Title	Initial Review ~~–~~ Criteria for REB Approval
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~~Site Approvals~~

Status	Name and Title	Date
~~Authored~~Author of Harmonized Template	~~CAE, Manager~~SOPs, Institutional REBs	~~2017-02-20~~2019-04-01
Approved	~~Director, MUHC Centre for Applied Ethics~~MUHC REB Full Board Meeting	~~2017~~2020-02-~~20~~13
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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 ~~Office Personnel~~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 ~~Office Personnel~~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 ~~will render~~should be prepared to make a ~~decision~~determination as ~~per SOP 401.002~~to the approvability of the research.

5.1 Minimal Criteria for ~~Ethics~~ Approval of Research

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

5.1.1 The application has been signed by the Researcher or designee[1] The ~~researcher must demonstrate having~~REB may require the Researcher to submit the following documents indicating that the Researcher has the qualifications to conduct ~~research as demonstrated by either: Valid~~the research ~~privileges to conduct research with human participants at the MUHC (RI SOP 500_01), or~~[2]:

a. CV,

b. For clinical trials, licence to practice,

[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.

~~a. For MNI researchers, not recruiting MUHC patients or using MUHC resources, being a full time or part time McGill faculty member with the rank of Assistant Professor or above;~~

~~b.~~c. Proof of research privileges;

~~is a state of clinical equipoise i.e. genuine uncertainty regarding which study intervention is most effective when there is a comparison of two or more intervention arms, and neither arm falls below standard of care;~~

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 ~~could~~ 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 ~~unnecessarily~~ 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.~~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~~. The REB will consider the scientific and ethical reasons for including vulnerable populations, if applicable~~;

[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.

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

5.1.10 When some or all of the participants ~~(such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self- determination~~ are likely to be vulnerable to coercion or undue influence~~),~~ additional safeguards have been included in the research~~, and in the REB review process to protect the rights and welfare of these~~.[9] Vulnerability may depend on participant status, role in the institution, or circumstances surrounding participation in the study;

~~1.1.10.~~ The amount paid to participants~~;~~

~~5.1.10~~5.1.11 ~~The amount and~~ to cover losses and constraints and the method of ~~compensation offered~~payment to participants ~~–~~is appropriate to ensure that there is no coercion or undue influence~~ and that information~~.[10] Information regarding ~~compensation for time and inconvenience~~ payment to participants including method, amounts and schedule is provided to participants when applicable[11];

~~1.1.11. Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and guidelines as per SOP404.002;~~

~~5.1.11~~5.1.12 The informed consent form ~~will accurately explain the research and contain the required elements of consent, as per SOP 404.002~~and the informed consent process will be in accordance with applicable standards and relevant SOPs[12];

~~1.1.12. The MUHC REB requires the use of the wording, provided by the Quebec Ministry of Health, verbatim for the regulatory clauses of all clinical trials in both French and English. This wording is provided in red on the MUHC REB's informed consent template for clinical trials. Additions, deletions or changes to the mandatory wording will only be considered if/when compelling justification is provided.~~

~~5.1.12~~5.1.13 ~~Informed consent will be appropriately~~ The informed consent process will be documented in appropriate manner, in accordance with ~~the relevant~~ regulations ~~(s. 24 C.c.Q.);~~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*

[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.

(MSSS), available in both French and English. Any changes, deletions, or additions must be justified by exceptional circumstances;

~~5.1.13~~5.1.15 There will be provisions for ~~on-going~~ongoing data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research ~~when relevant.~~, if any.[14] The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;

~~5.1.14~~5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data[15];

~~5.1.15~~5.1.17 There will be adequate provisions for continued access to the ~~agent or device~~study product or adequate replacement of the ~~test agent~~study product after the research is complete, ~~when~~as appropriate[16];

~~5.1.16~~5.1.18 There will be adequate provisions for the timely publication and dissemination ~~(i.e. no undue restrictions, as described in TCPS2 art.11.12)~~ of all the research results, ~~unless justification for a longer delay is provided at the satisfaction of~~except where additional delays are deemed justifiable by the Contracts Office after consultation with the REB[17];

~~5.1.17~~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. ~~If the research is not yet registered, the~~[18] The researcher shall provide the REB with the registration number upon registration.[19]

5.2 Additional Criteria

~~5.2.1. Studies proposing access to or collection of personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to. Where the REB has approved waiver of consent, the DPS authorization must be obtained prior to accessing medical records as per section 19.2 LSSSS;~~

~~5.2.2. Additional criteria for research involving Aboriginal peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations.~~

~~5.2.3. It is the REB's position that judging the financial arrangements offered by third party vendors (i.e. evaluating the financial risks, safety risks, confidentiality of the participant's personal information towards the financial institutions, balance of risks and benefits, etc.) falls outside of the scope of~~

[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.
[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.

~~its mandate. Nevertheless, competent adults can choose to use the financial and/or personal services of their choice without an REB's participation or approval. Consequently, the REB will not review or approve the information documents specifically relating to the third-party vendor or ICF's for the use of their services.~~

~~However the REB requires the following in order to approve the study:~~

~~1. That the use of third party vendors not be mandatory to participate in the research project and/or to receive compensation.~~

~~2. An undertaking from the sponsor that they will maintain confidentiality and will not obtain the participant's personal information from the third-party vendor.~~

~~AND~~

~~3. That participants be informed that:~~

- ~~The REB review by the MUHC/Neuro did not include any evaluation of the risks associated with the use of these third party services;~~
- ~~Use of these services is not mandatory in order to participate or to receive compensation;~~
- ~~Their personal info will not be shared with the sponsor.~~

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]

~~REB may require review more often than annually when there is a high degree of risk to participants relative to the population;~~

~~The REB may consider reviewing the research more often than annually as required by the continuing review procedure.~~

[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.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
~~MUHC~~ REB-SOP~~-~~ 403.001	~~2017-02-24~~N.A.	Original ~~Version~~version
~~MUHC~~ REB-SOP~~-~~ 403.001~~_~~-1	~~2017-07-07~~2020-03-20	~~5.1.4. Minor wording editing~~ ~~5.1.18. Addition of reference to TCPS2~~5.2.1: "Quebec Public Health Department" corrected for "Director of Professional Services"
~~MUHC REB SOP-403.001_2~~	~~2018-07-10~~	~~Addition of new point 5.1.14 and section 5.2.3~~
~~MUHC REB SOP-403.001_3~~	~~2018-07-30~~	~~5.1.14 Minor wording editing~~

8 APPENDIX