Title	Initial Review – Criteria for REB Approval
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Author of Harmonized Template	SOPs, Institutional REBs	2019-04-01
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1 PURPOSE

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet in order to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e. Full Board or delegated review).

2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

The REB members are responsible for determining whether the research meets the criteria for approval.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

All research involving human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB. The REB and/or REB Support Staff may consult the Researcher for additional information as necessary.

Following initial review of the research in accordance with the relevant SOPs, the REB should be prepared to make a determination as to the approvability of the research.

5.1 Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration:

5.1.1 The application has been signed by the Researcher or designee.[1] The REB may require the Researcher to submit the following documents indicating that the Researcher has the qualifications to conduct the research[2]:

- CV,
- For clinical trials, licence to practice,
- Proof of research privileges;

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[1] *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, *Ministère de la Santé et des Services sociaux*, DGAERA, 2004, hereafter "*Modèle*", s. 9.3.

[2] *Modèle*, s. 9.3 and 10.3; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.3; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 5.1, 5.3.7, 6.2.3.1; *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*, Part I, vol. 35, 1998, hereafter "*Avis*", p. 1039; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, *Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, June 1998, hereafter "PAM", p. 23.

5.1.2 Any conflicts of interest (real, potential, or perceived) are declared and managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data[3];

5.1.3 Where relevant, there is a state of clinical equipoise;

5.1.4 The research will generate knowledge that could be generalized and lead to improvements in health or well-being[4];

5.1.5 The methodology is scientifically sound and capable of answering the research question[5];

5.1.6 The risks to participants are minimized by:

- Using procedures that are consistent with sound research design and that do not expose participants to unnecessary risk, and
- By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate;

5.1.7 The risks to participants are reasonable in relation to the anticipated benefits, if any, and to the importance of the knowledge that will be generated[6];

5.1.8 The selection of participants is equitable, i.e. inclusive for anyone who might benefit from the research.[7] Participants are not to be excluded for reasons of culture, language, religion, race, disability, sexual orientation, ethnic origin, gender, or age. Such exclusions would require sound scientific and ethical reasons.[8] In making this assessment, the REB will take into account the purpose of the research and the research setting;

5.1.9 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research;

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[3] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 7.4 and p. 98; *Modèle*, s. 10.3. See also REB SOP on Conflicts of Interest – Researcher.

[4] *Modèle*, s. 10.3; TCPS2, p. 20-22; *Avis*, p. 1039.

[5] *Modèle*, s. 10.3; TDR, s. 6.2.

[6] Civil Code of Québec (CCQ), c. CCQ-1991, art. 20 and 21; *Modèle*, s. 10.3; TCPS2, p. 20-23, art. 2.9, art. 11.4 (a); TDR, s. 6.2.1.2; *Avis*, p. 1039; PAM, p. 23.

[7] TCPS2, art. 4.1; TDR, s. 2 and 6.2.2.4; *Modèle*, s. 10.3; *Avis*, p. 1039; PAM, p. 23.

[8] TCPS2, art. 4.1.

5.1.10 When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research.[9] Vulnerability may depend on participant status, role in the institution, or circumstances surrounding participation in the study;

5.1.11 The amount paid to participants to cover losses and constraints and the method of payment to participants is appropriate to ensure that there is no coercion or undue influence.[10] Information regarding payment to participants including method, amounts and schedule is provided to participants when applicable[11];

5.1.12 The informed consent form and the informed consent process will be in accordance with applicable standards and relevant SOPs[12];

5.1.13 The informed consent process will be documented in appropriate manner, in accordance with regulations and relevant SOPs[13];

5.1.14 The REB requires that informed consent forms for clinical trials be drafted using the Standard Legal Clauses for Informed Consent Forms of the *Ministère de la Santé et des Services sociaux du Québec* (MSSS), available in both French and English. Any changes, deletions, or additions must be justified by exceptional circumstances;

5.1.15 There will be provisions for ongoing data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research, if any.[14] The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;

5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data[15];

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9 TCPS2, art. 3.1.

10 "A person's participation in research that could interfere with the integrity of his person may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenience suffered." (Civil Code of Québec (CCQ), c. CCQ-1991, art. 25, para. 2). See also: TCPS2, p. 27; ICH GCP, s. 3.1.8; TDR, 5.3.12, 5.3.13, 6.2.3.10; *Modèle*, s. 9.3.

11 ICH GCP, s. 3.1.9.

12 Civil Code of Québec (CCQ), c. CCQ-1991, art. 10 para. 2; TCPS2, art. 3.1, 3.2 and 3.9; TDR, 6.2.5 and 5.3.11; *Modèle*, s. 9.3 and 10.3; *Avis*, p. 1039; PAM, p. 23; ICH GCP, s. 3.1.9.

13 Civil Code of Québec (CCQ), c. CCQ-1991, art. 24; TCPS2, art. 3.12.

14 TCPS2, art. 11.6, 11.7; TDR, s. 6.2.1.6.

15 TCPS2, art. 5.1 à 5.3; Québec Charter of Human Rights and Freedoms, CQLR, c. C-12, art. 5; Civil Code of Québec (CCQ), c. CCQ-1991, art. 3 and 35-37; Act Respecting Health Services and Social Services, art. 19; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A-2.1, art. 53; TDR, s. 6.2.4; *Modèle*, s. 10.3; *Avis*, p. 1039; PAM, p. 23.

5.1.17 There will be adequate provisions for continued access to the study product or adequate replacement of the study product after the research is complete, as appropriate[16];

5.1.18 There will be adequate provisions for the timely publication and dissemination of all the research results, except where additional delays are deemed justifiable by the Contracts Office after consultation with the REB[17];

5.1.19 If applicable, the research has been or will be registered via an internationally recognized clinical trial registry and a registration number has been/will be submitted to the REB.[18] The researcher shall provide the REB with the registration number upon registration.[19]

5.2 Additional Criteria

5.2.1 In cases where it is impossible, practically impossible, or impractical to obtain individual consent, the Director of Professional Services (*DPS*)[20] may grant access to medical chart data for research purposes. The REB must first approve the waiver of consent;

5.2.2 Additional criteria may apply depend on the type of research.

5.3 Length of Approval Period

5.3.1 The REB shall review research at periods appropriate to the degree of risk and at least annually.[21]

6 REFERENCES

See footnotes.

16 TDR, s. 6.2.3.6 and 6.2.3.8.
17 TCPS2, art. 11.12; TDR, s. 6.2.1.8.
18 TCPS2, art. 11.3.
19 TCPS2, p. 161.
20 Act Respecting Health Services and Social Services, art. 19.2.
21 ICH GCP, s. 3.1.4; *Modèle*, s. 11; TCPS2, p. 82; TDR, s. 2.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 403.001	N.A.	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)
REB-SOP 403.001-1	2020-03-20	5.2.1: “Quebec Public Health Department” corrected for “Director of Professional Services”

8 APPENDIX