TRAQ – HSREB & GREB

Event Forms
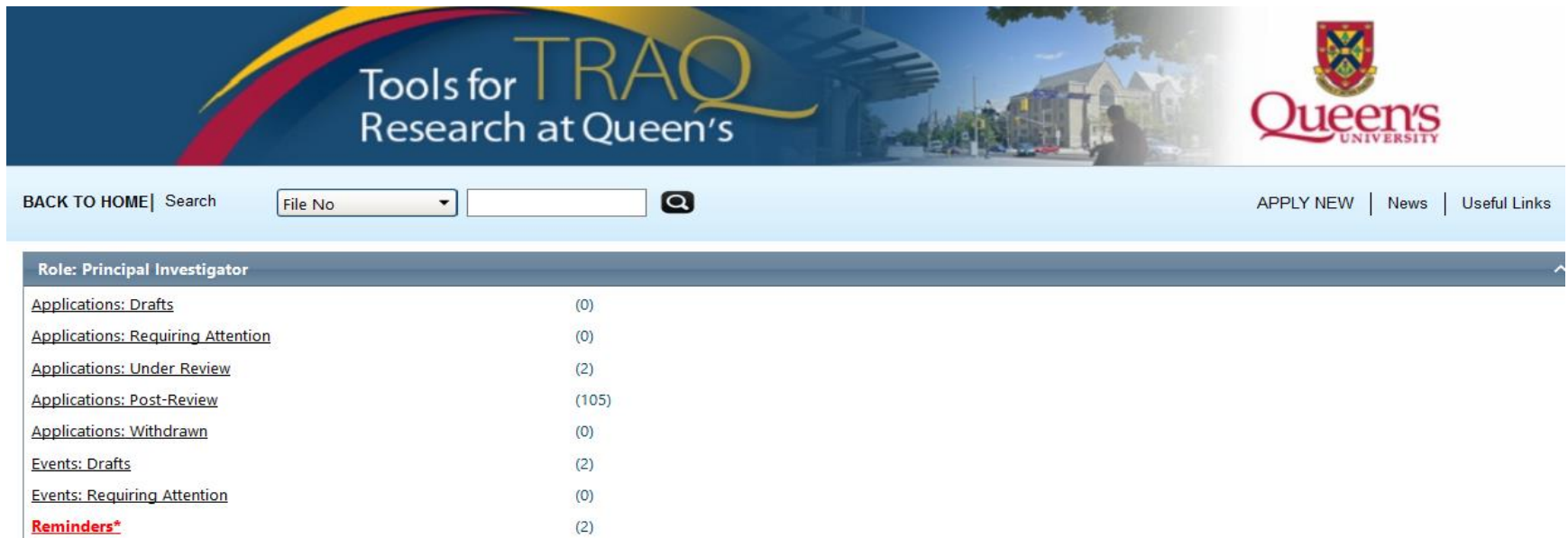
NEW – Changes to the Event Workflow

- **NEW:** The PI and project team members will receive a confirmation email after:
  - submitting an event;
  - an event is returned to the project team for revision;
  - an event is re-submitted by the PI or a project team member.

- **NEW:** An event will be returned to the research team if revisions are requested by University Research Services – Ethics office.

- **NEW:** An event may be re-submitted after the event has been revised.

- **NEW:** An event that has been started, but not submitted, may be opened directly from the home page by clicking **Events: Drafts.** Prior to the upgrade, an event that started but not submitted was only accessible by locating the file from the Applications: Post Review link on the Research Portal homepage and then clicking the Events button. Now there is a direct link to the saved event.

Event Forms

- Event Forms allow researchers to request amendments to their active ethics studies. advice about change in the study team, submit annual renewals, study closure or report Serious Adverse Events (SAEs) or protocol deviations.

- Event Forms are available through the Researcher's Portal, accessible through Researcher Portal/MyQueensU/Solus, for Queen's faculty and staff. External users who do not have a Queen's email address (i.e. KGH, HDH, Providence Care, Gmail, Hotmail, Sympatico, etc.) will log into the Researcher's Portal through the Post-Registration/Students and External Users Login Site using their full email address, as their username, and the password that has been created during registration.

- **Event Forms** may be accessed, completed submitted by any member of the project team (i.e. the PI, Co-investigator, Research Coordinator, Research Assistant, etc.).

Creating a New Event

By clicking on **Applications Post Review**, you may view all of your approved files (Biohazard/Human Ethics Certifications, and Awards files). Click on the **Events** button to the left of the applicable file to start an event for an active ethics file.

Accessing Event Forms

- There are ten Event Forms available from the Create New Event table.
  - Three events used by the GREB
  - Seven events used by the HSREB
- To create an event, click on one of the hyperlinks in the **Event Form Name** column.
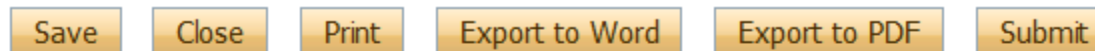
Create New Event

Event Form Name	Description
GREB (General Research Ethics Board) Event Forms	
General Research Ethics Board Annual Renewal/Closure Form for Cleared Studies	To maintain ethics clearance, applications must be renewed annually. Use this form to also close a completed/terminated/abandoned project. Form to be completed by PI or a project team member. Form updated April 2016.
General Research Ethics Board Request for the Amendment of Approved Studies	Required for changes to approved application (e.g., changes to participants, recruitment, protocols, instruments, investigators, etc.). Form to be completed by PI or a project team member.
General Research Ethics Board Adverse Event Form	Required when there is an adverse event identified by researchers, or a complainant or participant, or by the GREB/Unit REB. Form to be completed by PI or a project team member.
HSREB (Health Sciences Research Ethics Board) Event Forms	
NEW - HSREB Annual Renewal Form	This form can only be used to renew your ethics clearance annually. Ethics Clearance from the HSREB must be renewed at least once per year (TCPS2 2014, Article 6.14). If you would like to close your ethics file, submit the HSREB Study Closure Form in TRAQ.
NEW - HSREB Study Closure Form	This form is to be used to request closure of the ethics file. Study closure is defined as having no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed. The HSREB recommends that all studies remain open until a manuscript has been accepted for publication in the event that further follow up with respect to data collection is required. Once an ethics file has been closed, no further data collection, query resolution, data clarification, data transfer or contact with participants is permissible. If you require an active ethics clearance, delete this draft and submit the HSREB Annual Renewal From in TRAQ.
NEW - HSREB Amendment Form	This form should be used to communicate all changes to the ethically cleared research with the exception of adverse events and protocol deviations. Annual renewals will NOT be processed on this form. Please submit the HSREB Annual Renewal Form or HSREB Study Closure Form to provide an update regarding study status.
NEW - HSREB Change in Study Team Request Form	This form is to be used to request changes to the study team members ONLY. If study team members will be performing significant study-related duties, have access to study data, or require access to the ethics files/correspondence in TRAQ, they must be listed as a study team member within the study files and/or be listed on the ethics file. A confidentiality agreement may suffice for some roles (e.g., transcriber, statistician).
HSREB Serious Adverse Event (SAE) Form - Local	This form should be used to submit LOCAL adverse events that meet the definition of an unanticipated problem of unexpected and relations or possibly related to research participation) per HSREB SOP 410 HSREB Reporting Adverse Events posted. Refer to HSREB's website under 'Resources' to find the Multi-Event External Unexpected SAE Reporting Form if you are reporting multiple adverse events. The HSREB will no longer be accepting adverse event report submissions that do not meet the HSREB reporting criteria.
HSREB Serious Adverse Event (SAE) Form - Non-Local	This form should be used to submit NON-LOCAL adverse events that meet the definition of an unanticipated problem of unexpected and relations or possibly related to research participation) per HSREB SOP 410 HSREB Reporting Adverse Events posted. Refer to HSREB's website under 'Resources' to find the Multi-Event External Unexpected SAE Reporting Form if you are reporting multiple adverse events. The HSREB will no longer be accepting adverse event report submissions that do not meet the HSREB reporting criteria.
HSREB Protocol Deviation Form	This form should be used to report protocol deviations which are unanticipated or unintentional divergences or departures from the ethically cleared research/protocol on part of the research team. Deviations that result from participant non-compliance (i.e. they did not take medication, did not show up for a visit) do not need to be reported to the REB. Form created April 2016.

Completing an Event

- Events are short and simple to complete. Although each type of event has it's own set of questions and requirements, the process for completing and submitting any of the Awards Event Forms is the same.

- The first tab – Event Info tab – does not contain any required question. However, it may be used for any additional information to be communicated to the ethics office.
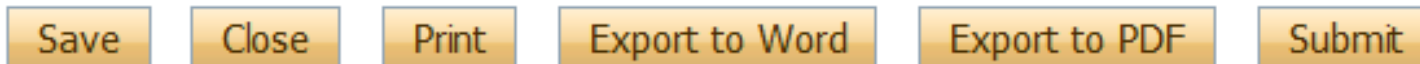
> TRAQ Tip! Remember that TRAQ does not have an *automatic save* feature. You should hit the "Save" button after completing each tab.

| Save | Close | Print | Export to Word | Export to PDF | Submit |

| Event Info | * NEW - HSREB Annual Renewal Form | Attachments | Logs | Errors |

| * 1. Study Information | * 2. Participant Information |

ℹ 1.1* If your project was suspended due to a lapse in ethics clearance outline the reason(s) for the lapse:

If not applicable enter 'N/A'.

Completing the Event Form

- Complete the form by answering all the required questions (all required questions have a red asterisk next to them) on the second tab of the Event Form (Health Sciences Research Ethics Board Annual Renewal Form for Approved Studies in the example below). Any required question left unanswered will be tracked in the Errors tab.
- The second tab may have two or more sub-tabs depending on the type of event.

| Save | Close | Print | Export to Word | Export to PDF | Submit |

| Event Info | * NEW - HSREB Annual Renewal Form | Attachments | Logs | Errors |

| * 1. Study Information | * 2. Participant Information |

ⓘ 1.1* If your project was suspended due to a lapse in ethics clearance outline the reason(s) for the lapse:
If not applicable enter 'N/A'.

Attachments Tab

- Researchers are able to attach document(s) to their Event Form. Users may upload multiple documents, provided that each individual attachment is no larger than 5MB. Attachments may be Word documents, Excel spreadsheets, JPEG files, PDFs, etc.
- To add an attachment to your Event Form, navigate to the Attachments tab, and click on the **Add Attachment** button.

You can select the document/agreement type you are attaching by using the 'Doc/Agreement' dropdown menu, or by typing a brief description of the document in the 'Description' textbox.
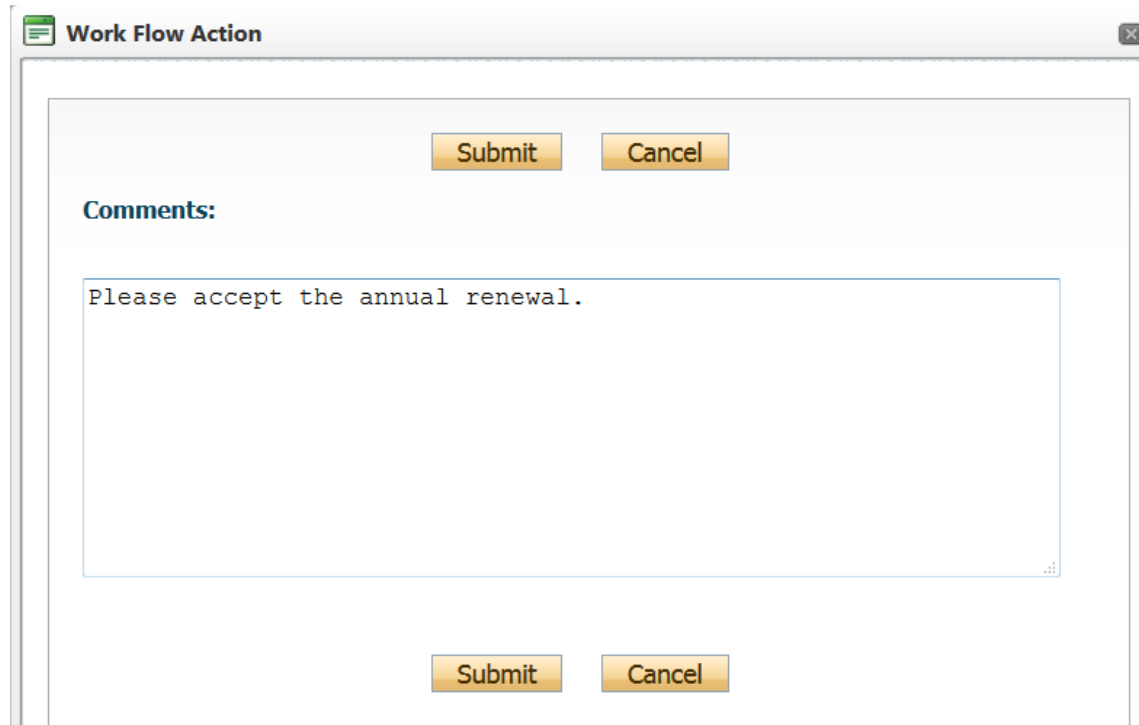
Click on "Browse" to select the document from your computer

Use the calendar icon to select the version date of your document.

Click "Add Attachment" to complete the process

Submitting the Event

- Once all the required questions have been answered, the event has been saved and the Errors tab is no longer visible, click the **Submit** button, enter a comment in the **Work Flow Action** text box (see below), and click **Submit**.
- The event is immediately forwarded to the appropriate ethics office.

Tracking the Event Form

- **NEW:** Once the event form has been submitted, it will move down to **Events: Under Review**. You will be able to view the event but will no longer be able to edit it.
- **NEW:** Events in **Drafts** will have a unique **5-digit** number preceded by the 7-digit file number.
- **NEW:** Events **Under Review** or **Post Review**, the unique event number will change to a **6-digit** number preceded by the 7-digit file number.

Research Accounting Form	Please note: This form can be prepared by a project team member but can only be submitted by the Principal Investigator. To be completed upon request from Research Accounting once the application has been approved by University Research Services. Final Budget and/or Signing Authority Form documents need to be attached to this form. You may also need to complete this form if you have received additional years of funding.
Transfer of Funds	This form can be completed and submitted by either the Principal Investigator or Research Coordinator when a PI would like to transfer funds to an external co-applicant or co-investigator. Please submit one event form for each transfer.

File No: 6018953

Project Title: SSHRC application

When the event has just been submitted, its status will be **Submitted by Researcher**.

Events: Drafts

	Event No	Event Category	Event Form	Comments	Latest Update
View Event Edit Delete	6018953 - **Ref No : 29253**	PeopleSoft Project set-up	Research Accounting Form		Researcher Queen's (traq_su) on 8/26/2016 10:33:3... [See more, inside under Logs section]

Events: Requiring Attention

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
No records to display.					

Events: Under Review

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event	6018953 - **832427**	Amendment (Amendment Form)	2016/08/29	Submitted by Researcher	Researcher Queen's (traq_su) on 8/29/2016 11:59:3... [See more, inside under Logs section]
View Event	6018953 - **832416**	Amendment (Amendment Form)	2016/08/26	Submitted by Researcher	Researcher Queen's (traq_su) on 8/26/2016 10:02:4...

Under Review - Tracking the Event Form

- Once the Event Form is under review the **Status** of the application will change from "Submitted by Researcher " to "Pending".

File No: 6018954

Project Title: HSREB application

Events: Drafts					
Events: Requiring Attention					
Events: Under Review					
	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event	6018954 - **832430**	Renewal (Health Sciences Research Ethics Board Annual Renewal Form for Approved Studies)	2016/08/30	Pending	ambrosep_awards on 8/30/2016 2:23:25 PM
Events: Post Review					
Reminders					

Events: Requiring Attention*

- **NEW:** Once the Event Form has been reviewed, the event may be sent back to the research team for revisions.
- **NEW:** If the event is sent back for revisions, the Role link will be expanded and the font for the link **Events: Requiring Attention*** will be red with an asterisk.

Tools for TRAQ
Research at Queen's

BACK TO HOME| Search   File No ▼   🔍

Role: Principal Investigator

Applications: Drafts	(0)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(55)
Applications: Withdrawn	(0)
Events: Drafts	(4)
Events: Requiring Attention*	(1)

Accessing the Event

- Click the **Events** button to the left of the file number.
- When the event is open, click **Edit** to make the requested change.

File No: 6018953

Project Title: SSHRC application

Events: Drafts					
Events: Requiring Attention					
	Event No	Event Category	Event Submission Date	Event Status	La
View Event Edit	6018953 - **832427**	Amendment (Amendment Form)	2016/08/29	Pending	an PN
Events: Under Review					
Events: Post Review					
Reminders					

Re-Submitting an Event

- Re-submitting an event is the same process as re-submitting a file.
- Click the Re-Submit button and complete the Workflow comment.

Event: Renewal   **File No:** 6018955 - **832432**
PI : Queen's Researcher
Project Title : GREB application

Event Form: General Research Ethics Board Annual Re

Save	Close	Print	Export to Word
Export to PDF		Re-Submit	

Event Info	General Research Ethics Board Annual Renewal/Closure Form for Cleared Studies	Attachments	Logs

Project status update

ℹ 1.1* Do any co-investigators need to be added or dropped? New Project Team Members must self-register in TRAQ to be added to the Queen's University non-faculty researchers must complete CORE, and a copy of the CORE certificate must be attached to the file.

○ YES
◉ NO

ℹ 1.2 If, YES above, please identify new personnel added by their name, status, department and email address or if any co-investigator dropped, just indicate their name.

Logs Tab

- The Logs tab is a useful tool that allows researchers and research administrators to track the history of the event and communicate with one another.

- The Event Workflow Log option time stamps approvals and messages. The Event Workflow Log starts to populate after the event has been submitted. Refer to the Workflow Log to review all workflow history.

Need assistance/have a question?

Contact the TRAQ Helpdesk:

- Webform: to submit an issue to the TRAQ Help Desk;
- Email: traq@queensu.ca or;
- Phone: (613) 533-6000, ext. 78426.