
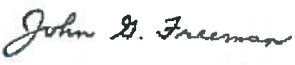



Section 300:	Functions and Operations
Title:	GREB Meeting Administration
SOP Code:	302.001
Effective Date:	2016FEB08

Site Approvals

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

1.0 PURPOSE

This SOP describes the required activities for the preparation, management, and documentation of Full Board meetings of GREB.

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 meeting agenda provides the meeting content and establishes a sequence of review. It also provides an overview of all items that have been previously (i.e., during the preceding time between GREB meetings) reviewed and ethically cleared by delegated review procedures. Information documented in the GREB meeting agenda provides the foundation for the GREB meeting minutes.

The GREB meeting minutes document the actions that occur during a GREB meeting. The minutes should enable a reader who was not present at the GREB meeting to determine how and with what justification the GREB arrived at its decisions. They should also provide GREB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

Although the delegated review procedure is used most frequently for GREB reviews because of the low risk involved in most applications, when the GREB full board review procedure is deemed necessary by the GREB Chair or designee, a quorum must be present at the GREB meeting. A quorum is defined as having as a majority of members present (50% + 1).

5.1 Agenda Preparation

5.1.1 The GREB agenda follows a structured format that is consistent for all meetings. It includes the following items:

- Acceptance of the Agenda,
- Conflict of Interest declarations and confidentiality reminders,
- Minutes of the last meeting,
- Business arising from the last meeting,
- Full Board Reviews,
- Report on all delegated reviews since the last meeting,
- Protocols for assisted delegated review,
- Amendment Report,
- Renewal Report,
- Adverse Events Report,
- Actionable Items,
- Report from the Chair,
- Other and Continuing Business,
- New Business,
- Adjournment;

5.1.2 Prior to the meeting, the Ethics Coordinator develops a summary of all delegated reviews that have been cleared since the last GREB meeting. The Ethics Coordinator also attaches all of the comments made by the reviewers and asks members to reduce this list to the most relevant points prior to the GREB meeting. These summary reports and summary comments are included in the agenda;

5.1.3 The Ethics Coordinator or designee, in consultation with the GREB Chair or designee as necessary, reviews the agenda, confirms GREB meeting attendance, and assigns the reviewers for any full board reviews;

- 5.1.4 The reviewer assignment and the agenda are issued in a timely manner prior to the GREB meeting date. GREB members attending the GREB meeting will receive a copy of the GREB meeting agenda;
- 5.1.5 The minutes of the previous meeting include a summary of the discussion and the final letter(s) from full board reviews that were sent out to researchers;
- 5.1.6 At each GREB meeting, there is a complete list of all of the amendments and all of the renewed projects. These are presented to GREB members in organized charts for approval at the GREB meetings;
- 5.1.7 The Ethics Coordinator or designee adds any other items for information or discussion at the GREB meeting (e.g., Report from the Chair, SOPs, educational articles, presentations, reports);
- 5.1.8 The GREB Chair or designee invites the appropriate alternate GREB member to the meeting when a regular GREB member is not able to attend. Ad hoc advisors will receive copies of relevant submissions;
- 5.1.9 Any changes to the agenda, including convening unscheduled meetings to deal with contingencies, are communicated to all GREB members and GREB office personnel. The Ethics Coordinator or designee also may issue an updated agenda notice depending on the nature of the changes;
- 5.1.10 The agenda is drafted by the Ethics Coordinator or designee and ratified by the GREB Chair.

5.2 Primary and Secondary Reviewers

- 5.2.1 Prior to the meeting, the Ethics Coordinator or designee, in consultation with the GREB Chair or designee, will assign a primary and secondary reviewer for each full board review application. The assigned reviewers will receive early notification of this assignment;
- 5.2.2 GREB members will not be assigned as reviewers on submissions for which they are a researcher or co-researcher or in which there is a declared Conflict of Interest (COI);
- 5.2.3 If any of the assigned reviewers declare a COI, the submission is reassigned to another reviewer.

5.3 In Advance of the GREB Meeting

- 5.3.1 All GREB members are expected to conduct a review of each agenda item prior to the GREB meeting, including previous GREB meeting minutes on the agenda and any attachments to the agenda for review or discussion;
- 5.3.2 The primary and secondary reviewers will conduct in-depth reviews of their assigned submissions and should submit reviewer comments prior to the GREB meeting. The primary reviewer should be prepared to lead the discussion at the GREB meeting;
- 5.3.3 GREB members who are not assigned as primary or secondary reviewers on full board reviews are expected to submit their individual comments for each submission in TRAQ prior to the meeting;
- 5.3.4 All GREB members should be prepared to present their comments and participate in the discussion at the GREB meeting.

5.4 During the GREB Meeting

- 5.4.1 A quorum must be present to proceed with a GREB meeting;
- 5.4.2 Should quorum fail during a Full Board meeting (e.g., through recusal of GREB members with Conflicts of Interest or early departures), GREB may not make further decisions unless quorum can be restored;
- 5.4.3 An alternate GREB member may attend in the place of a regular GREB member to meet quorum requirements. When a GREB member and the alternate both attend the GREB meeting, only one is allowed to participate in the deliberations and final decisions regarding ethical clearance;
- 5.4.4 Although discouraged, a GREB member who cannot be physically present during a GREB meeting may participate via videoconference or teleconference. GREB members participating by videoconference or teleconference count toward quorum;
- 5.4.5 Ad hoc advisors will not be used to establish a quorum;
- 5.4.6 GREB members recusing themselves due to a COI are not counted toward quorum;
- 5.4.7 Only those GREB members present (i.e., in person, or via videoconference or teleconference) at the GREB meeting may participate in the deliberation and final decision regarding ethical clearance; however, written comments from absent members can be submitted for review for consideration of an application;
- 5.4.8 When there is less than full attendance at a GREB meeting, decisions should be adopted only when the members in attendance have the specific expertise, relevant competence, and knowledge necessary to provide an adequate review;
- 5.4.9 GREB may be required to convene unscheduled meetings due to exigencies (i.e. publically declared emergencies);
- 5.4.10 During publicly declared emergencies, the GREB Chair or designee may use discretion to conduct a GREB meeting with all GREB

- members attending via simultaneous videoconference or teleconference, provided all members have access to the review materials and quorum is met (see TCPS2 (2014), Chapter 6);
- 5.4.11 GREB attempts to forego the monthly meetings in July and August, if possible. For these months only, full board reviews are handled by a minimum of five GREB members present to make the decisions. All GREB members are encouraged to submit their comments, even if not present for the discussion;
- 5.4.12 Observers may be invited or permitted to attend GREB meetings, subject to the agreement of GREB and execution of a Confidentiality Agreement. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the GREB meeting;
- 5.4.13 If requested, researchers may (in person or via teleconference) attend the GREB meeting to present their research and respond directly to any comments or questions raised by GREB, subject to the agreement of GREB; however they cannot participate in deliberations or votes;
- 5.4.14 Any individual not listed on the official GREB membership roster may not participate in the decisions of GREB;
- 5.4.15 At the meeting, lead reviewers on delegated review reports are asked to comment on their reports. These delegated review reports serve to educate and train GREB reviewers in applying the same standards across applications. Once all delegated review reports have been presented and discussed, GREB is asked to approve the delegated review reports. If any questions arise about any reports, they are clarified before the next meeting with more information and approved at the later meeting.

5.5 Meeting Minutes Preparation

- 5.5.1 The Ethics Coordinator or designee will draft the GREB meeting minutes including attendance, key discussions, decisions, and votes;
- 5.5.2 The key GREB discussions and decisions for submissions are recorded;
- 5.5.3 GREB's concerns, clarifications, and recommendations to researchers as discussed at the GREB meeting are drafted by the Ethics Coordinator, and then edited by the Chair and primary and secondary reviewers before being sent to the researcher via TRAQ;
- 5.5.4 If the concerns are consequential, then the letter is sent to the entire GREB before being sent to the researcher via TRAQ;
- 5.5.5 The information documented in TRAQ is included in the GREB meeting minutes;
- 5.5.6 The meeting may be audio tape recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
- 5.5.7 The minutes are intended to reflect what GREB decided, how it resolved controverted issues, and any determinations required by the regulations;
- 5.5.8 The draft minutes must be completed prior to the next GREB meeting and vetted by the Chair.

5.6 Meeting Minutes Approval

- 5.6.1 The minutes are made available at the next appropriate GREB meeting and are presented at the GREB meeting for review and approval;
- 5.6.2 GREB motions and votes on the previous GREB meeting minutes are recorded in the current GREB meeting minutes;

5.6.3 If the previous GREB meeting minutes are approved pending revisions, the Ethics Coordinator or designee makes the required changes, and, unless the GREB requests further review of the minutes prior to approval, the Ethics Coordinator or designee records the minutes as approved.

5.7 Documentation

5.7.1 The GREB meeting minutes include the following items:

- Date, place, and time the GREB meeting commenced and adjourned,
- Names of GREB members in attendance (present, teleconference, videoconference),
- Names of GREB members absent,
- Names of GREB office personnel present at the meeting,
- Presence of observers,
- Use of ad hoc advisors and their specialty,
- List of declared Conflicts of Interest, a summary of any discussions, and the decision taken by GREB to address concerns raised in the discussions (as applicable),
- Decisions taken by GREB regarding ethical clearance for each submission, as applicable,
- A summary of key discussions and disputed issues and their resolution for each submission, as applicable,
- The basis for requiring changes or for not granting ethics clearance for submissions,
- GREB member(s) recused related to Conflicts of Interest for each submission requiring a decision,
- Number(s) voting for, against, or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;

- 5.7.2 All GREB meeting agendas and minutes are retained in the GREB records;
- 5.7.3 The agendas, GREB meeting minutes, and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Meeting Administration	v.302.001 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).