TITLE:	Standard Operating Procedure (SOP) Development and Maintenance	**NUMBER:**	NSHA REB-SOP-1-002
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB members and REB Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the processes necessary to establish and maintain written SOPs. The purpose of having written SOPs is to facilitate compliance with the principles, guidelines and regulations applicable to the ethical review and oversight of research involving human participants or human materials.

This SOP demonstrates the Nova Scotia Health Authority Research Ethics Board's (NSHA REB) commitment 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. POLICY:

Regulations stipulate that Research Ethics Boards (REBs) must have, and must comply with, written policies and procedures regarding their operations and requirements. Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants or human materials. SOPs describe the processes that must be followed and documented to ensure REB functions are conducted in a uniform manner, and that the rights and welfare of the human participants of such research are overseen and protected.

3. DEFINITIONS:

Standard Operating Procedure (SOP): document used to standardize the format of all standard operating procedures. Written statements that typically describe a series of steps required to complete various tasks.

4. RESPONSIBILITIES:

The REB Manager or designee is responsible for coordinating the development, review and revision of the SOPs. Additions, deletions, and modifications must be approved by the NSHA REB Executive Committee. The Executive Chair is responsible for granting

final SOP approval.

5 PROCEDURES:

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

5.1.1 SOP's will be reviewed by the qualified REB Office Personnel at intervals (at least annually) established by the Executive Chair, in consultation with members of the Executive Committee;

5.1.2 Changes to applicable regulations, federal or international ethical guidelines, or standard research practice, policies and procedures of the Nova Scotia District Health Authority may warrant revisions to a previously approved SOP or the creation of new SOPs;

5.1.3 The qualified REB 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 REB Office Personnel, REB Executive Chair and members of the Executive Committee, as well as REB 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 'SOP History' section of each SOP;

5.1.6 Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions;

5.1.7 Each SOP will be identified by a number. The number format follows the sequence: The letters NSHA REB, followed by the letters SOP, followed by the section number, followed by the SOP number and version number (i.e. NSHA REB-SOP-I-002);

5.1.8 Standard Operating Procedure(s) and Policies will be archived as per Health Canada requirements.

5.2 Policy Dissemination and Training

5.2.1 The Executive Chair or designee is responsible for ensuring new or revised SOPs, policies and associated guidance documents will be

communicated and disseminated to pertinent individuals and/or departments;

5.2.2 The SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;

5.2.3 Qualified REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

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

5.2.5 All new REB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the REB office;

5.2.6 The Manager shall maintain documentation of SOP training in the member/employee file.

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 Researchers and researcher sites as applicable;

5.3.4 The qualified REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.

6 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS 2 2014)
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) 3.3;
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108(a), 56.115;

5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103(4), 46.108.

7 RELATED DOCUMENTS: n/a

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
September 01, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonized with CAREB/N2 SOP's