TITLE:	Standard Operating Procedure (SOP) Health Canada REB Attestation (REBA) Form	**NUMBER:**	NSHA REB-SOP-1-009
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB Executive Chair, Co-Chairs, and REB Office Personnel for the review and approval of Health Canada regulated human participant research.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to facilitate the regulatory requirement of a Research Ethics Board Attestation (REBA) for Health Canada regulated research.

2. POLICY:

The Nova Scotia Health Authority Research Ethics Board (NSHA REB) will not issue a signed REBA Form for Health Canada regulated research. The Guidance for Clinical Trial Sponsors states that the REBA Form, or similar documentation, meeting the requirements of Part C, Division 5 of the Food and Drug Regulations, is acceptable.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

The NSHA REB approval letter contains the following statements to satisfy the required elements of the attestation:

The Nova Scotia Health Authority Research Ethics Board operates in accordance with:

1. *Food and Drug Regulations, Division 5 "Drugs for Clinical Trials Involving Human Subjects"*
2. *Natural Health Products Regulations, Part 4 "Clinical Trials Involving Human Subjects"*
3. *ICH Good Clinical Practice: Consolidated Guideline (ICH-E6)*
4. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

5. REFERENCES

1) Division 5 of the Food and Drug Regulations;
2) Guidance for Clinical Trial Sponsors: Clinical Trial Applications, 2003/06/25;
3) Health Canada, Drugs and Health Products Frequently Asked Questions.

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.)
June 3, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonize with CAREB/N2 SOP's