
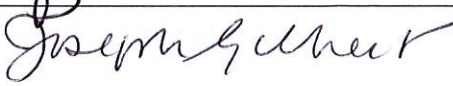


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| <b>SOP Title</b>      | Using the Ontario Cancer Research Ethics Board (OCREB) as the Board of Record |
| <b>Number.Version</b> | 102.002   |
| <b>Version Date</b>   | 05/10/2016  |

## Approvals

| <b>Name and Title of Signatories</b>                               | <b>Signature</b>   | <b>Date<br/>mm/dd/yyyy</b> |
|--|--|----------------------------|
| Erika Basile<br>Director, Research Ethics                          |   | 05/11/2016                 |
| Dr. Joseph Gilbert<br>Chair, Health Sciences Research Ethics Board |  | 05/11/2016                 |

### 1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the types of research being conducted at the University of Western Ontario (UWO) and its affiliated institutions that may use the Ontario Cancer Research Ethics Board (OCREB) as a delegated Research Ethics Board (REB) of Record.

### 2. GENERAL POLICY STATEMENT

All research that involves living human participants, human remains, cadavers, tissues, biological fluids, embryos or fetuses requires review and approval by a Health Sciences Research Ethics Board (HSREB) prior to commencement of intervention or interaction with human participants in research, including study recruitment. Through a formal relationship and board of record agreement, OCREB may be delegated as a research ethics board of record for UWO's REB for multi-centre clinical trials in oncology.

### 3. RESPONSIBILITY

This SOP applies to the HSREB Chair and Vice-Chair(s), Office of Human Research Ethics (OHRE) staff, Investigators and associated research staff for the purpose of understanding the type of human subject/materials research that may be submitted to OCREB for review and approval.

### 4. DEFINITIONS

See Glossary of Terms

### 5. SPECIFIC POLICIES AND PROCEDURES.

#### 5.1. Scope of OCREB Review

Details on the scope of OCREB review can be found in the OCREB policies and procedures.

#### 5.2. Determination of Whether Research Falls Within the Scope of OCREB Review

5.2.1. The opinion of OCREB should be sought whenever there is any doubt about the applicability of submitting a particular research project to OCREB prior to completing an application form.

5.2.2. The research ethics coordinator at OCREB will correspond with the investigator as needed to assist in the determination of whether their research falls within the scope of OCREB review.

5.2.3. When the determination of scope is unclear, the decision will be made by the Executive Director and/or Chair at OCREB.

**5.3. Notification of Board of Record Agreement and OCREB Approval**

5.3.1. Upon receipt of OCREB approval, the Investigator or designee will send an electronic copy of the Board of Record Agreement and Approval Letter to the HSREB on a study-by-study basis.

5.3.2. The HSREB logs the study and relevant approval information for tracking and reporting purposes. OCREB maintains responsibility for ethical oversight of the conduct of the study.

5.3.3. The Director functions as Institutional Representative for OCREB and is notified by OCREB of each approval.

5.3.4. The Director is the primary contact person for any changes related to the formal relationship with OCREB.

**6. REFERENCES**

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
- 6.2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
- 6.3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;
- 6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 50.3; 50.24; 56.108;
- 6.5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.102; 46.103;
- 6.6. FDA Information Sheets for IRBs and Investigators.

**7. SOP HISTORY**

| <b>SOP<br/>Number.Version</b> | <b>Key Changes</b>           | <b>Effective<br/>Date<br/>mm/dd/yyyy</b> |
|-------------------------------|------------------------------|--|
| 102.001                       | Original                     | 05/22/2014                               |
| 102.002                       | Minor Administrative Changes | 05/10/2016                               |
|                               |                              |  |