




<b>Section 900:</b>	<b>Quality Management</b>
<b>Title:</b>	<b>Quality Assurance Inspections</b>
<b>SOP Code:</b>	<b>902.001</b>
<b>Effective Date:</b>	<b>2016MARCH30</b>

## Site Approvals

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

## 1.0 PURPOSE

This SOP describes processes for monitoring, evaluating, and improving the effectiveness of the human participant research protection and review process.

## 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**

Quality Assurance (QA), and Quality Control (QC) activities and Quality Management programs, such as inspections of GREB and of researchers, allow for a continuous evaluation and subsequent assurance of the human participant research protection and review process.

Findings from these activities and programs are measured against established policies and procedures and all applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

#### **5.1 GREB Quality Assurance Inspections (Internal)**

5.1.1 The Ethics Compliance Advisor will develop a schedule for routine QA Inspections or initiate inspections in response to complaints or other concerns;

5.1.2 QA Inspections may include GREB and the GREB office;

5.1.3 When the Ethics Compliance Advisor conducts a QA Inspection of GREB and the GREB office, the inspection may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,

- A review of research files, GREB membership rosters, GREB attendance records, and GREB Meeting agendas and minutes,
- A review of workload, performance metrics, and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with GREB members, GREB office personnel, researchers, sponsors, and regulators,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether or not any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any feedback from sponsors, funders, research participants, and regulators relevant to the protection of the rights, safety, and well-being of research participants,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from Queen's University's policies, and whether or not the deviations require remediation,
- An assessment of compliance with all applicable requirements;

5.1.4 The Ethics Compliance Advisor compares the findings against established policies, SOPs, and applicable ethical, legal, and regulatory requirements;

- 5.1.5 The Ethics Compliance Advisor prepares a written summary of the inspection, including areas requiring improvement;
- 5.1.6 The Ethics Compliance Advisor reports the findings to the GREB Chair or designee, GREB members, and appropriate Queen's University officials, as required;
- 5.1.7 The Ethics Compliance Advisor works with the GREB Chair or designee to implement improvements (e.g., new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

## **5.2 Researcher Quality Assurance Inspections**

- 5.2.1 The Ethics Compliance Advisor will develop a schedule for routine QA Inspections and implement inspections in response to researcher requests;
- 5.2.2 The Ethics Compliance Advisor will work with GREB and the appropriate Queen's University officials where the research is being conducted to determine if and when an inspection of a researcher's research is warranted;
- 5.2.3 GREB may direct the Ethics Compliance Advisor to conduct inspections;
- 5.2.4 The Ethics Compliance Advisor or designee may request copies of the sponsor's monitoring reports for a designated research project or the completion of a questionnaire from GREB;
- 5.2.5 The criteria for selecting researchers or research projects for inspection may include:
  - The results of a previous external audit or inspection,
  - The results of a sponsor audit,
  - Researcher-initiated studies (i.e., where the researcher is also the sponsor),
  - Studies that involve a potentially high risk to participants,

- Studies that involve vulnerable populations,
- Studies in which researchers are enrolling large numbers of participants,
- Suspected non-compliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported non-compliance,
- Participant complaints,
- Research staff complaints,
- Any other situation that GREB deems appropriate;

5.2.6 The Ethics Compliance Advisor or designee will notify the researchers of the inspection and a mutually acceptable time will be scheduled. It may be necessary to schedule an inspection without first obtaining the formal consent of researchers (e.g., participant safety or suspected non-compliance);

5.2.7 The Ethics Compliance Advisor or designee will conduct the inspection using appropriate evaluation tools;

5.2.8 When the Ethics Compliance Advisor conducts an inspection of researchers, the inspection may include some or all of the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of all regulatory binders including the GREB Ethical Clearance documentation, all versions of GREB ethically-cleared Consent Forms, signed Consent Forms, research protocols and amendment documentation, documentation for renewal of ethics clearance, correspondence between the researchers and sponsor (if applicable), etc.,
- Interviews with the research staff and/or researchers,

- A review of computer hardware and/or software associated with the research, and
  - A review of other documentation, as relevant and available;
- 5.2.9 GREB or the Ethics Compliance Advisor may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;
- 5.2.10 At the conclusion of the evaluation, the Ethics Compliance Advisor or designee will discuss the findings with the researchers;
- 5.2.11 The Ethics Compliance Advisor or designee will draft a report or provide a summary of the inspection including: positive findings, areas for improvement, and recommendations for corrective action, for submission to the GREB Chair or designee for review;
- 5.2.12 Researchers will be given an opportunity to respond to the report with clarifications and/or corrective action plans within a time specified by GREB;
- 5.2.13 The Ethics Compliance Advisor or designee will send a copy of the final report to the researchers and GREB. When applicable, the GREB Chair or designee will provide the findings to the appropriate Queen's University officials.

### **5.3 Corrective Action**

- 5.3.1 The Ethics Compliance Advisor may recommend corrective action based on the findings;
- 5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of or revisions to the SOPs, and changes to forms, checklists, or templates;
- 5.3.3 The Ethics Compliance Advisor will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4 The Ethics Compliance Advisor will follow-up with researchers in a timely manner to determine if the recommended corrective actions have been implemented.

#### **5.4 Documentation**

5.4.1 The Ethics Compliance Advisor or designee files all reports and correspondence concerning QA Inspections in the appropriate QA Files.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICES**

None.

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Quality Assurance Inspections	v.902.001 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.

