

Title	Signatory Authority
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Approvals

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Approved	Director, MUHC Centre for Applied Ethics <u>MUHC REB Full Board Meeting</u>	2017-03-31 <u>2020-02-13</u>
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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~~ 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.¹ 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;

¹ Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 8.14.

- 5.1.2 The REB Chair or ~~Co~~Vice-Chair may delegate signing authority for documents related to REB review and approval;
- 5.1.3 The REB Chair or ~~Co~~Vice-Chair may only delegate signing authority to REB members, ~~CAE~~ or REB ~~support staff~~Support Staff with the skill and knowledge necessary for the effective exercise of the authority;

- 5.1.4 The REB Chair or ~~Co~~Vice-Chair should clearly define the parameters of the delegated authority, including the scope of the signing authority and ~~length~~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 or~~ Support Staff must be documented ~~in a delegation log~~ and kept on file. ~~See Appendix A~~

- ~~5.1.6 The REB Chair or Co-Chair 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 ~~Co-Chair of the reviewing panel or~~ designee or Vice-Chair or as otherwise delegated by the REB Chair, ~~Co-Chair~~ or ~~designee~~Vice-Chair;

- 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 Vice-Chair or designee~~, the responsible ~~CAE or REB support staff~~ 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

- 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

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

8 APPENDICES