WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Procedures

Health Canada Research Ethics Board Attestation (REBA)

SOP NO:	REB-SOP-III-04.003	**Revision Date:**	January 5, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	January 5, 2017
SUB-CATEGORY	Section III: REB Operations	**Original Issue Date:**	December 21, 2012
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1. POLICY STATEMENT:

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 at Women's College Hospital (WCH).

Health Canada requires sponsors to collect and retain contact information, the name of the Research Ethics Board (REB) Chair and a statement that the REB follows Division 5 of the Food and Drug Regulations. **Confirmation of compliance is required, however, use of the Health Canada's Research Ethics Board Attestation (REBA) Form is not**.

The WCH 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 WCH REB approval letter contains the following required elements for the attestation:

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

2. DEFINITION(S):

See Glossary of Terms

3. RESPONSIBILITY:

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

4. PROCEDURES:

4.1. Approval Letter Preparation

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4.1.1. The Research Ethics Coordinator prepares the REB approval letter using the approved template language
4.1.2. The approval letter is signed by the REB Chair or delegate;
4.1.3. All REB approvals and discussion are documented in writing.

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