SOP Title	SOP Maintenance
Number.Version	N101.003
Effective Date	08/10/2018

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 describe the processes for establishing and maintaining written SOP's. The purpose of having written SOPs is to: promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

2. GENERAL POLICY STATEMENT

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to assure that the rights and welfare of the human participants of such research are overseen and protected in a uniform manner.

3. RESPONSIBILITY

This SOP applies to all Non-Medical Research Ethics Board (NMREB) members including the NMREB Chair, Vice-Chairs and to all Office of Human Research Ethics (OHRE) personnel.

The Director of Research Ethics is responsible for coordinating the review and modification of the SOPs.

The Director of Research Ethics and NMREB Chair and/or Vice-Chair is responsible for granting final SOP approval.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Development, Review, Revision and Approval of Policies and Procedures

5.1.1 The Director of Research Ethics or designee will review the SOPs at least biannually. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs.

5.1.2 SOPs may be revised for reasons including but not limited to: changes to regulations or guidelines, new policies, or changes to REB or administrative practices;

5.1.3 The Director of Research Ethics, the research Ethics Officer (EO) or qualified NMREB office personnel will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of "DRAFT version date" and removal of the previous "Final Version Date';

5.1.4 The revised SOP(s) will be circulated to the OHRE personnel and NMREB Chair and/or Vice-Chair(s), as well as NMREB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

5.1.5 Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the "Final Version Date". The history of revisions will be recorded in the tracked copies of each SOP;

5.1.6 Signatures of the Director of Research Ethics and the NMREB Chair and/or Vice Chair will denote SOP approval. A new final version of the SOP supersedes any previous versions;

5.1.7 SOPs will be archived for 10 years.

5.2 **Distribution and Communication**

5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the "Responsibilities" section of each SOP;

5.2.2 The SOPs will be available to the research sites served by the NMREB;

5.2.3 The EO or designee will train all members of the NMREB and the OHRE office on any new or revised policy and/or relevant procedures, as applicable;

5.2.4 Each new NMREB member must review all applicable policies and procedures prior to undertaking his/her responsibilities as an NMREB members;

5.2.5 Each new OHRE staff member must review all applicable policies and procedures prior to undertaking his/her responsibilities with the OHRE;

5.2.6 The OHRE shall maintain all documentation of SOP training.

5.3 **Forms, Memos and Guidance Documents**

5.3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

5.3.3 Memos and guidance documents will be made available to the investigator sites;

5.3.4 The Director of Research Ethics or designee will evaluate the need for new or revised forms, memos or guidance documents.

6. REFERENCES

6.1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans*. December 2014 (TCPS2);
6.2. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines;
6.3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5
6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115;

6.5. US Department of Health and Human Services (HHS) CFR Title 45 Parts 46.103, 46.108, 46.115.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N101.001	Original	12/07/2015
N101.002	Change from ORE to OHRE	06/09/2016
N101.003	Update to NMREB Chair & Administrative Corrections	08/10/2018