
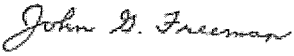



<b>Section 400:</b>	<b>Review of Research</b>
<b>Title:</b>	<b>GREB Full Board Reviews</b>
<b>SOP Code:</b>	<b>403.001</b>
<b>Effective Date:</b>	<b>2016MARCH07</b>

## 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 decisions that GREB may make during full board review of proposed research for ethical acceptability.

## 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.

The GREB Chair or designee is responsible for ensuring that: (1) each ethics application requiring a full board review is evaluated based on criteria set out by the TCPS2 (2014) and this SOP; (2) GREB members act with due diligence in completing the review; (3) changes needed are communicated clearly to the researchers; (4) a decision is made in a timely manner; and (5) researchers are informed of their responsibilities for the duration of the application.

### **4.0 DEFINITIONS**

See Glossary of Terms.

### **5.0 PROCEDURES**

Full board review is the default for new research projects submitted to GREB (Article 6.12, TCPS2 [2014]). GREB members with a Conflict of Interest (COI) in the research under review must not participate in the deliberations or in the vote of the GREB, in accordance with GREB and Queen's University Conflict of Interest (COI) policies (see SOPs 105A.001, 105B.001, 105C.001).

GREB's primary duty is to protect the rights and welfare of human research participants. However, a secondary role is to support the research enterprise by assisting researchers in fulfilling their obligations to research participants according to the TCPS2 (2014) guidelines and Queen's policies. In this capacity, GREB members endeavour to provide feedback in a positive and supportive manner, regardless of whether it is a full board or delegated review. In this spirit, GREB normally interacts with the researchers until all concerns are either addressed or justifications accepted, thus leading to ethics clearance.

## **5.1 Determining When a Full Board Review is Required**

- 5.1.1 Full board review is the default for new research projects submitted to GREB (Article 6.12, TCPS2 [2014]).
- 5.1.2 Referral of an ethics application for a full board review may be recommended by a Unit REB, the researchers themselves, the GREB Chair or any GREB members who are in the process of reviewing a delegated review file. Full board review may also occur because of regulations such as the U.S Federalwide Assurance regulations.
- 5.1.3 The GREB Chair or designee will examine the ethics application and attachments to examine the level of risk and potential for harm based on TCPS2 (2014) definitions;
- 5.1.4 “Risk” is defined as the level of foreseeable risk posed to participants by their involvement in research. Level of risk is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties;
- 5.1.5 “Harm” is defined as any occurrence that has a negative effect on participants’ welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical, or economic;
- 5.1.6 While level of risk is the primary rationale for full board review of an ethics application, other rationale for a full board review includes concerns related to: research methods; recruitment practices; participant population; rights, safety, and well-being of research participants; confidentiality of data; and, as applicable, all regulatory and ethics guidance requirements.

## **5.2 Full Board Review Procedures:**

- 5.2.1 The Ethics Coordinator will use the on-line Human Ethics Application System to inform the researchers if a full board review will occur at the next GREB meeting;
- 5.2.2 Prior to the meeting, all GREB members will be asked to insert their comments into the online Human Ethics Application System;
- 5.2.3 A minimum of two GREB members will be assigned to lead the discussion at the full board review meeting;
- 5.2.4 The GREB Chair will ask if anyone is in a Conflict of Interest (COI) situation with the researchers or the ethics application. If declared, the GREB member will be excused from the meeting for the duration of the discussion;
- 5.2.5 The GREB Chair will lead the discussion, summarize the main comments, and ask for consensus, if possible, or, failing consensus, a vote on whether the ethics application should be cleared or returned for clarifications/modifications;
- 5.2.6 GREB full board decisions are made by consensus, if possible, or, failing consensus, a majority vote of GREB members who are present at a GREB meeting at which there is a quorum. Quorum is defined as 50% +1 of the membership., excluding those GREB members who have recused themselves in accordance with the Conflict of interest policies;
- 5.2.7 The GREB Chair will abstain from voting except to break a tie vote or to meet quorum requirements;
- 5.2.8 GREB shall notify the researchers in writing of its decision to grant ethics clearance, require modifications/clarifications to the proposed research, or not grant ethics clearance;
- 5.2.9 If discrepancies exist among good clinical practices, statutory or regulatory requirements, and ethical considerations, GREB shall document the rationale for its decisions. The rationale shall be based on GREB's role, as described in Chapter 6 of TCPS2 (2014),

of ensuring that research complies with TCPS2 (2014) core principles as well as other applicable regulatory and ethical requirements for ensuring the protection of the rights, safety, and well-being of research participants.

- 5.2.10 The GREB Chair will ask GREB members if they wish to see the letter to the researchers and the researchers' response or if the review can be completed by the GREB Chair and two lead GREB reviewers;
- 5.2.11 Any GREB members who so desire will be included in the ongoing communications with the researchers;
- 5.2.12 The Ethics Coordinator will summarize the discussion at the meeting and the on-line comments in a letter form before the GREB Chair makes any necessary edits; the letter will then be sent to the two lead GREB reviewers and other interested GREB members for further review/edits; the Ethics Coordinator will then send the letter to the researchers;
- 5.2.13 Once the researchers respond to the letter, the GREB Chair and GREB reviewers will review the changes and request further changes, if needed;
- 5.2.14 This exchange process will continue until the GREB Chair and GREB reviewers feel that the TCPS2 (2014) guidelines and Queen's policies have been met;
- 5.2.15 Results of the clearance process will continue to remain on the GREB monthly meeting agenda until the project is cleared or not cleared;
- 5.2.16 If the research cannot be ethically cleared through the full board review procedures, the researcher may request that GREB reconsider its decision, followed by an appeal of the GREB decision to an independent ad hoc committee.

### **5.3 Ethics Clearance Granted**

- 5.3.1 If the application is cleared through the full board review process, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;
- 5.3.2 The Ethics Coordinator will prepare, on GREB's behalf, an Ethics Clearance Letter to be issued to the researchers with its date used to calculate the one-year expiry date of GREB Ethics Clearance. The letter will inform the researchers that they must submit an annual renewal form prior to the anniversary date or ethics clearance will expire. The Ethics Clearance Letter will also contain a statement that any adverse event must be reported to GREB within 48 hours using the Serious Adverse Event form, and any changes to protocol, consent, etc., must be submitted as an amendment on an Amendment Form.

### **5.4 Ethics Clearance Denied**

- 5.4.1 GREB may deny ethics clearance of the research when it fails to meet the ethical standards for clearance and where revision is unlikely to enable GREB to reach a positive determination;
- 5.4.2 Refusal of ethics clearance can only be decided after an initial full board review and two additional discussions after receiving the researchers' responses at subsequent GREB meetings;
- 5.4.3 The GREB Chair or designee shall ensure that the reasons for denying ethics clearance are documented in the GREB meeting minutes for communication to the researchers;
- 5.4.4 If the research is denied ethics clearance, the reasons will be communicated to the researchers in writing and the researchers will be given an opportunity to respond in person or in writing.

## **5.5 Reconsideration and Appeal of GREB Decisions**

- 5.5.1 Researchers may appeal the decision of GREB if the disagreement between the researchers and GREB cannot be resolved through a reconsideration process at a GREB meeting at which the researchers shall have the right to speak;
- 5.5.2 Researchers must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons, and only after a final decision has been issued by GREB;
- 5.5.3 Appeals are conducted in accordance with the established GREB and Queen's University policies. GREB will ask the Vice-Principal (Research) to appoint an independent ad hoc committee that reflects a range of expertise and knowledge similar to that of GREB, and that meets the procedural requirements of this SOP;
- 5.5.4 As stated in Article 6.20 of the TCPS2 (2014), "the appeal committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final" and shall be communicated to the researchers and GREB in writing.

## **5.6 Documenting GREB Decisions**

- 5.6.1 The GREB meeting minutes will be used to document the discussion and record all letters sent to the researchers during the full board review process;
- 5.6.2 All GREB documentation must be included in the online Human Ethics Application System. This documentation includes: (TRAQ and departmental) application number, level of review (full or delegated), date of review, reviewers' comments and researchers' responses, decision of GREB, all documents cleared for use, the

Ethics Clearance Letter with standard conditions of ethics clearance, renewal date based on the Ethics Clearance Letter, and a statement that GREB was compliant with applicable guidelines and regulations;

- 5.6.3 Upon request, GREB can provide a detailed copy of the GREB membership roster in effect on the date of GREB meeting at which the research was reviewed. A copy of the GREB membership roster, which includes name and affiliation(s), is published on the [GREB website](#).

## 6.0 REFERENCES

TCPS2 (2014) Articles 2.9, 6.12, 6.14, 6.18, 6.19, 6.20

## 7.0 APPENDICES

None.

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Full Board Reviews	v.403.001 2016MAR07	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).