SOP Title:	Health Canada REB Attestation Form (REBA)		
SOP #:	III.04.001	Original Issue Date:	February 23, 2015
Category:	REB Operations	Reviewed/Effective Date:	October 1, 2019
Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 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.

2.0 POLICY STATEMENT

The SickKids Research Ethics Board (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. The SickKids REB approval letter contains the following required elements for the attestation:

- The SickKids REB membership complies with Part C Division 5 of the Food and Drug Regulations requirements;
- The SickKids REB carries out its functions in a manner consistent with Good Clinical Practices; and
- The SickKids REB has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named in the letter.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

5.0 PROCEDURES

5.1 Approval Letter Preparation

5.1.1 REO Personnel prepares the REB approval letter using the approved template language.

5.1.2 The approval letter is signed by the REB Chair or delegate.

5.1.3 All REB approvals and discussions are documented in writing.

6.0 REFERENCES

See References