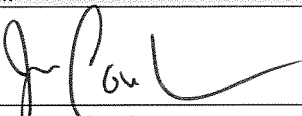




<b>Section 400:</b>	<b>Review of Research</b>
<b>Title:</b>	<b>Renewal of Ethics Clearance</b>
<b>SOP Code:</b>	<b>405.004</b>
<b>Effective Date:</b>	<b>2016SEP12</b>

### Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016 Sep 14
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		Date: Sept 14, 2016
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016 Sep 15
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the renewal of ethics clearance that is overseen by the HSREB, and the criteria for the renewal of HSREB ethics clearance.

## 2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

## 3.0 RESPONSIBILITIES

HSREB Members and the HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The HSREB Chair or designee and the assigned HSREB reviewers are responsible for conducting reviews of all submitted materials for their assigned research projects.

All other HSREB Members are responsible for reviewing the submitted materials for discussion at a Full Board meeting.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

The HSREB must establish procedures for conducting renewal reviews of ethically cleared research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether ethics clearance should be continued or withdrawn.

### 5.1 Renewal of Ethics Clearance by Full Board Procedures

- 5.1.1 The Principal Investigator (PI) or their designee is required to submit an application for renewal of ethics clearance of research at a frequency to be determined by the HSREB, and which will be defined at the time of the initial ethics clearance of the research, or as otherwise revised;
- 5.1.2 At a minimum, the HSREB requires that an application for renewal be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the HSREB;
- 5.1.3 The HSREB recommends keeping research projects open until results have been reported and/or published;
- 5.1.4 The HSREB may determine that the research requires renewal more frequently than once per year by considering the following:
  - The nature of any risks posed by the research,
  - The degree of uncertainty regarding the risks involved,
  - The vulnerability of the participant population,
  - The projected rate of enrolment and estimated research closure date,
  - Whether the research involves novel interventions,
  - The HSREB believes that more frequent review is required;
- 5.1.5 The HSREB Annual Renewal Form for Approved Studies should be completed and submitted using Tools for Research at Queen's (TRAQ). Alternatively, the HSREB Multi-Use Amendment/Full Board Renewal Form can be submitted for annual reviews that require full board review;
- 5.1.6 Annual renewal applications are due two weeks in advance of the anniversary date. Annual renewal applications requiring Full Board review must be submitted by the submission deadline for the applicable HSREB meeting (i.e. the expiry date must be on or after the HSREB meeting date), to ensure no lapse in ethics clearance;

- 5.1.7 The HSREB does allow an anniversary date to be used for Full Board renewals; however the HSREB review must occur prior to, but no more than thirty days in advance of the anniversary date. If the application for a renewal is reviewed outside of this timeframe, a new renewal date will be issued;
- 5.1.8 Any research projects set to lapse in ethics clearance will be noted in the 'My Reminders' section in TRAQ thirty days prior to the ethics clearance expiry date;
- 5.1.9 A courtesy reminder letter (Appendix 1) will be sent to all roles on the research team, as noted in TRAQ, approximately once month prior to the ethics clearance expiry date;
- 5.1.10 The HSREB Ethics Coordinator or designee reviews the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable;
- 5.1.11 The HSREB may request verification from sources other than the investigator that no material changes have occurred since previous HSREB review. This may include:
- The results of a previous audit or inspection (internal or external),
  - Suspected non-compliance,
  - Studies involving vulnerable populations,
  - Studies involving a potentially high risk to participants,
  - Suspected or reported protocol deviations,
  - Participant or Research Staff complaints,
  - Any other situation that the HSREB deems appropriate;
- 5.1.12 The HSREB Ethics Coordinator or designee will assign the application to the agenda of the next HSREB meeting if the research meets the criteria for Full Board review;
- 5.1.13 A summary report of the renewal applications assigned to the HSREB meeting may be attached to the HSREB meeting agenda;
- 5.1.14 For research that meets the criteria for Full Board review, the HSREB will discuss the research at a Full Board meeting and will make a decision regarding the renewal of ethics clearance for the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

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

- 5.2.1 When the research received initial ethics clearance using delegated review procedures, it may undergo delegated review at the time of renewal;
- 5.2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of renewal using delegated review procedures if certain conditions are met;

- 5.2.3 The HSREB does allow an anniversary date to be used for delegated renewals; however the HSREB review must occur prior to, but no more than thirty days in advance of the anniversary date. If the application for a renewal is reviewed outside of this timeframe, a new renewal date will be issued;
- 5.2.4 Biomedical clinical trials may qualify for delegated review in the following circumstances; however this is based on the discretion of the HSREB Chair or designee:
- No additional risks have been identified and no changes have been made that would increase risks to research participants, or that would substantially change the conduct of the biomedical clinical trial, its design or objectives,
  - The trial is permanently closed to the enrollment of new research participants, all participants have completed the research intervention, and the research remains active only for long term follow up of research participants,
  - No research participants have been enrolled and no additional risks have been identified,
  - The remaining research activities are limited to data analysis;
- 5.2.5 The HSREB Ethics Coordinator or designee reviews the renewal application for completeness, including verification of the currently ethically cleared informed consent form(s), and requests any clarifications, missing documents or other information as applicable;
- 5.2.6 The HSREB Ethics Coordinator or designee will forward the application to the appropriate HSREB reviewer;
- 5.2.7 The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the renewal of ethics clearance of the research and the continued conduct of the research;
- 5.2.8 Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

### **5.3 HSREB Documentation**

- 5.3.1 To grant a renewal of the ethics clearance, the HSREB 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 ethically 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,
  - 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;
- 5.3.2 The HSREB may also make additional determinations, including:
- Request changes to the informed consent form(s),
  - Request changes for the renewal interval (based on risks),
  - Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of ethics clearance period),
  - Require modifications to the research,
  - Suspend or terminate HSREB ethics clearance.

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

- 5.4.1 HSREB Ethics Clearance will expire at 11:59pm on the date the renewal is due, as indicated in TRAQ;
- 5.4.2 Once ethics clearance has lapsed, the PI is expected to cease all study related activities, except where necessary to continue for the well-being of previously enrolled participants;
- 5.4.3 Following a lapse in ethics clearance, a Suspension of Ethics Clearance Letter (Appendix 2) will be issued to the PI and copied to the entire research team, as listed in TRAQ, by the HSREB Chair or designee, advising the PI that their study's research ethics clearance has lapsed and that all research activity must be suspended;
- 5.4.4 Once suspended, a Full Board review may be required to lift the suspension (see SOP 407 Suspension or Termination of HSREB Ethics Clearance);
- 5.4.5 In the event of a suspension in ethics clearance, the PI or their designee will be responsible for notifying the HSREB if there is need to continue research-related medical treatment of current research participants for their safety and well-being. The PI or their designee should provide as much detail as possible about the proposed continued activities. The HSREB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the PI or their designee;

- 5.4.6 The PI or their designee must document the reasons for the lapse and identify the steps taken to prevent future lapses on the HSREB Annual Renewal Form for Approved Studies in TRAQ;
- 5.4.7 If the research study has been abandoned, completed, or terminated by the PI or sponsor, then it is the responsibility of the PI or their designee to inform HSREB of such through the completion of the HSREB Annual Renewal Form for Approved Studies in TRAQ;
- 5.4.8 If HSREB ethics clearance lapses and the PI or their designee wishes to continue with the research, the HSREB will complete the review of the research as soon as possible. The PI may resume the suspended activities once ethics clearance of the research has been issued;
- 5.4.9 The lapse in ethics clearance will be documented on the renewal letter issued by the HSREB;
- 5.4.10 The HSREB may refuse to review new research submissions until lapses in ethics clearance have been resolved for any ongoing research projects;
- 5.4.11 In the event that the HSREB Annual Renew Form is not submitted within ten business days from the date of the Suspension of Ethics Clearance Letter (Appendix 2), a Termination of HSREB Ethics Clearance Letter (Appendix 3) will be issued to the PI and will be copied to the entire research team, as listed in TRAQ, and the Department Head, or other applicable Queen's University Personnel, to notify them that ethics clearance is terminated and that the PI must cease all research activities;
- 5.4.12 When ethics clearance is terminated, the Principal Investigator must cease all research activities as specified by the HSREB;
- 5.4.13 The Ethics Compliance Advisor or designee will follow-up with the PI or other applicable individuals, to ensure that all research activities have ceased;
- 5.4.14 In the event of termination of ethics clearance, the PI or their designee will be responsible for notifying the HSREB if there is need to continue research-related medical treatment of current research participants for their safety and well-being. The PI or their designee should provide as much detail as possible about the proposed continued activities. The HSREB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the PI or their designee;
- 5.4.15 If HSREB ethics clearance has been terminated and the PI or designee would like to have ethics clearance reinstated, they will be required to submit the HSREB Annual Renewal Form for Approved Studies in TRAQ;

- 5.4.16 The HSREB chair or designee may complete the review of the Annual Renewal Form for Approved Studies or may forward the review for the next HSREB full board meeting;
- 5.4.17 Pending the review by the HSREB chair or designee or by the HSREB in full board meeting, ethics clearance may be reinstated;
- 5.4.18 If the HSREB makes the decision not to reinstate ethics clearance, the PI or designee will have to complete and submit a new HSREB ethics application in TRAQ in order to resume research activities.

## 6.0 REFERENCES

See References.

## 7.0 APPENDICES

1. Courtesy Reminder Email (Template)
2. Suspension of Ethics Clearance Letter (Template)
3. Termination of Ethics Clearance Letter (Template)

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
Renewal of Ethics Clearance	v.405.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.
Renewal of Ethics Clearance	v.405.002 2015OCT22	Revised to reflect new process for closing backlog of inactive files that have lapsed research ethics clearance
Renewal of Ethics Clearance	v.405.003 2016APR04	Revised to reflect new process for suspending lapsed research ethics clearance.
Renewal of Ethics Clearance	v.405.004 2016SEP12	<ol style="list-style-type: none"> <li>1. Minor revisions to scope, responsibilities and grammatical updates made to document.</li> <li>2. 5.4.1 updated to state HSREB Ethics Clearance will expire at 11:59pm on the date the renewal is due, as indicated in TRAQ;</li> <li>3. 5.1.5: Updated to reference the renewal forms in TRAQ.</li> <li>4. 5.1.6: Moved to 5.1.7.</li> <li>5. 5.1.8: Section added about 'My Reminders' in TRAQ.</li> <li>6. Section 5.1.8 now starts at 5.1.10, with subsequent sections to follow.</li> <li>7. Section 5.4: Numerous updates to reflect the current process.</li> </ol>

## Appendix 1

### HSREB Courtesy Reminder Letter Template

Dear [[PrincipallInvestigatorLongName]],

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

TRAQ File No. [[FileNo]]

This is a courtesy reminder that according to our records, the above-noted protocol is coming up for annual renewal on [[RenewalDue]].

The Principal Investigator (PI) or delegate is required to submit a **Health Sciences Research Ethics Board Annual Renewal Event Form for Approved Studies** in TRAQ at a minimum of at least once per year.

**If your project is complete or abandoned, you still need to submit this form for HSREB review.**

The HSREB requires that an application for renewal be submitted **2 weeks in advance of the annual anniversary date** to ensure that there is not a lapse in your study's ethics clearance.

In the event that a **Health Sciences Research Ethics Board Annual Renewal Event Form for Approved Studies** is not submitted before 11:59pm on the expiry date as noted in TRAQ, ethics clearance will be **suspended**.

In the event of suspended HSREB Ethics Clearance:

- Any further research activity must be discontinued pending reinstatement of HSREB ethics clearance.
- The PI must document the reasons for the suspension and identify the steps taken to prevent future suspensions on the **HSREB Annual Renewal Event Form for Approved Studies**.
- The **HSREB Annual Renewal Event Form for Approved Studies** may go to a full board review.
- If HSREB does not hear from the PI or designee in a timely manner, the study will be **terminated**.
- Please log in to the **TRAQ Researcher Portal** to complete, and submit, the **Health Sciences Research Ethics Board Annual Renewal Event Form for Approved Studies** as outlined below:



1. Visit [https://eservices.queensu.ca/romeo\\_researcher/](https://eservices.queensu.ca/romeo_researcher/) if you use SSO (Single Sign On) or [https://eservices.queensu.ca/romeo\\_researcher\\_admin/](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' (if due within 30 days) or 'Applications (Submitted-Post Review)'.
4. Click the 'EVENTS' link next to the file no [[FileNo]].
5. Select the form titled **Health Sciences Research Ethics Board 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,

Elizabeth Heinrichs

HSREB Ethics Office Assistant  
University Research Services  
Fleming Hall-Jemmett Wing, 3<sup>rd</sup> Floor  
78 Fifth Field Company Lane  
Queen's University  
Kingston, ON K7L 3N6  
Tel: (613) 533-2988 ext 32988  
[elizabeth.heinrichs@queensu.ca](mailto:elizabeth.heinrichs@queensu.ca)

## Appendix 2



### SUSPENSION OF ETHICS CLEARANCE

#### QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

DATE

PI ADDRESS

Dear [PI NAME]

Re: Study Title: [Study Title]

TRAQ File No. [FILE #]

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

**Your HSREB Ethics Clearance has lapsed and is now suspended. Any further research activity must be discontinued.** If your project is complete or abandoned, you still need to submit an HSREB Annual Renewal Event Form in TRAQ through your Researcher Portal indicating the study is complete or abandoned. If recruitment is complete but data analysis has not been completed, then the study renewal should indicate that the study is continuing.

The Principal Investigator or delegate is responsible for maintaining HSREB Ethics Clearance for their active studies. Per the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014, Article 6.14) and in accordance with HSREB Standard Operating Procedures (available on the HSREB website), applicable regulations and current best practices, studies with ethics clearance from the HSREB must be renewed at least once per year. It is at the discretion of the HSREB to require renewals more often.

The Principal Investigator should contact the HSREB in the event of a suspension and the HSREB Annual Renewal Event Form may go to a full board review as the result of the lapse in ethics clearance. The Principal Investigator should outline the reasons for the suspension and identify steps to prevent future suspensions on the HSREB Annual Renewal Event form.

In the event that an HSREB Annual Renewal Event Form is not submitted within **10 business days from the date of this letter, the study's HSREB Ethics Clearance will be terminated** (see HSREB SOP 407 – HSREB Suspension or Termination of Ethical Clearance).

1. Visit <http://www.queensu.ca/traq/signon.html> if you use SSO (Single Sign On) or [https://eservices.queensu.ca/romeo\\_researcher\\_admin/](https://eservices.queensu.ca/romeo_researcher_admin/) if you use your full email address as

## Appendix 2

Username

2. Sign on with your Queen's Net ID (or full email address) and password
3. Click 'My Reminders' (if due within 30 day) or 'Applications (Submitted-Post Review)'
4. Click the 'EVENTS' link next to the file no **[FILE #]**
5. Select the form titled *Health Sciences Research Ethics Board Annual Renewal Form for Approved Studies* by clicking on its hyperlink under "New Event Forms" section.
6. Complete all fields.
7. Save.
8. Submit.

If you have problems/questions as you complete your renewal event form, please contact Kathy Reed, HSREB Ethics Coordinator, at [reedk@queensu.ca](mailto:reedk@queensu.ca) or call 613-533-6000 x 77000. If you are having problems accessing the application in TRAQ, please contact the TRAQ Help Desk at [traq@queensu.ca](mailto:traq@queensu.ca) or call 613-533-6000 x 78426.

Sincerely,



Dr. Albert Clark  
HSREB Chair  
University Research Services  
Fleming Hall-Jemmett Wing, 3<sup>rd</sup> Floor  
78 Fifth Field Company Lane  
Queen's University  
Kingston, ON K7L 3N6  
Tel: (613) 533-6000 x 78223  
[clarkaf@queensu.ca](mailto:clarkaf@queensu.ca)

## Appendix 3



### TERMINATION OF ETHICS CLEARANCE

### QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

DATE

PI ADDRESS

Dear [PI Name],

Re: Study Title: [STUDY TITLE]

TRAQ file No: [FILE #]

According to our records, the above-noted research study was due for annual renewal on **DATE** and is now past due. If your project is complete or abandoned, you still need to submit an annual renewal event form in TRAQ through your Researcher Portal indicating the study is closed or abandoned.

#### **All further research activity must cease.**

The Principal Investigator or delegate is responsible for maintaining HSREB Ethics Clearance for their active studies. Per the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014, Article 6.14), and in accordance with HSREB Standard Operating Procedures (available on the HSREB website), applicable regulations, and current best practices, studies with Ethics Clearance from the HSREB must be renewed at least once per year. It is at the discretion of the HSREB to require renewals more often.

Several attempts to contact you have failed. This letter is to advise you that HSREB Ethics Clearance for your research study has been terminated as per HSREB's Standard Operating Procedures (SOPs) 405 Renewal of Ethics Clearance and 407 HSREB Suspension or Termination of Ethics Clearance, which are posted on the HSREB website.

Sincerely,

A handwritten signature in cursive script that reads "Albert Clark".

Dr. Albert Clark  
HSREB Chair  
University Research Services  
Fleming Hall-Jemmett Wing, 3<sup>rd</sup> Floor

## Appendix 3

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Cc Department Head