



Research Ethics Board Standard Operating Procedures

Authorized Signing Authority

SOP NO:	REB-SOP-I-03.003	Revision Date:	November 1, 2016
CATEGORY:	Research Ethics Board	Reviewed/Effective Date:	November 1, 2016
SUB-CATEGORY:	Section I: General	Original Issue Date:	December 21, 2012
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research; REB Chair		

The WCH Research Ethics Office (REO) webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to define the individual who has authority to sign documents on behalf of the Women's College Hospital (WCH) Research Ethics Board (REB), and to describe the responsibilities of such individuals and the circumstances under which signing authority may be delegated.

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

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB members, Manager and REO Staff

The REB Chair is responsible for signing documents related to the REB review and approval of research. If the task of signing is delegated, the responsibility for oversight remains with the REB Chair.

The Medical Advisory Committee (MAC) is responsible for delegating signing authority on behalf of WCH.

4.0 PROCEDURES:

4.1 Delegation of Signing Authority

- 4.1.1 WCH REB Chair may delegate his/her signing authority for documents related to REB review and approval at WCH.
- 4.1.2 If the task is delegated, the responsibility for oversight remains with the WCH REB Chair.



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- 4.1.3 The WCH REB Chair may only delegate signing authority to REB members or REO staff with the skill and knowledge necessary to effectively exercise the authority.
- 4.1.4 The WCH REB Chair may not delegate his/her signing authority to external reviewers or independent contractors/consultants.
- 4.1.5 The WCH REB Chair should clearly define the parameters of the delegated authority using the WCH Delegated Signing Authority Form (see Appendix 1).
- 4.1.6 The WCH REB Chair may delegate signing authority indefinitely, or for defined periods of time (e.g. for absences).
- 4.1.7 Delegation of signing authority must be made in writing and kept on file in the REO.

4.2 REB Reviews, Approvals and Other Correspondence with Investigators

- 4.2.1 The results of reviews and decisions made by the WCH REB, either by the full board or delegated review, including investigation of ongoing research, that grant or may appear to grant investigators with initial or continuing approval of research involving human subjects, or suspends or terminates such research, must be signed by the WCH REB Chair, or as otherwise delegated in writing by the WCH REB Chair.
- 4.2.2 Any letters, memos, or emails between the WCH REB and/or REO and investigators that provide information concerning the review of research (e.g. requests for consent form changes, requests for additional information, renewal reminder notices) and that do not grant or appear to grant approval of the research may be signed by the appropriate REO staff member.
- 4.2.3 Individuals sending letters, memos or emails to investigators must sign their own name using either manual or electronic instruments.

4.3 Correspondence with External Agencies

- 4.3.1 The WCH REB Chair, Manager or appropriate authorized WCH personnel signs all correspondence to federal government agencies (Health Canada, OHRP, FDA) and funding agencies or sponsors as applicable.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2)
2. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada
3. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115
4. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108



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- 5. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure–
Authorized Signatory/Signing Authority (REB-SOP-IV-03.003)

APPENDIX 1.0 WCH DELEGATED SIGNING AUTHORITY FORM

Delegation of Signing Authority Form

TO WHOM IT MAY CONCERN, I HEREBY DELEGATE SIGNING AUTHORITY FOR THE APPROVAL OF RESEARCH ETHICS BOARD RELATED TO THE FOLLOWING RESEARCH ETHICS BOARD SUBMISSION(S):

_____ (print name) - Delegatee

_____ (title)

Authorization

REB CHAIR (Delegator):

To

Name (Delegatee)

√	Types of Reviews	Initial all that are applicable
	All Annual Renewals	
	All Amendments	
	All Administrative Changes	
	All Minor Amendments	
	Expedited Initial Reviews	
	Protocol Deviations	
	SAE Reports	
	Full Board Initial Reviews	
	Amendments Requiring Full Board Review	
	Annual Renewals Requiring Full Board Review	
	Safety Updates Requiring Full Board Review	



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	PI Responses to Expedited Reviews	
	PI Responses to Full Board Reviews	
	Other _____	

*Other restrictions: _____

In effect from _____ **until:** Revoked
 (start date) or
 Specify end date _____

Delegate Statement

I hereby accept responsibility as delegated signing authority for the above referenced research ethics board approval(s). I have an appropriate level of knowledge of the applicable Women's College Hospital policies and procedures. Where applicable I have an appropriate level of knowledge of any externally imposed conditions, regulations and guidelines:

I hereby accept all responsibilities mentioned above and in the Delegation of Signing Authority document.

 SIGNATURE OF DELEGATOR

 DATE

 SIGNATURE OF DELEGATEE

 DATE

Form should be kept on file and be readily available as required for Internal or External Audit