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