

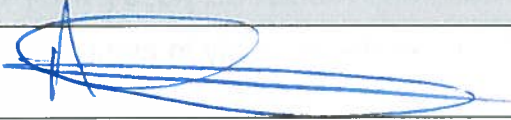


Section 900:	Quality Management
Title:	External Audits or Inspections
SOP Code:	901.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures to be followed before, during, and following an external inspection or audit.

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, GREB office personnel, and researchers are responsible for ensuring that the requirements of this SOP are met

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The U.S. Department of Health and Human Services (HHS), Office for Human Research Protection (OHRP), has the authority to audit Canadian REBs that oversee studies that are supported by the US federal government.

Sponsors, funding entities, or others authorized by regulations or agreements with the organizations may have the authority to audit or inspect research-related documents and procedures.

These audits or inspections may involve GREB; therefore, GREB must have policies in place for dealing with external audits or inspections. Researchers are responsible for notifying GREB of any planned audits or inspections of research projects overseen by GREB.

5.1 Preparing for an Inspection or Audit

- 5.1.1 The Ethics Compliance Advisor or designee will confirm with the Sponsor and/or the researchers (or inspector/auditor, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit, and the inspection/audit plan and procedures;

- 5.1.2 The Ethics Compliance Advisor or designee will notify GREB members and GREB office personnel of the inspection/audit;
- 5.1.3 The Ethics Compliance Advisor or designee will review the inspection/audit procedures with GREB members and GREB office personnel and conduct a thorough review of the required documentation;
- 5.1.4 The Ethics Compliance Advisor or designee will arrange for access to the appropriate documents for the inspector/auditor;
- 5.1.5 The Ethics Compliance Advisor or designee will confirm that GREB members and GREB office personnel are available for interviews or to assist the inspector/auditor;
- 5.1.6 The Ethics Compliance Advisor or designee will arrange for a suitable work area (e.g., private and with sufficient space, with access to a computer and in close proximity to a photocopier and telephone) for the inspector/auditor.

5.2 Participating in an Inspection or Audit

- 5.2.1 The Ethics Compliance Advisor or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific GREB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;
- 5.2.2 The Ethics Compliance Advisor or designee will record the name, contact information, and title of the inspector/auditor and retain any written notices of inspection/audit for the GREB files;
- 5.2.3 The Ethics Compliance Advisor or designee will provide a brief orientation to the inspector/auditor of GREB procedures;
- 5.2.4 The Ethics Compliance Advisor or designee will provide access to the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;

- 5.2.5 The Ethics Compliance Advisor or designee will accompany the inspector/auditor at all times while in confidential areas of the GREB office and/or Queen's University;
- 5.2.6 The Ethics Compliance Advisor or designee will ensure that the inspector/auditor's questions are answered by the most appropriate personnel. The GREB Chair or designee, GREB office personnel, and GREB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;
- 5.2.7 The Ethics Compliance Advisor or designee will request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the GREB Chair or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;
- 5.2.8 The Ethics Compliance Advisor or designee will ensure that the required personnel are present at the exit interview and that observations are understood before the inspector/auditors leave the facility;
- 5.2.9 The Ethics Compliance Advisor or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

5.3 Follow-up after an Inspection or Audit

- 5.3.1 The Ethics Compliance Advisor or designee will request a copy of the report from researchers if applicable;
- 5.3.2 The Ethics Compliance Advisor or designee and any other designated individuals will review any findings relevant to the GREB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The

response to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the researchers);

5.3.3 The Ethics Compliance Advisor or designee and any other designated individuals will institute any correction actions as applicable and revise the GREB SOPs as needed;

5.3.4 The Ethics Compliance Advisor or designee will file the original inspection/audit and response documents in the Office of Research Ethics.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
External Audits or Inspections	v.901.001 2016MAR30	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.

