d’exercice des comités d’éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l’article 21 du Code civil*, Gazette officielle du Québec, Partie I, vol. 35, 1998, p. 1039
- *Act respecting health services and social services*, CQLR, c. C-4.2
- *Cadre de référence ministériel pour la recherche avec des participants humains*, October 2020;
 - *Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l’autorisation d’une recherche menée dans plus d’un établissement*, Government of Québec, Ministère de la Santé et des Services sociaux, 2016.

Federal:

- *Food and Drugs Act*, R.S.C., 1985, c. F-27
 - *Food and Drug Regulations*, C.R.C., c.870
 - *Good Clinical Practice, International Council for Harmonisation, GCP – ICH E6(R2)*
- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2* (2018).

IV. Policy

In accordance with the *Cadre de référence ministériel*, the MUHC Board of Directors establishes and empowers the REB to review the research that is carried out under the auspices of the MUHC.⁶

activities are indirect costs of research because they are costs divided between a range of activities that are not related to a specific research project.

⁵ *Cadre de référence ministériel*, standard 4.

⁶ *Cadre de référence ministériel*, standard 4 and section 2.4.1; *REB-SOP 101.001*, s. 5.1.1.



4.1 Administrative structure and independence

The REB reports directly to the MUHC Board of Directors.

The REB is an autonomous entity within the institution.⁷ It must benefit from total decisional independence regarding the projects it reviews.

The MUHC REB is an REB that is designated by the *Ministère de la Santé et des Services sociaux*.⁸

The REB must provide an annual report to the MUHC Board of Directors and to the *Ministère de la Santé et des Services sociaux*.⁹

4.2 Nomination of members

REB members are nominated or relieved of their duties by the MUHC Board of Directors on the recommendation of the REB Chair.¹⁰ Department heads and scientific directors propose candidates with suitable scientific expertise to the REB Chair.

Selection criteria are set out in the REB SOP 201.001.

The following criteria can lead to a member being relieved of their duties:

- Lacking civility;
- Failing to uphold recognized ethical standards; or
- Being found guilty of research misconduct.

New members will have an initial mandate of one year. Each subsequent mandate will be renewed on the recommendation of the REB Chair and approved by the Board of Directors for a term of up to 3 years.

The REB's membership complies with the relevant laws, regulations, and guidelines. The REB consists of at least five members who are represented by the following categories¹¹:

- At least two members with expertise in disciplines, fields, and methodologies that fall under the purview of the REB (biomedical clinical trials will involve at least one member who practices medicine, dentistry, or pharmacy and who is a member in good standing of the Council of Physicians, Dentists, and Pharmacists (CPDP); clinical trials with natural products will involve at least one member with knowledge of complementary or alternative healthcare).
- At least one member whose primary experience was acquired in a non-scientific field.
- At least one member with expertise in ethics.
- At least one member with legal expertise, including with knowledge of the laws relevant to the types of research being reviewed.
- At least one member from the community or a representative from an organization who is interested in the field of research to be approved who has no affiliation with the institution or the sponsor.

⁷ *Cadre de référence ministériel*, section 2.4.4. and 2.4.5.;

⁸ *Civil Code of Québec*, s. 21.

⁹ *Cadre de référence ministériel*, standard 4.

¹⁰ *Cadre de référence ministériel*, standard 4 and section 2.4.3.

¹¹ *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil*, Gazette officielle du Québec, Partie I, vol. 35, 1998, p. 1039, hereinafter called "Notice"; *Food and Drug Regulations*, C.R.C., c. 870, s. C.05.001 under "research ethics board"; *GCP*, paragraph 3.2.1 a; *TCPS 2*, s. 6.4, *REB-SOP 201.002*, MUHC.



The number of members must be proportional to the volume of requests made to the REB. The number of scientific members must be sufficient to ensure a pertinent scientific evaluation of research projects.

4.3 Decisional power

The REB has the authority to approve, to approve conditionally, or to disapprove a research project. This decision must be made within a reasonable timeframe. If issues need to be resolved before a decision can be made, the REB may defer its decision.¹²

The REB also has the power to suspend or terminate the ethics approval of a research project.¹³

4.4 Rules governing operations

4.4.1 Jurisdiction

The REB executes its mandate within the MUHC or within another public body of the RSSS.¹⁴

The MUHC REB's jurisdiction is provided for in the *Cadre de référence ministériel*¹⁵ and the TCPS 2.¹⁶ All or part of the research will be carried out under the auspices of the MUHC. This implies, in particular, that:

- a) Participants are recruited at the MUHC (in physical locations or via technological tools under the responsibility of the MUHC) among users or staff members, or from records or data under the institution's responsibility;
- b) The research project involves a database or a biobank that is created for research purposes and that is hosted at the MUHC or at an RSSS institution or that is under the responsibility of a researcher affiliated with an RSSS institution under the provisions of the bank's management framework;
- c) The research project uses the MUHC's technical platforms, such as medical imaging, operating rooms, care units, examination rooms, etc.;
- d) The research project relies on services provided by MUHC staff as part of the conduct of research activities, such as nursing and pharmacy;
or
- e) The sponsor or researcher states or implies either their affiliation with the institution or an MUHC participation in the project.

Inter-institutional agreements may be entered into with RSSS public or private institutions.

4.4.2 Exceptions to jurisdiction¹⁷

The REB is not required to evaluate a research project when:

- The researcher responsible for the project (with human research privileges granted by the Research Institute of the MUHC (RI) or with researcher status) is neither an employee of the MUHC or of the RI nor a member of the MUHC CPDP;
and
- the project does not involve the MUHC REB's jurisdiction under 4.4.1 a) to d).

¹² REB-SOP 401.001. See also TCPS 2, s. 6.3; GCP, paragraph 3.1.2.

¹³ REB-SOP 407.001; GCP, c. 3.1; TCPS 2, s. 6.3.

¹⁴ *Cadre de référence ministériel*, standard 4 and section 2.4.2.

¹⁵ *Cadre de référence ministériel*, standard 5 section 2.5.3

¹⁶ TCPS 2, s. 6.1

¹⁷ TCPS 2, s. 6.1

4.4.3 Applicants (researcher responsible for the project)

- a) When recruitment involves users, their data, or their biological material, requests for REB review must come from a researcher with, in addition to human research privileges granted by the RI or researcher status at the Montreal Neurological Institute, an affiliation with the MUHC, i.e., a membership with the CPDP or employment either with the MUHC or RI;
- b) When a research project involves a student, requests for REB review must come from the student's research director¹⁸. The director must have human research privileges granted by the RI or a researcher status at the Montreal Neurological Institute, and, if recruitment involves users, their data, or their biological material, the director must be affiliated with the MUHC (membership with the CPDP; MUHC or RI employment);
- c) In the case of a research project under the jurisdiction of the REB, as specified in 4.4.1 a) to d), requests for REB review must come from a researcher with either human research privileges granted by the RI or researcher status at the Montreal Neurological Institute;
- d) In the case of a research project under the jurisdiction of the REB, as specified in 4.4.1 e) only, requests for REB review must come from a member of the CPDP, an employee of the MUHC, or an employee of the RI.

4.4.4 REB Standard Operating Procedures (SOP)

The REB operates in accordance with the REB SOPs developed in collaboration with the REBs at other CHUs.

The CAE is responsible for ensuring that SOPs are updated, in collaboration with participating REBs. SOPs, as well as any update, are submitted to the Board of Directors for adoption, in accordance with the mechanism established in the corresponding SOP.

The REB SOPs are available on the [MUHC REB](#) website.

V. Special Considerations

N/A

VI. Relevant Forms

All relevant forms associated with the policy are available on the Nagano platform (<https://nagano.muhc.mcgill.ca/login>).

VII. Revision History

Revision Date	Summary or changes
2021-08-13	Revision of sections relevant to the REB from the "Regulatory framework in health research at the MUHC" and development of a separate policy. Update to reflect the 2020 <i>Cadre de référence ministériel</i> . Integration of criteria on access to the MUHC REB (jurisdiction and applicants).
2021-09-30	The following administrative revisions: <ul style="list-style-type: none"> - Addition to footnote 1: "Standard 2, section 2.3.3 (Student Projects)," - 4.4.3 B) addition of note 18 to first sentence: "<i>Cadre de référence ministériel</i>, standard 2 chapter 2.3.3"

¹⁸ *Cadre de référence ministériel*, standard 2 chapter 2.3.3.



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