

<b>TITLE</b>	<b>108: Standard Operating Procedures Maintenance</b>
<b>SCOPE</b>	The Human Research Ethics Board operating under the direct authority of Trinity Western University
<b>RESPONSIBILITIES</b>	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
<b>APPROVAL AUTHORITY</b>	The Vice-Provost, Research & Graduate Studies
<b>EFFECTIVE DATE</b>	November 14, 2019
<b>Supersedes documents dated</b>	N/A

### **1.0 PURPOSE**

This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

### **2.0 DEFINITIONS**

See Glossary of Terms.

### **3.0 PROCEDURE**

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

#### **3.1 Development, Review, Revision and Approval of Policies & Procedures**

- 3.1.1 The qualified HREB Office Personnel will review the SOPs at least biannually. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;
- 3.1.2 SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to HREB or administrative practices;
- 3.1.3 The qualified HREB Office Personnel will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled

documents and new drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”;

3.1.4 The revised SOP(s) will be circulated to the HREB Office Personnel and HREB Chair or designee, as well as HREB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;

3.1.5 Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the “Final Version Date”. The history of revisions will be recorded in the ‘SOP History’ section of each SOP;

3.1.6 Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

### 3.2 Distribution and Communication

3.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the ‘Responsibilities’ section of each SOP;

3.2.2 The SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;

3.2.3 Qualified HREB Office Personnel will train members of the HREB and the HREB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

3.2.4 Each new HREB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an HREB member;

3.2.5 Each new HREB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the HREB office;

3.2.6 Evidence of training must be documented;

3.2.7 The HREB office shall maintain all documentation of SOP training.

### 3.3 Forms, Memos and Guidance Documents

3.3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

3.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

3.3.3 Memos and guidance documents will be made available to the Researchers and researcher sites as applicable;

3.3.4 The qualified HREB Office Personnel and/or HREB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.

**4.0 REFERENCES**

See References.

**5.0 REVISION HISTORY**

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
SOP 108	November 14, 2019	Original version