

**Document Owner:** Manager, Office of Research**Original Approval Date:** 04 April 2021**Approved By:** Chair, Oak Valley Health REB**Latest Version:** 19 Aug 2021

## 1.0 PURPOSE

The purpose of this standard operating policy and 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 Oak Valley Health 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 Oak Valley Health REB approval letter contains the following required elements for the attestation:

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

### 3.1 Approval Letter Preparation

- 3.1.1 The REB Coordinator prepared the REB approval letter using the approved template language;
- 3.1.2 The approval letter is signed by the REB Chair or delegate;
- 3.1.3 The REB approvals and discussions are documented in writing or electronically.

## 4.0 REFERENCES

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