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| **Title** | Initial Review - Criteria for REB Approval |
| **MUHC SOP Code** | MUHC REB-SOP-403.001_3 |
| **N2/CAREB SOP CODE** | SOP-403.002 |
| **Effective Date** | 2017-02-24 |

**Site Approvals**

| Status | Title | Date |
|---|---|---|
| ***Authored*** | CAE, Manager | 2017-02-20 |
| ***Approved*** | Director, MUHC Centre for Applied Ethics | 2017-02-20 |
| ***Acknowledge of receipt*** | MUHC Board of Directors | |

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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 REB Office Personnel 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. PROCEDURE

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 may consult the Researcher for additional information as necessary.

Following initial review of the research, the REB will render a decision as per SOP 401.002

### 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. The researcher must demonstrate having the qualifications to conduct research as demonstrated by either:

a. Valid research privileges to conduct research with human participants at the MUHC (RI SOP 500_01), or

b. 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;

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

5.1.3. There 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;

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

5.1.5. The methodology is scientifically sound and capable of answering the research question;

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 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 the importance of the knowledge that will be generated;

5.1.8. The selection of participants is equitable. 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;

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 participants;

5.1.11. The amount and method of compensation offered to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding compensation for time and inconvenience including method, amounts and schedule is provided to participants when applicable;

5.1.12. 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;

5.1.13. The informed consent form will accurately explain the research and contain the required elements of consent, as per SOP 404.002;

5.1.14. 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.

5.1.15. Informed consent will be appropriately documented in accordance with the relevant regulations (s. 24 C.c.Q.);

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

5.1.17. There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.18. There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate;

5.1.19. 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 research results, unless justification for a longer delay is provided at the satisfaction of the REB;

5.1.20. 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 researcher shall provide the REB with the registration number upon registration.

### 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 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:

o The REB review by the MUHC/Neuro did not include any evaluation of the risks associated with the use of these third party services;

o Use of these services is not mandatory in order to participate or to receive compensation;

o Their personal info will not be shared with the sponsor.

### 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;

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

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

## 6. REFERENCES

See References.

## 7. REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|---|---|---|
| MUHC-REB-SOP-403.001 | 2017-02-24 | Original Version |
| MUHC REB-SOP-403.001_1 | 2017-07-07 | 5.1.4. Minor wording editing<br>5.1.18. Addition of reference to TCPS2 |
| 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 |