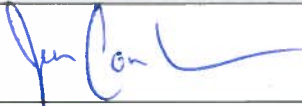




<b>Section 100:</b>	<b>General Administration</b>
<b>Title:</b>	<b>Standard Operating Procedures Maintenance</b>
<b>SOP Code:</b>	<b>108.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

## Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This 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 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

## 3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

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.

### 5.1 Development, Review, Revision and Approval of Policies & Procedures

- 5.1.1 The Ethics Compliance Advisor will review the SOPs annually. Applicable SOP(s) will be reviewed sooner if changes to regulations, guidelines or standard practice warrant revisions or the creation of new SOP(s). SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to HSREB or administrative practices;
- 5.1.2 The Ethics Compliance Advisor will make the necessary modifications to existing SOP(s), 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";
- 5.1.3 The revised SOP(s) will be circulated to the HSREB Office Personnel and HSREB Chair or designee, as well as HSREB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;
- 5.1.4 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;
- 5.1.5 Signatures on the SOP as determined by Queen's University policy, will denote SOP approval. A new final version of the SOP supersedes any previous versions.

### 5.2 Distribution and Communication

- 5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all applicable individuals;
- 5.2.2 The SOPs will be available to Researchers and Researcher sites, Sponsors and Regulatory Authorities as required;
- 5.2.3 The Ethics Compliance Advisor will inform members of the HSREB and the HSREB Office Personnel of any new or revised policy and or relevant procedure, as applicable;

- 5.2.4 Each new HSREB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an HSREB member;
- 5.2.5 Each new HSREB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the HSREB office;
- 5.2.6 Evidence of training must be documented;
- 5.2.7 The Office of Research Ethics shall maintain all documentation of SOP training.

**5.3 Forms, Memos and Guidance Documents**

- 5.3.1 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;
- 5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;
- 5.3.3 Memos and guidance documents will be made available to the Researchers and Researcher sites as applicable;
- 5.3.4 The Ethics Compliance Advisor will evaluate the need for new or revised forms, memos or guidance documents.

**6.0 REFERENCES**

See References.

**7.0 APPENDICES**

- 1. SOP Template

**8.0 REVISION HISTORY**

SOP Title	Version	Updates
Standard Operating Procedures Maintenance	v.108.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.



<b>Section 500:</b>	<b>SOP Section</b>
<b>Title:</b>	<b>SOP Title</b>
<b>SOP Code:</b>	<b>SOP Code</b>
<b>Effective Date:</b>	<b>YYYYMMDD</b>

Site Approvals

<b>Signature of Responsible Individual:</b>		
Ethics Compliance Advisor		Date
	Name: Jennifer Couture	
<b>Approval Authority:</b>		
Chair, HSREB		Date
	Name: Dr. Albert Clark	
<b>Approval Authority:</b>		
Director, Research Ethics Compliance		Date
	Name: Dr. Andrew Winterborn	

**1.0 PURPOSE**

The purpose of this standard operating procedure (SOP) is to...

**2.0 SCOPE**

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

**3.0 RESPONSIBILITIES**

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

**4.0 DEFINITIONS**

See Glossary of Terms.

**5.0 PROCEDURES**

TEXT

**5.1 Title**  
5.1.1 Text

**5.2 TITLE**  
5.2.1 Text

**5.3 Title**  
5.3.1 Text

**5.4 Title**  
5.4.1 Text

**5.5 Title**  
5.5.1 Text

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICIES**

None.

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
SOP Title	v.XXX.XXX YYYYMMDD	Original