
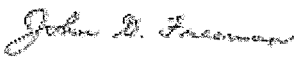



<b>Section 400:</b>	<b>Review of Research</b>
<b>Title:</b>	<b>Renewal of Ethics Clearance</b>
<b>SOP Code:</b>	<b>407.002</b>
<b>Effective Date:</b>	<b>2016MAY19</b>

## Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016May19
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016May19
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016May19
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This SOP describes the procedures and criteria for the renewal of GREB Ethics Clearance.

## 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**

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 reviewing all submitted materials for renewal of research projects.

### **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.

### **5.0 PROCEDURES**

GREB conducts research ethics clearance renewal reviews at intervals appropriate to the degree of risk associated with the research study, but not less than once a year. Periodic review of research activities is necessary to determine if the level of risk has changed and what actions (if any) need to be taken to satisfy continued ethics clearance for the research study.

#### **5.1 Application for Ethics Renewal**

- 4.1.1 According to the TCPS2 (2014), Article 6.14, ethics clearance can be granted for only one year and must be renewed annually on or before the date of initial ethics clearance;
- 4.1.2 Researchers will be sent a courtesy reminder notice by the Ethics Coordinator of the need to submit their annual renewal form, 2-4 weeks prior to the anniversary date;
- 4.1.3 Researchers must submit an Annual Renewal Event Form available in TRAQ before the anniversary date to maintain their ethics clearance.

## **5.2 Renewal of Ethics Clearance by Delegated Review Procedures**

- 5.2.1 When the research received initial ethics clearance via delegated review, it may undergo delegated review at the time of renewal;
- 5.2.2 Research that was previously reviewed by the full board may be assigned to delegated review at the time of renewal if conditions warrant this change;
- 5.2.3 The Ethics Coordinator or designee reviews the renewal application for completeness, including verification of the currently cleared informed Consent Form(s), and requests any clarifications, missing documents, or other information as applicable;
- 5.2.4 The Ethics Coordinator will forward the application to the GREB Chair or designee for review, if required;
- 5.2.5 The GREB Chair or designee may request additional information or clarification, as necessary, and will make a decision regarding the renewal of ethics clearance and the continued conduct of the research;
- 5.2.6 Upon reviewing the delegated renewal application, the Chair may determine that the risks are now greater than minimal and refer the application for review by the full board.

## **5.3 Renewal of Ethics Clearance by Full Board Procedures**

- 5.3.1 Although infrequent, GREB may require researchers to submit an application for renewal of research ethics clearance at a frequency to be determined by GREB and defined at the time of the initial ethics clearance of the research, or as otherwise revised;
- 5.3.2 GREB will request and assess the renewal based on:
  - The nature of any risks posed by the research,
  - The vulnerability of the participant population,

- Whether or not the research involves novel approaches,
  - Any concerns GREB may have related to compliance or other ethical issues.
- 5.3.3 The Ethics Coordinator or designee reviews the application for completeness, and requests any clarifications, missing documents or other information from researchers, as applicable;
- 5.3.4 The Ethics Coordinator or designee will assign the application to the agenda of the next GREB meeting if the research meets the criteria for full board review;
- 5.3.5 For research that meets the criteria for full board review, GREB will discuss the research at a full board meeting and will make a decision regarding renewed ethics clearance of the research, as well as any additional determinations regarding the conduct of the research, as applicable.

#### **5.4 GREB Documentation**

- 5.4.1 To grant a renewal of the ethics clearance of the research the GREB Chair/designee or GREB must determine that:
- There have been no material changes to the research or to the informed Consent Form that have not been previously submitted and cleared,
  - There is no new Conflict of Interest or new information that has emerged that might adversely affect the safety or the well-being of research participants,
  - Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
  - Informed consent processes continue to be appropriate and documented,

- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,
- Any complaints from research participants have been followed-up appropriately;

5.4.2 GREB may also make additional determinations, including:

- Request changes to the Letter of Information and/or informed Consent Form,
- Request changes for the renewal interval (based on risks),
- Request further details, if not evident in the initial application or renewal report,
- Require justifiable modifications to the research,
- Suspend or terminate GREB Ethics Clearance.

## **5.5 Renewal Applications not Received by the Expiry Date**

5.5.1 The Principal Investigator or designee is responsible for maintaining GREB Ethics Clearance for active studies. As per TCPS2 (2014) and in accordance with GREB SOPs, 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;

5.5.2 If an application for renewal is not submitted before the expiry date, then a letter (Suspension of Ethics Clearance) will be sent to the Principal Investigator by the Chair or designee advising the Principal Investigator that their ethics clearance has been suspended;

5.5.3 When ethics compliance is suspended, the Principal Investigator must cease all research activities. If, however, the safety, rights, and well-being of participants would be in jeopardy due to a suspension of research activity, then the Principal Investigator is

responsible for contacting GREB immediately to ask for a postponement of the suspension until the renewal form can be submitted;

- 5.5.4 In the event of a suspension in ethics clearance, the Principal Investigator or designee will be responsible for notifying GREB if there is a desire to continue the research project;
- 5.5.5 The Principal Investigator or designee must document the reasons for allowing the research ethics clearance to lapse on the renewal form and identify the steps taken to prevent future suspensions;
- 5.5.6 If the research study has been discontinued, then it is the responsibility of the Principal Investigator or designee to inform GREB of the discontinuation;
- 5.5.7 In the renewal form, the Principal Investigator or designee should provide as much detail as possible about the proposed continued activities. The GREB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Principal Investigator or designee, if required;
- 5.5.8 The Principal Investigator may resume research activities once ethics clearance of the research has been issued;
- 5.5.9 The suspension in ethics clearance will be documented on the renewal letter issued by GREB;
- 5.5.10 GREB may refuse to review new research submissions until suspensions in ethics clearance have been resolved for any ongoing research projects;
- 5.5.11 In the event that a GREB Annual Renewal Event Form is not submitted for review within **10 business days from the date of receiving the Ethics Clearance Suspension Letter**, the study's GREB Ethics Clearance will be terminated (see GREB SOP 410.001 Suspension and Termination of GREB Ethics Clearance);
- 5.5.12 When an ethics application is terminated, the Chair or designee will send the Principal Investigator a termination letter;

5.5.13 Upon termination of ethics clearance by the GREB, if the researchers wish to re-activate the closed research study, they will be required to:

- Communicate with the Ethics Coordinator to have their ethics application re-opened,
- Submit an Amendment explaining why the ethics clearance lapsed, and
- Outline the corrective measures taken to enable them to submit their renewal on time in the future.

## 6.0 REFERENCES

TCPS2 (2014), 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
Renewal of Ethics Clearance	v.407.001 2016APR01	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).
	v.407.002 2016MAY19	Correct termination process and PI option to re-open a terminated ethics application.

