Section 300:	Functions and Operations
Title:	GREB Submission Requirements and Administrative Review
SOP Code:	301.001
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Site Approvals

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

1.0 PURPOSE

This SOP describes the GREB submission requirements and administrative review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to ethically cleared research, and any new information.

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

GREB members must rely on the documentation provided by the researcher for initial reviews and renewals of ethical clearance. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

GREB is supported by administrative procedures that ensure that GREB members not only have adequate time to assess the proposed research, but also that the materials they receive allow them to adequately assess whether or not the research submission meets the criteria for GREB ethics clearance.

The requirements for GREB submissions are made available to all researchers. GREB office personnel are responsible for maintaining and disseminating this information to researchers.

5.1 Submission Requirements

5.1.1 The required documents, format, submission dates, and procedures are outlined on the GREB website and within the online submission program TRAQ (Tools for Research at Queen's).

5.1.2 Researchers can access the Ethics Application Form via the GREB website at http://www.queensu.ca/urs/ethics/general-research-ethics-board-greb. For first-time users, education is available under the heading of TRAQ; a registration process may be necessary;

5.1.3 All research applications must be submitted electronically including:

- Ethics Application Forms,
- Instructor's Course-Based Application Forms,
- Amendment Forms,
- Renewal Forms,
- Adverse Event Forms;

5.1.4 Additional resources, such as templates and checklists, can be found on the GREB website, which may include, but are not limited to:

- GREB Application guidelines,
- Submission checklist,
- Informed Consent Form required elements checklist,
- Examples of Letters of Information and Consent Forms;

5.1.5 All Queen's University research students at the graduate and undergraduate level are required to complete the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2 - 2014) Course on Research Ethics (CORE) and submit a copy of the completion certificate with their ethics application. CORE is additionally recommended for all faculty researchers;

5.1.6 All Queen's University research students at the graduate and undergraduate level must have their supervisor review the application and have the supervisor submit an email/letter of approval that the project can go forward to UREB and/or GREB review;

5.1.7 GREB may request any additional documentation it deems necessary for the ethics review or research ethics oversight;

5.1.8 **Research Requirements:** The research question and methodology should be written in sufficient detail to permit evaluation of the ethical aspects of the project. As a general rule, reviewers need to see a copy or a description of all items that participants in the project will encounter (e.g., documents, procedures, instructions, stimuli). Such items include, for example, simple demographic questionnaires, physical measurements (e.g. height), and perceptual stimuli (e.g., a small flashing red light). The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology,
- How information will be collected (e.g., observation, interview, questionnaire, measurements),
- The population to be studied,
- Eligibility/exclusion criteria,
- Sample size,
- Reimbursement, compensation, or gifts,
- Recruitment and consent process, including the Letter of Information, Consent Form, and communication scripts,
- Research interventions, and justification for deception if used,
- Assessment of risks and strategies to minimize these risks,

- Benefits,
- Measures in place to protect privacy and confidentiality,
- Data security and storage;

5.1.3 More information regarding application requirements is available in SOP 402.001, GREB Delegated Review, and SOP 403.001, GREB Full Board Review.

5.2 Administrative Review Procedures

5.2.1 The TRAQ file number is generated by the TRAQ electronic system at the time the application is initiated;

5.2.2 A unique second file number is assigned to each submission at the time of the receipt of the application by the Ethics Coordinator or designee;

5.2.3 The Ethics Coordinator or designee performs an administrative review of the submission for overall completeness (especially CORE certificate and supervisor's statement of preparedness) ;

5.2.4 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the GREB reviewers will follow up with the researcher and/or research coordinator to request the required information for inclusion with the submission;

5.2.5 For submissions requiring full board review, the Ethics Coordinator or designee includes the application into the agenda of the next GREB meeting. Primary and secondary reviewers are designated by the GREB Chair and informed by the Ethics Coordinator before the agenda is completed;

5.2.6 For submissions to be reviewed by the delegated review procedures, the Ethics Coordinator or designee, in consultation with the GREB Chair, will assign the application to GREB members or the GREB Chair will complete the review with GREB members.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Submission Requirements and Administrative Review	v.301.001 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).