Health Canada REB Attestation (REBA) Form

Sunnybrook Health Sciences Centre		SOP No:	REB-SOP-III-04.004
Title	Health Canada REB Attestation Form	**Original Issue Date:**	August 27, 2009
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Issued By:	Human Research Protections Program (HRPP), Research Ethics Office		
Approved By:	Executive Director, Research Integrity & Clinical Research Operations; REB Chair		

The Sunnybrook REO web page version of this document is considered the most current.
Please ensure that you have reviewed all linked documents and other referenced material within this SOP.

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 Sunnybrook 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 Sunnybrook REB approval letter contains the following required elements for the attestation:

- The Sunnybrook REB membership complies with Part C Division 5 of the *Food and Drug Regulations* requirements;
- The Sunnybrook REB carries out its functions in a manner consistent with Good Clinical Practices; and
- The Sunnybrook 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

This SOP applies to the REB Chair, Vice-Chair, Executive Director and Research Ethics Office (REO) staff for the review and approval of Health Canada regulated human participant research.

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5.0 PROCEDURES

5.1 Approval Letter Preparation

5.1.1 The REO Coordinator 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

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.