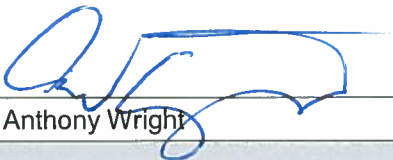
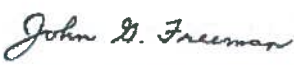



| | |
|------------------------|---|
| Section 400: | Review of Research |
| Title: | Suspension or Termination of GREB Ethics Clearance |
| SOP Code: | 410.001 |
| Effective Date: | 2016APRIL01 |

Site Approvals

| | | |
|---|--|-----------------|
| Signature of Responsible Individual: | | |
| Ethics Compliance Advisor |  | Date: 2016APR01 |
| | Name: Anthony Wright | |
| Approval Authority: | | |
| Chair, GREB |  | Date: 2016APR01 |
| | Name: Dr. John Freeman | |
| Approval Authority: | | |
| Director, Research Ethics Compliance |  | Date: 2016APR01 |
| | Name: Dr. Andrew Winterborn | |

1.0 PURPOSE

This SOP describes the procedures associated with the suspension or termination of GREB Ethics Clearance of research.

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.

GREB is responsible for determining whether or not any information received throughout the course of the research requires the suspension or termination of GREB Ethical Clearance.

Researchers are responsible for notifying GREB and Queen's University officials (if applicable) if their research is abandoned or completed, or if ethics clearance is suspended or terminated by another REB (in the case of multijurisdictional studies) or by a regulatory agency. They need to provide a detailed explanation for the action.

4.0 DEFINITIONS

Suspension is defined as a temporary or permanent halt to all research activities pending future action by GREB, by the sponsor and/or by researchers.

Termination is defined as a permanent halt by GREB, by the sponsor, and/or by researchers to all or some research activities.

5.0 PROCEDURES

As a result of ongoing review activities, GREB may require that research be modified, or may suspend or terminate GREB Ethics Clearance if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of Serious Adverse Events or when there is evidence that researchers are not conducting the research in compliance with applicable regulations and guidelines. GREB also has the authority to suspend new enrollment while additional information is being requested.

A decision to suspend or to terminate GREB's Ethics Clearance of the research must include consideration of the safety, rights, and well-being of the participants already

enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

Researchers may decide to voluntarily suspend or terminate some or all research activities; however, this action is not considered a suspension or termination of GREB Ethics Clearance.

5.1 Suspension or Termination of GREB Ethics Clearance

5.1.1 If any concerns are raised during GREB's oversight of research that are related to new information or to the conduct of the research, GREB may suspend or terminate ethics clearance of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with GREB cleared protocol or GREB requirements,
- The research is associated with unexpected serious harm to participants (as may be determined following GREB review of reportable events),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by GREB (e.g., under a suspension or ethics clearance with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,
- Repeated or deliberate failure to comply with conditions placed on the research by GREB or by regulatory agencies,
- Repeated or deliberate failure to obtain prior GREB review and ethics clearance of amendments or modifications to the research, or

- Repeated or deliberate failure to maintain accurate research records or submit required reportable adverse events to GREB;
- 5.1.2 The GREB Chair or designee is authorized to suspend GREB Ethics Clearance of research; however, the GREB Chair or designee is not authorized to terminate GREB Ethics Clearance. If the Chair or designee suspends ethics clearance of the research, he or she must notify GREB of this suspension at its next GREB meeting;
- 5.1.3 GREB is authorized to terminate ethics clearance of the research following a review at a GREB meeting;
- 5.1.4 Prior to suspending or terminating GREB Ethical Clearance, GREB must consider:
- Risks to current participants,
 - Actions to protect the safety, rights, and well-being of currently enrolled participants,
 - The appropriate care and monitoring of research participants,
 - Whether or not withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
 - Whether or not participants should be informed of the termination or suspension,
 - Identification of a time frame during which corrective measures are to be implemented;
- 5.1.5 If GREB Ethics Clearance is suspended or terminated, the GREB Chair or designee will issue a formal letter to the researchers with the reasons for GREB action and the corrective measures required by GREB;

- 5.1.6 Unless otherwise stated by GREB, when the GREB Chair or designee suspends ethics clearance, no further research activities can take place other than the submission of event forms;
- 5.1.7 If GREB Ethical Clearance has been suspended, the suspension may be lifted after corrective actions are completed to GREB's satisfaction.
- 5.1.8 Upon termination of ethics clearance by the GREB, if the researchers wish to re-activate the research study, they will be required to resubmit a new ethics application to GREB.

5.2 Reporting Suspensions or Terminations

- 5.2.1 The GREB Chair or designee will report any suspension or termination of GREB Ethics Clearance to appropriate officials at Queen's University and has the authority to notify the regulatory authorities (as applicable). GREB may delegate regulatory authority reporting as applicable.

6.0 REFERENCES

TCPS2 (2014), [Article 6.3](#) and [Article 6.14](#)

7.0 APPENDICES

1. Ethics Coordinator Courtesy Reminder Letter Template
2. Chair Suspension Letter to Principal Investigator Template
3. Chair Letter of Termination Template

8.0 REVISION HISTORY

| SOP Title | Version | Updates |
|---|--------------------------|---|
| Suspension or Termination of GREB Ethical Clearance | v.410.001 2016APRIL01 | 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). |

Appendix 1

ETHICS COORDINATOR COURTESY REMINDER LETTER

Dear [[PrincipallInvestigatorSalutation]]:

RE: [[ProjectTitle]]

File# [[FileNo]]

According to our records, the above-noted protocol is due for annual renewal on [[RenewalDue]]. Please login to the **TRAQ Researcher Portal** to complete, and submit, the *GREB Annual Renewal Form for Approved Studies*. **If your project is complete or abandoned, you still need to submit this form for GREB review.**

The Principal Investigator is responsible for maintaining GREB Ethical Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions. If GREB does not hear from the Principal Investigator or designee in a timely manner, the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

How to Submit a Renewal Form:

1. Visit https://eservices.queensu.ca/romeo_researcher/ if you use SSO (Single Sign On) or https://eservices.queensu.ca/romeo_researcher_admin/ if you use your full email address* as Username
2. Sign on with your Queen's Net ID (or full email address*) and password
3. Click 'My Reminders' or 'Applications (Submitted-Post Review)'
4. Click the 'EVENTS' link next to the file no **[[FileNo]]**.
5. Select the form titled *GREB Annual Renewal Form for Approved Studies* by clicking on its hyperlink under "New Event Forms" section.
6. Complete all fields.
7. Save.
8. Submit.

Sincerely,

Gail Irving
Ethics Coordinator
General Research Ethics Board
University Research Services

Room 302C, Fleming Hall/Jemmett Wing
Queen's University

Note: Instructional video: "Submitting and Tracking Event Forms" can be found at:
<http://www.youtube.com/watch?v=IVH7t9ezZIk>

Instructional video: "General Research Ethics Board (GREB) - Event Forms" can be found at:
<http://www.youtube.com/watch?v=sVSBNPVeVzo>

Appendix 2

CHAIR - SUSPENDED ANNUAL RENEWAL EMAIL

[[Today]]

Dear [[PrincipalInvestigatorLongName]],

Re: Study Title: "[[ProjectTitle]]

ROMEO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due. **Your GREB research ethics clearance is now suspended. All research activity under this ethics application must be stopped.** Failure to respond to this notice will result in termination of your research ethics clearance.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions in the renewal form in TRAQ. If GREB does not hear from the Principal Investigator or designee in a timely manner, ethics clearance for the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]

GREB Chair

University Research Services

Fleming Hall-Jemmett Wing, 3rd Floor

78 Fifth Field Company Lane

Queen's University

Kingston, ON K7L 3N6

Tel: (613) 533-6081 ext 78281

chair.GREB@queensu.ca

Appendix 3

CHAIR – GREB TERMINATION OF ETHICS CLEARANCE

[[Today]]

Dear [[PrincipalInvestigatorLongName]] ,

Re: Study Title: "[[ProjectTitle]]"

ROMEIO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's Standard Operating Procedures (SOPs) 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from the GREB must be renewed at least once per year.

Attempts to contact you have failed. This letter is to advise you that your research study's ethics clearance has been terminated (see GREB's SOP 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]
GREB Chair
University Research Services
Fleming Hall-Jemmett Wing, 3rd Floor
78 Fifth Field Company Lane
Queen's University
Kingston, ON K7L 3N6
Tel: (613) 533-6081 ext 78281
chair.GREB@queensu.ca