TITLE:	Standard Operating Procedure (SOP) Signing Authority	**NUMBER:**	NSHA REB-SOP-1-003
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB Office Personnel and NSHA REB members		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to specify who has the authority to sign documents on behalf of the Nova Scotia Health Authority Research Ethics Board (NSHA REB), and to describe the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2. POLICY:

The NSHA REB is accountable for their activities and decisions, thus 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.

The NSHA REB Executive Chair or designee (i.e. Co-Chair) is responsible for signing documents related to the review and approval of research projects which have been reviewed and approved pursuant to NSHA REB policies and procedures and upon decision of the NSHA REB. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the Executive Chair.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Delegation of Signing Authority

4.1.1. The Executive Chair and the Co-Chairs are authorized to sign documents pertaining to the approval and ongoing review of specific research studies. In order to avoid unnecessary delays, it is permissible for the NSHA REB chair and Co-Chairs to sign on behalf of one another.

4.1.2. The REB Executive Chair may only delegate signing authority to REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority;

4.1.3. The REB Executive Chair may not delegate his/her signing authority to ad hoc advisors or to independent contractors;

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

4.1.5. If a Co-Chair acts as a primary or secondary reviewer for a research study, he/she will have no signing authority as it pertains to any correspondence associated with that research study.

4.1.6. The REB Office Manager is authorized to sign documents related to administrative and managerial aspects of NSHA REB operations;

4.1.7. Delegation of signing authority must be documented and retained on file in the REB Office.

4.2. Correspondence with External Agencies

4.2.1. The REB Executive Chair or designee is responsible for signing all correspondence with agencies of the federal government (Health Canada, OHRP, and FDA) and with all funding agencies and/or sponsors.

5 REFERENCES

1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014) Article 6.17;
2) The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;
4) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.108, 56.115.

6 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.)
April 2014		Reflect the change from nine DHA's to one
September 29, 2017		Harmonized with CAREB/N2 SOP's