
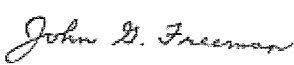



Section 400:	Review of Research
Title:	Amendments to Cleared GREB Applications
SOP Code:	405.001
Effective Date:	2016MARCH07

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR07
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR07
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR07
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures for the ongoing review activities that occur after the initial GREB Ethical Clearance of a research project and prior to the formally scheduled renewal of ethics clearance for the research project. These changes in procedures are referred to as Amendments

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.

Researchers are responsible to report and gain clearance for any changes that are required throughout the course of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

TCPS2 (2014) Article 6.16 states: “Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review”.

5.1 Amendments to Cleared Ethics Applications

5.1.1 Researchers are responsible for submitting to the GREB any changes to the ethically cleared research using the TRAQ Amendment Form with attached materials;

5.1.2 Submitted information could include:

- Modifications or changes to any previously cleared methodology or participant materials (e.g., Letter of Information/Consent Form),
- Changes in the recruitment procedures or compensation amounts,

- Changes made to protect participant privacy and confidentiality,
 - Any new procedures added to the protocol,
 - New members added to/removed from the research team,
 - Any discontinuation of the research components;
- 5.1.3 The GREB Chair or designee reviews the amendment to determine the appropriate level of GREB review required (i.e., full board or delegated review);
- 5.1.4 If the proposed change represents more than minimal risk, it should be reviewed at a GREB meeting. Amendments that might be classified as more than minimal risk would include emergency amendments that arise because of participant safety, such as:
- A change in recruitment with the potential to affect confidentiality or the perception of coercion,
 - A change in experimental procedure or research population;
- 5.1.5 If the determination is for full board review, researchers must be notified of this decision and the Ethics Coordinator or designee must place the amendment on the agenda of the next available GREB meeting;
- 5.1.6 For amendments that meet the criteria for delegated review, the Ethics Coordinator or designee will forward the Amendment Form and original application to the GREB Chair or designee;
- 5.1.7 For delegated reviews, the GREB Chair or designee will review the amendment in light of original application to determine if the amendment request falls within the purpose and procedures of the original application. If the amendment request appears to be a new or unrelated study, the GREB Chair or designee will require a new TRAQ human ethics application;
- 5.1.8 The GREB Chair or designee must decide if the changes requested are sufficiently large or significant to require the consent process to

be repeated for participants who have already participated in the research;

- 5.1.9 Modifications to the ethically cleared research may not be initiated without prior GREB review and ethical clearance except where necessary to eliminate apparent immediate hazards to participants. If changes are made to eliminate immediate hazards, researchers must notify GREB immediately.

5.2 Documenting GREB Decisions

- 5.2.1 If the amendment is cleared, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;
- 5.2.2 The Ethics Coordinator will prepare, on GREB's behalf, an Ethics Amendment Clearance Letter to be issued to the researchers. This letter will acknowledge the actual items cleared via the amendment request. The anniversary date of the original application will remain unchanged;
- 5.2.3 The Ethics Coordinator will prepare an Amendment Report for GREB approval at the next GREB meeting. This report will consist of: the Principal Investigator's name, the GREB file number, amendment date, title of the study, and a point-form outline of the amendment request;
- 5.2.4 GREB members are expected to identify any concerns or questions with amendments if they were initial GREB reviewers;
- 5.2.5 GREB members then vote at the GREB meeting to accept the Amendment Report.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Ongoing GREB Review Activities	v.405.001 2016MAR07	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).

