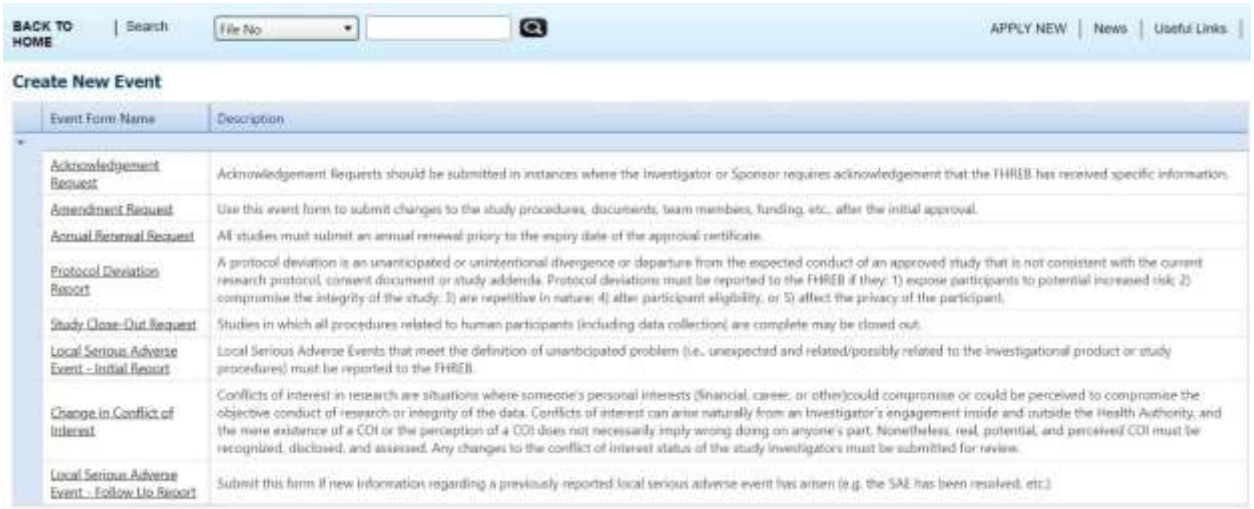
EVENT FORMS

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.

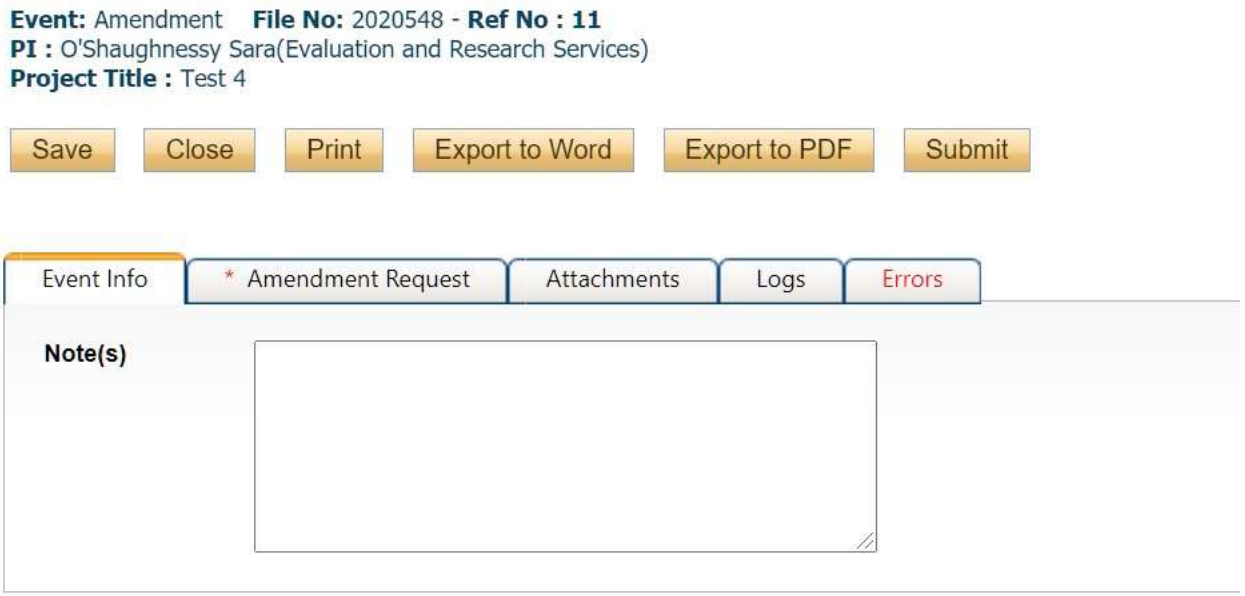
1. Accessing Event Forms: You can access Event Forms at any time under the quick link, "Applications: Post Review".

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

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

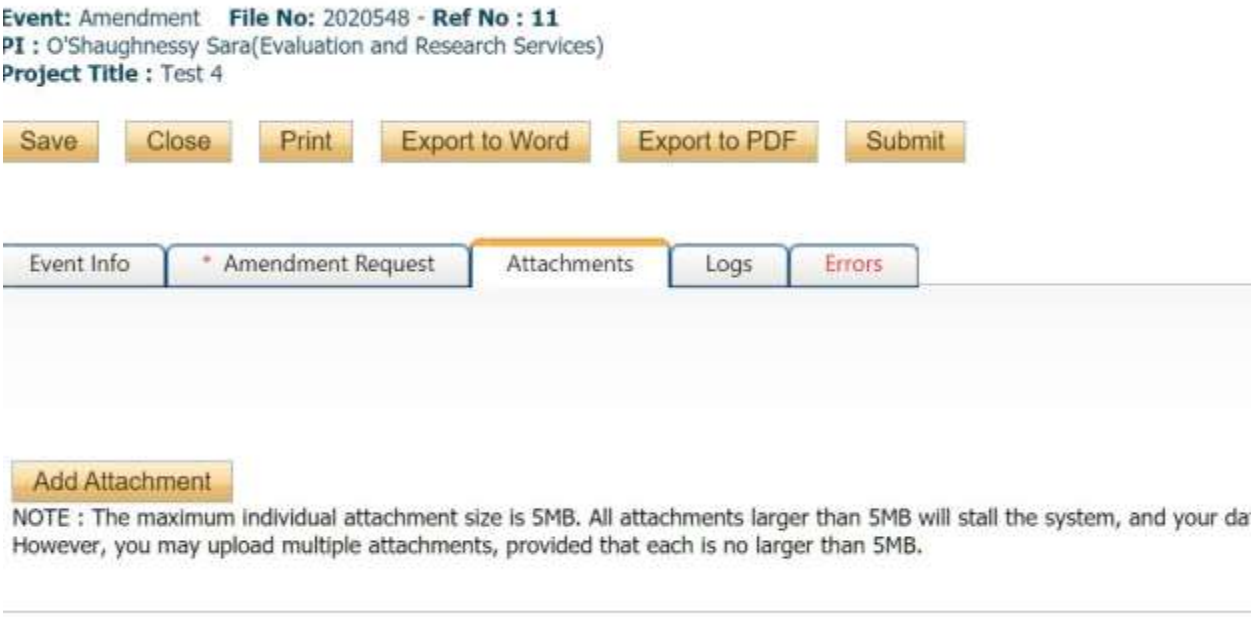


4. Event Info Tab: In the "Notes" sections, add any comments related to the submission, as required (e.g. if an amendment to the consent form is required by the study sponsor but the Fraser Health site is closed to requirement, indicate so here).



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 he middle of a file name, or at either the start or end of a file name
    c. File names should not exceed 128 characters

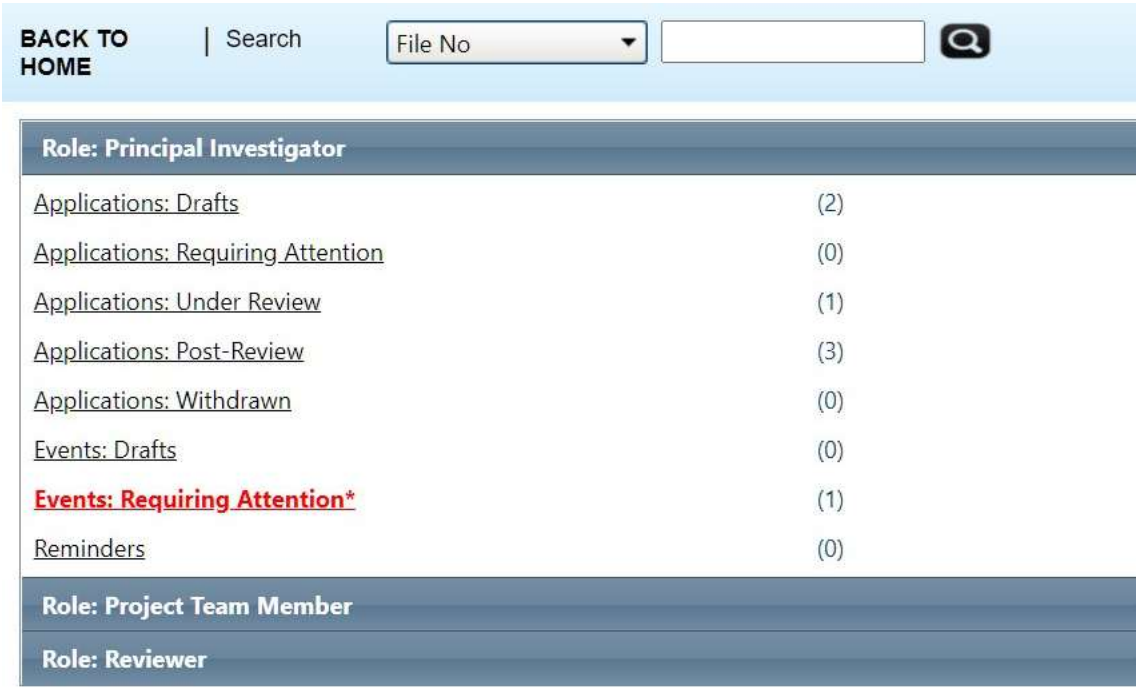


7. Any member of the study team can submit an Event Form in the ROMEO portal. The PI should maintain a delegation of authority log for the study indicating which team members have been delegated responsibility for this task.

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”.

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”.



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.

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.