Submit Unanticipated Event Form for an approved application on RAIS

Basic navigation for users creating and submitting an unanticipated event form for research ethics application approved on Research Administration Information System (RAIS). Additional resources for users are available in <u>RAIS login and support page</u>.

Instructions for creating and submitting an unanticipated event form for harmonized application, approved on the Provincial Research Ethics Platform (PREP) start on page 5 of this guidance document

	Instructions	Screenshot
i	 Note for Faculty Supervisors of Student Researchers & Post-doctorial Fellows for Capstone Projects, Theses & Dissertations. Only faculty members, adjunct professors or sessional instructors as Principal Investigators (PI) can start an unanticipated event form. Once the PI has started the unanticipated form the added Principal Applicant (student researcher, or post-doctoral fellow), or team members with "View and Edit" permissions, will have access to the application in order to complete it. Only the PI has the option to submit the unanticipated form for review. VPN Requirements: If you are accessing RAIS off-campus connect to Virtual Private Network (VPN). Otherwise, you will be taken to a white screen with an error message. 	
1	You can access UVic- RAIS through <u>RAIS</u> <u>login & Support</u> page.	 How to access RAIS 1. Log in to RAIS P using your NetLink ID and password. 2. Access from off-campus requires use of the UVic VPN. If your personal computer or laptop is not connected to the VPN, you'll get a white screen with no instructions.

	Instructions	Screenshot
2	From the "Human Ethics" page select the application you need to submit the unanticipated event form for.	Home Funding Human Ethics human ethics RESEARCHER

	Instructions	Screenshot
3	Once in the Project Page select the "Unanticipated event" When initiated, the unanticipated event form can be found under the "Post- approval activity (PAA)" tab. You should now be able to edit the	POST-APPROVAL ACTIVITY (PAA) ~ Amendments Annual renewal Mith amendments Ompletion Unanticipated event Unanticipated event MISTORY POST-APPROVAL ACTIVITY (PAA) MEB RESPONSES SUBMISSIONS
	to the amendment.	ID PAA type PAA status Last status View/ change Edit app
		02 Event Pre-submission Feb. 22, 2022, 9:07 a.m.

	Instructions	Screenshot
4	Completing the "Summary" first (see instructions at the top of the summary form). Then go to relevant sections under "Application" to make the changes.	Summary + Unanticipated events Not started Application + A. Research team Complete + B. Project information Complete Submit report Submit report Exit report
5	Save your work as each section is completed.	 I. Instructions 1. Complete the "Description of the unanticipated event" section 2. Submit II. Description of the unanticipated event Image: Save as in progress Save as complete

	Instructions	Screenshot	
6	Once all the changes are made you as the PI will have the option to submit the report, save the information and/or exit the report. You can return to it later by going to the "Post-Approval Activity (PAA)" tab.	Summary + Unanticipated events Application + A. Research team Complete + B. Project information Complete ✓ Submit report Exit report	0
	NOTE: Post-Approval Activity (PAA) tab contains all actions related to your post- approval application	HISTORY POST-APPROVAL ACTIVITY (PAA) HREB RESPONSES SUBMISSIONS	
		Post-approval activities (PAA) on the application.	
		ID PAA type PAA status Last status View/ change Edit app	
	(amendment,	02 Event Pre-submission Feb. 22, 2022, 9:07 a.m.	
	etc.) such as View/Edit, Download PDF, Withdraw, etc.		

Instructions for submitting the Unanticipated event report form on the Provincial Research Ethics Platform – PREP (harmonized studies)

	Instructions	Screenshot
1	Go to PREP: https://www.rise.ubc. ca/ and login with your Campus Wide Login credentials. Select the application you want to submit the event form for. (The RISE/PREP guide will have more detailed instructions on starting the acknowledgement form on RISe/PREP)	My Inbox Conflict of Interest Human Ethics Animal Care Biosafety Radiation Safety This folder contains all of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as well as Post Approval Activities (i.e. amendments, renewals, requests for acknowledgements) the results of your Human Ethics applications as your Human E
2	Click on the "New Post Approval Activity" action button to start the PAA.	Create: Changes Required Changes Required Cha
2	From the list of post- approval activities, select "Request for Acknowledgment" option to start completing the form.	 Annual Renewal with Amendments to the Study (UBC BREB, UBC CREB and C&W REB studies only) Amendments to Study Completion of Clinical Study Completion of Behavioural Study Request for Acknowledgement Response to Request for Information (RFI) Clear

	Instructions	Screenshot
3	Under the "Nickname" field make sure you put the following: "Unanticipated event report"	* Nickname Enter a nickname for this PAA. What would you like this PAA to be known as to the Principal Investigator and study team? (If you are notifying the REB of a protocol deviation or an unanticipated event or local serious adverse event please include the words "protocol deviation" or "unanticipated event" or "local SAE" as applicable in the nickname) Unanticipated event report
4	In the meantime, complete UVic's " <u>Unanticipated event</u> form" in MS Word format and add it as an attachment to section 1.b of the "Request for Acknowledgement"	 1.B. DOCUMENTS Attach documents for this submission. The filenames you enter when attaching documents will appear "AS IS" on the REB Acknowledgement Certificate. + Add Title There are no items to display
5	Once you reach the end of the coversheet, click "Continue" to be taken to the PAA homepage.	End of PAA Coversheet - PAA + Click "Continue" to save and close the PAA Coversheet. You will automatically be taken to the PAA Homepage.
6	In the PAA homepage you have the option to submit the PAA form or edit it further. Only the PI has the option to submit the form for review.	Current State Pre Submission Edit PAA Coversheet Activities Pr Submit PAA Pr Inactivate PAA