SOP Title	**Signing Authority**
Number.Version	N105.003
Effective Date	05/11/2018

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		2019-02-26
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		2019-03-06

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to specify who has the authority to sign documents on behalf of the Non-Medical Research Ethics Board (NMREB), and to describe the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2. GENERAL POLICY STATEMENT

Research Ethics Boards (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.

3. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice-Chair(s), NMREB members and OHRE staff.

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

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. **Delegation of Signing Authority**

5.1.1. The NMREB Chair may delegate signing authority for documents related to NMREB review and approval;

5.1.2. The NMREB Chair may only delegate signing authority to Vice-Chair(s) and OHRE staff with the skill and knowledge necessary to effectively exercise the authority;

5.1.3. The NMREB Chair may not delegate his/her signing authority to consultants;

5.1.4. The NMREB Chair may delegate signing authority indefinitely, or for defined periods of time (e.g., for absences);

5.1.5. Delegation of signing authority must be made in writing and kept on file.

5.2. **REB Reviews, Approvals and Other Correspondence with the Investigator**

5.2.1. The results of reviews and decisions made by the NMREB, either 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 participants, or suspends or terminates such research, must be signed by the NMREB Chair, Vice-Chair(s), or as otherwise designated in writing by the NMREB Chair;

5.2.2. Any letters, memos, or e-mails between the NMREB and/or OHRE and investigators that provide written 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 and sent by the appropriate OHRE staff as delegated in writing by the NMREB chair;

5.2.3. Individuals must sign their own name. The individual's title must be documented.

5.3. **Correspondence with External Agencies**

5.3.1. Unless authorizing signature by the VP Research is required, the NMREB Chair, Vice-Chair(s) or designee signs all correspondence to federal government agencies (Health Canada, OHRP, FDA) and funding agencies or sponsors as applicable.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Article 6.17;

6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;

6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;

6.4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.108, 56.115.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N105.001	Original	12/07/2015
N105.002	Change ORE to OHRE	06/09/2016
N105.003	Update to NMREB Chair & Administrative Corrections	05/11/2018