
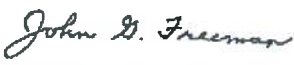



<b>Section 300:</b>	<b>Functions and Operations</b>
<b>Title:</b>	<b>Document Management</b>
<b>SOP Code:</b>	<b>303.001</b>
<b>Effective Date:</b>	<b>2016FEB08</b>

Site Approvals

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

**1.0 PURPOSE**

This SOP describes the requirements for electronic documentation and signatures, and document management, including document retention and document archiving. This SOP applies to documents submitted to GREB for review, as well as to all GREB administrative documents.

**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**

The GREB office must retain all relevant records (e.g., documents reviewed and cleared or not cleared, GREB meeting minutes, correspondence with researchers, written SOPs, GREB membership rosters) to provide a complete history of all actions related to the GREB review and clearance of submitted research. Such records must be retained for the length of time required by applicable regulations and guidelines.

Relevant records must be made accessible to authorized regulatory authorities, representatives of these organizations, researchers, and funding agencies within a reasonable time upon request.

#### **5.1 Research-Related Documents**

5.1.1 University Research Services (URS) retains the submission materials for all research that have been submitted for GREB review and have been either cleared, acknowledged, or not ethically cleared;

5.1.2 Research-related documents include, but are not limited to, the following (as applicable):

- Initial application form,
- Correspondence between GREB and the researcher, including, but not limited to, GREB clearance letters and requests for modifications;
- Records of ongoing review activities such as:
  - Reportable event submissions, including adverse events, privacy breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
  - Modifications to the application including amendments to the research and/or any changes to the consent processes and participant materials,
  - Renewal applications,
- Copies of correspondence between GREB and regulatory agencies,
- Reports of any complaints received by GREB and their resolution.

## **5.2 GREB Administrative Documents**

5.2.1 University Research Services (URS) retains all administrative records related to GREB review activities;

5.2.2 GREB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all GREB meetings,
- Submitted GREB member reviews,
- GREB member records:

- Current and obsolete GREB membership rosters, including alternate GREB members,
- GREB membership Appointment Letters,
- Signed Conflict of Interest Disclosure Forms and Confidentiality Agreements,
- Current and obsolete SOPs,
- Current and obsolete documentation of the GREB Chair or designee's delegation of authority, responsibilities, or specific functions,
- Records of registration of GREB with the US Office of Human Research Protection, if applicable, and GREB membership updates,
- Submission deadlines, guidelines for submitting applications, and all associated attachments/templates.

### **5.3 Document Access, Storage, and Archiving**

- 5.3.1 All electronic documents associated with GREB ethics applications are housed in TRAQ, which is an online system that is accessible only to authorized individuals. Each user is provided with a unique user ID and password to login to the system;
- 5.3.2 Access to individual research projects and related documents, and researcher profiles is role-based to ensure that users only have access to documents and activities that are required by their role;
- 5.3.3 System validation checks are conducted by Process Pathways to ensure accuracy, reliability, and program consistency;
- 5.3.4 Secure, time stamped audit trails are in place to record the data and time of activities, which are identifiable by user;
- 5.3.5 The GREB TRAQ and administrative electronic records are stored on Queen's University's local server with back-up, disaster, and

recovery systems in place. Access to electronic GREB TRAQ and administrative files are accessible only to authorized individuals;

5.3.6 GREB closed paper research files are securely stored in the Office of Research Ethics or archived with Iron Mountain, an off-site storage facility.

## **5.4 Electronic Signatures**

5.4.1 All electronic signatures on documents include the printed name of the signer, the date/time the signature was executed, and the meaning associated with the signature (e.g., review, clearance, responsibility, authorship);

5.4.2 All documents containing electronic signatures will be encrypted, to ensure the signatures cannot be excised, copied, transferred, or manipulated;

5.4.3 Each electronic signature will be verified as an individual's electronic signature by GREB office personnel. Each electronic signature will be unique (i.e., not reused by or reassigned to another individual);

5.4.4 All electronic signatures used on GREB documentation are intended to be the legally binding equivalent of traditional handwritten signatures.

## **5.5 Confidentiality and Document Destruction**

5.5.1 All submissions received by GREB are considered confidential and are accessible only to GREB members (including the GREB Chair and Vice-Chair), as well as to applicable Queen's University officials and GREB office personnel;

5.5.2 Relevant research projects' files and associated documents may be made accessible to other Queen's University officials, as well as to funding agencies and/or industry sponsors (if applicable), if

researchers or their research teams submit a request for guest access to the research;

- 5.5.3 The GREB Chair, in consultation with the Director of Research Ethics, may make relevant research projects and associated documents accessible to “authorized representatives of the institution, researchers, sponsors and funders when necessary to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals” (see TCPS2, 2014, Article 6.17);
- 5.5.4 GREB will retain required records (e.g., research-related or GREB administrative documents, as applicable) for a minimum of 10 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulations;
- 5.5.5 Any confidential materials in paper format in excess of the required documentation will be shredded;
- 5.5.6 Researchers may access the Queen’s Research Data Management Services or the Queen’s Research Data Centre for long-term storage of their research data.

## **5.6 Storage of Confidential Personal Identifying Information**

- 5.6.1 Any information that is obtained by GREB that is confidential in nature and that can personally identify an individual (e.g., name and contact information of a complainant) will be kept securely on hard copy in University Research Services (URS). Any electronic copies of personally identifying information will be de-identified and stored electronically in a secure network drive with restricted access. In addition, a copy of the de-identified information will be attached to the TRAQ file within the secure electronic system.

## 6.0 REFERENCES

See References.

## 7.0 APPENDICES

None.

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
Document Management	v.303.001 2016FEB08	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous documents or policies (using the format of CAREB/N2).

