

## EVENT FORMS

Event forms are used for any action on a file (i.e. amendment, renewal, acknowledgement request, close out, SAE, protocol deviation, or request for operational approval) after the initial application is submitted. Event Forms can be accessed, completed and submitted by any member of the project team.

1. Accessing Event Forms: You can access Event Forms at any time under the quick link, "Applications: Post Review".



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**Role: Principal Investigator**

Applications: Drafts	(2)
Applications: Requiring Attention	(0)
Applications: Under Review	(1)
<b>Applications: Post-Review</b>	(3)
Applications: Withdrawn	(0)
Events: Drafts	(0)
Events: Requiring Attention	(0)
Reminders	(0)

**Role: Project Team Member**

**Role: Reviewer**

2. To submit an Event Form, click on the Events button beside the study you wish with to submit an event for.

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	File No	Project Title	Principal Investigator	Application Type	Status Snapshot
	[ ]	[ ]	[ ]	[ All ]	[ ]
View <b>Events</b> Close Cancel Workflow	2020548	Test 4	Dr. Sara O'Shaughnessy (Evaluation and Research Services)	Initial Application for Clinical Studies (Certification/Human Ethics)	<b>Project Status:</b> Active <b>Workflow Status:</b> Approval Decision Made

### 3. Select the Event form that corresponds to the post-approval submission

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#### Create New Event

Event Form Name	Description
Acknowledgement Request	Acknowledgement requests should be submitted in instances where the Investigator or Sponsor requires acknowledgement that the FHREB has received specific information.
Amendment Request	Use this event form to submit changes to the study procedures, documents, team members, funding, etc., after the initial approval.
Annual Renewal Request	All studies must submit an annual renewal prior to the expiry date of the approval certificate.
Protocol Deviation Request	A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda. Protocol deviations must be reported to the FHREB if they: 1) expose participants to potential increased risk; 2) compromise the integrity of the study; 3) are repetitive in nature; 4) alter participant eligibility; or 5) affect the privacy of the participant.
Study Close-Out Request	Studies in which all procedures related to human participants (including data collection) are complete may be closed out.
Local Serious Adverse Event - Initial Report	Local Serious Adverse Events that meet the definition of unanticipated problem (i.e., unexpected and related/possibly related to the investigational product or study procedures) must be reported to the FHREB.
Change in Conflict of Interest	Conflicts of interest in research are situations where someone's personal interests (financial, career, or other) could compromise or could be perceived to compromise the objective conduct of research or integrity of the data. Conflicts of interest can arise naturally from an Investigator's engagement inside and outside the Health Authority, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real, potential, and perceived COI must be recognized, disclosed, and assessed. Any changes to the conflict of interest status of the study investigators must be submitted for review.
Local Serious Adverse Event - Follow Up Report	Submit this form if new information regarding a previously reported local serious adverse event has arisen (e.g. the SAE has been resolved, etc.)

### 4. Event Info Tab: In the "Notes" sections, add any comments related to the submission, as required (e.g. if an amendment to the consent form is required by the study sponsor but the Fraser Health site is closed to requirement, indicate so here).

**Event:** Amendment    **File No:** 2020548 - **Ref No :** 11  
**PI :** O'Shaughnessy Sara (Evaluation and Research Services)  
**Project Title :** Test 4

Save    Close    Print    Export to Word    Export to PDF    Submit

Event Info    \* Amendment Request    Attachments    Logs    Errors

**Note(s)**

### 5. Complete the Event Form specific tabs. Required questions are indicated with an \*. If any required questions have been missed, an Error tab will appear listing the required questions that have been missed.

6. Upload all study documents (protocol, consent, etc.) in the Attachments tab. Attachments may be Word documents, Excel spreadsheets, PDFs, jpeg files, etc. The maximum size ROMEO allows is 5MB. For larger files, compress the file or simply break the file into pieces equal to or less than the maximum size allowable, and clearly label each piece (e.g., Part 1 of 5 – IB).
  - a. Do not attach files that include the following characters in the file name: “, # % & \* : < > ? / [ ] | ~
  - b. Do not use the period character in the middle of a file name, or at either the start or end of a file name
  - c. File names should not exceed 128 characters

**Event:** Amendment **File No:** 2020548 - **Ref No :** 11  
**PI :** O'Shaughnessy Sara (Evaluation and Research Services)  
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Save Close Print Export to Word Export to PDF Submit

Event Info \* Amendment Request Attachments Logs Errors

Add Attachment

NOTE : The maximum individual attachment size is 5MB. All attachments larger than 5MB will stall the system, and your data will be lost. However, you may upload multiple attachments, provided that each is no larger than 5MB.

7. Any member of the study team can submit an Event Form in the ROMEO portal. The PI should maintain a delegation of authority log for the study indicating which team members have been delegated responsibility for this task.
8. Tracking the Event Form: To check the status of the Event Form, click “Applications – Post Review” and then click on “Events”. Event Forms that were started and saved, but not submitted will appear under “Events: Drafts”. 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.

9. Event Status: Once submitted, the Event Status is marked as “Submitted by Researcher”. After it is assigned for review by the FHREB, the status will be updated to “Pending”.


**File No: 2020548**

Principal Investigator: Dr. Sara O'Shaughnessy

Project Title: Test 4

Events: Drafts				
	Event No	Event Category	Event Form	Comments
<a href="#">View Event</a> <a href="#">Edit</a> <a href="#">Delete</a> <a href="#">Latest Workflow</a>	2020548 - Ref No : 11	Amendment	Amendment Request	
Events: Requiring Attention				
Events: Under Review				
	Event No	Event Category	Event Submission Date	Event Status
<a href="#">View Event</a> <a href="#">Latest Workflow</a>	2020548 - 3475	Amendment (Amendment Request)	2021/08/09	Submitted by Researcher
Events: Post Review				
Reminders				

10. Event Forms – Requiring Attention: If the Event Form requires clarifications or revisions, it will be returned by the REB Office to the research team and can be found under “Events: Requiring Attention”.

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Role: Principal Investigator	
<a href="#">Applications: Drafts</a>	(2)
<a href="#">Applications: Requiring Attention</a>	(0)
<a href="#">Applications: Under Review</a>	(1)
<a href="#">Applications: Post-Review</a>	(3)
<a href="#">Applications: Withdrawn</a>	(0)
<a href="#">Events: Drafts</a>	(0)
<b><a href="#">Events: Requiring Attention*</a></b>	(1)
<a href="#">Reminders</a>	(0)
Role: Project Team Member	
Role: Reviewer	

11. Navigate to the event and Click the Edit button to view the Modifications Memo in the Event Attachments tab and make any required changes to the submission. Once the required changes/clarifications have been addressed, click “Re-Submit” button at the top of the screen to send the Event back to the FHREB for review.
12. If the Event is approved, the Event Status will change to “Approved” and the study team will be notified via a confirmation email. The certificate of approval will be visible in the Event Attachments tab. The Event will now be in the “Events: Post-Review” section of the application.

**File No: 2020548**

Principal Investigator: Dr. Sara O'Shaughnessy  
Project Title: Test 4

Events: Drafts				
Events: Requiring Attention				
Events: Under Review				
Events: Post-Review				
	Event No.	Event Category	Event Submission Date	Event Status
<a href="#">View Event</a> <a href="#">Latest Workflows</a>	2020548 - 3495	Amendment (Amendment Request)	2021/08/13	Approved
<a href="#">View Event</a> <a href="#">Latest Workflows</a>	2020548 - 3464	New Approval Process (N/A)	2021/07/29	Active

13. Reminders: Reminders will show you the upcoming due dates of any Milestones (e.g. expiry dates for the certificate of FHREB Approval, 6-month deadlines to respond to modification requests by the FHREB, etc.). Dates in yellow are those coming due. Those in red are past due.