
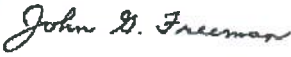



Section 100:	General Administration
Title:	Standard Operating Procedures Maintenance
SOP Code:	106.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	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

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen's University. The scope

of GREB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants."

3.0 RESPONSIBILITIES

All GREB members and GREB 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 and Procedures

- 5.1.1 The Ethics Compliance Advisor will review the SOPs annually. Applicable SOP(s) will be reviewed more frequently 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 GREB or administrative practices;
- 5.1.2 The Ethics Compliance Advisor will make the necessary modifications to existing SOP(s) or draft new SOP(s). SOPs are controlled documents. 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 GREB office personnel and GREB Chair or designee, as well as GREB 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, researcher sites, sponsors, and regulatory authorities as required;
- 5.2.3 The Ethics Compliance Advisor will inform GREB members and GREB office personnel of any new or revised policy and/or relevant procedure, as applicable;
- 5.2.4 Each new GREB member is expected to review the applicable policies and procedures prior to undertaking responsibilities as a GREB member;
- 5.2.5 Each new GREB office personnel must review the applicable policies and procedures prior to undertaking responsibilities with the GREB office.

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 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 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.106.001 2016FEB08	Original: This SOP was developed based on the CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to reflect institutional policies.