REB-SOP 106.001
Research Ethics Board
Standard Operating Procedure

Title Signatory Authority
MUHC SOP Code MUHC REB-SOP-106.002001
N2/CAREB SOP CODE SOP-106.002
Effective Date 2017-2020-03-31

Approvals

<table>
<thead>
<tr>
<th>Status</th>
<th>Name and Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authored Author of Harmonized Template</td>
<td>CAE, Manager SOPs, Institutional REBs</td>
<td>2017-03-31 2019-04-01</td>
</tr>
<tr>
<td>Approved</td>
<td>Director, MUHC Centre for Applied Ethics MUHC REB Full Board Meeting</td>
<td>2017-03-31 2020-02-13</td>
</tr>
<tr>
<td>Acknowledge of receipt</td>
<td>MUHC Board of Directors</td>
<td>2020-03-20</td>
</tr>
</tbody>
</table>

Table of Content

1 Purpose .................................................................................................................................................. 1
2 Scope ................................................................................................................................................... 2
3 Responsibilities ....................................................................................................................................... 2
4 Definitions ............................................................................................................................................... 2
5 Procedures ............................................................................................................................................. 2
   5.1 Delegation of Signing Authority ..................................................................................................... 2
   5.2 REB Reviews, Decisions and Other Correspondence with the Researcher Error! Bookmark not defined.
   5.3 Correspondence with External Agencies .......................................................................................... 3
6 References ............................................................................................................................................... 4
7 Revision History ...................................................................................................................................... 4
8 Appendices ............................................................................................................................................. 4
1 PURPOSE

This standard operating procedure (SOP) specifies who has the authority to sign documents on behalf of the MUHC—Research Ethics Board (REB) and describes the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2 SCOPE

This SOP pertains to the delegation of signatory authority for REBs that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All REB members and Personnel of the Centre for Applied Ethics (CAE) designated REB staff are responsible for ensuring that the requirements of this SOP are met.

The REB Chair and Co-Chair, or designee, is responsible for signing documents related to REB review and approval of research. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair and Co-Chair.

1. DEFINITIONS

REB Chair and Co-Chair: There is a single MUHC REB with 5 specialised panels. Each Panel operates with Co-Chairs. Hence, while there is a single Chair of the MUHC REB, decision-making regarding review and approval of research is equally shared by all Co-Chairs.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

REBs are accountable for their activities and decisions, and appropriate controls must be applied to ensure that documentation related to REB review and approval of research are signed by a person or persons having the appropriate authority to do so.

5.1 Delegation of Signing Authority

5.1.1 It is understood that each MUHC The REB Co-Chair is designated signatory authority or Vice-Chair, as a function part of their position duties, have the authority to act as signing officers for the duration of their designation as Co-Chair term.

5.1.2 The REB Chair or CoChair may delegate signing authority for documents related to REB review and approval;

5.1.3 The REB Chair or CoChair may only delegate signing authority to REB members, CAE or REB support staff, with the skill and knowledge necessary for the effective exercise of the authority;

5.1.4 The REB Chair or CoChair should clearly define the parameters of the delegated authority, including the scope of the signing authority and the duration of time said the delegation of signing authority is delegated;

5.1.5 Delegation of signing authority to other REB members of the REB, to CAE or REB support staff, must be documented in a delegation log and kept on file. See Appendix A

5.1.6 The REB Chair or CoChair may not delegate his/her signing authority to ad hoc advisors or to independent contractors who are not member of the MUHC REB;

5.2 REB Reviews, Decisions and Other Correspondence with the Researcher

5.2.1 For each submission reviewed at a Full Board meeting, the responsible CAE or REB support staff documents REB Support Staff records the decision made by the Full Board;

5.2.2 Communication of the REB decision made either at a Full Board meeting or following at a delegated review, must be reviewed and authorized by the REB CoChair of the reviewing panel or designee, or ViceChair or as otherwise delegated by the REB Chair, CoChair or designee, ViceChair;

5.2.3 For each submission that undergoes delegated review, the reviewer’s decision is documented;

5.2.4 Once a final decision is documented by the REB Chair, Co or ViceChair or designee, the responsible CAE or REB support staff may issue the decision or letter;

5.2.5 All activities are documented in the research file;

5.2.6 Any letters, memos, or emails between the REB and Researchers that provide information concerning the review of research (e.g. requests for consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued as per delegated signing authority;

5.2.7 All correspondence, reviews, actions, decisions and signatures are filed within the research file;

5.2.8 All correspondence is retained in the research file.

5.3 Correspondence with External Agencies

Prepared with the collaboration of N2 CAREB, CATALIS, CHUM, CHU Sainte-Justine and MUHC
5.3.1 The Manager of the CAE or the REB Chair, co-Chair or designee signs all correspondence with agencies of the federal government (Health Canada, OHRP, FDA) and with all funding agencies and/or sponsors in accordance with their signatory authority.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

<table>
<thead>
<tr>
<th>SOP Code</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP-REB-SOP 106-EN01.001</td>
<td>2016-02-22 2020-03-20</td>
<td>Original version</td>
</tr>
<tr>
<td>SOP-REB-106-EN01</td>
<td>2017-01-20</td>
<td>5.1. &amp; 5.2. Included REB support staff to cover Neuro REB coordinator. 8. Delegation log updated.</td>
</tr>
<tr>
<td>MUHC REB-SOP-106.002</td>
<td>2017-03-31</td>
<td>Harmonized Code and Template</td>
</tr>
</tbody>
</table>

8 APPENDICES