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Standard Operating Procedure: Signatory Authority

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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 in compliance with applicable regulations and guidelines



3. RESPONSIBILITIES

All REB members and Personnel of the Centre for Applied Ethics (CAE) 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.

4. 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.

See Glossary of Terms.

5. PROCEDURE

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 REB Co-Chair is designated signatory authority as a function of their position for the duration of their designation as Co-Chair.
- 5.1.2. The REB Chair or Co-Chair may delegate signing authority for documents related to REB review and approval;
- 5.1.3. The REB Chair or Co-Chair 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 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;
- 5.1.5. The REB Chair or Co-Chair should clearly define the parameters of the delegated authority including the scope of signing authority and length of time said authority is delegated;
- 5.1.6. Delegation of signing authority to other members of the REB, to CAE or REB support staff must be documented in a delegation log and kept on file. See Appendix A

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



- 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-Chair 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;

5.3. 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 References.

7. REVISION HISTORY

Version		Insert Section Number	Summary of Revisions Made:
Number	Date		
SOP-REB-106-EN01	2016-02-22		First issue
SOP-REB-106-EN01	2017-01-20	5.1, 5.2	Included REB support staff to cover Neuro REB coordinator. Delegation log.

8. APPROVAL

	Date
Authored: CAE, Manager	2016-02-22
Approved: Director, MUHC Centre for Applied Ethics	2016-02-22
Submitted MUHC Board of Directors	forthcoming

9. APPENDICES

Delegation log on file with CAE.