



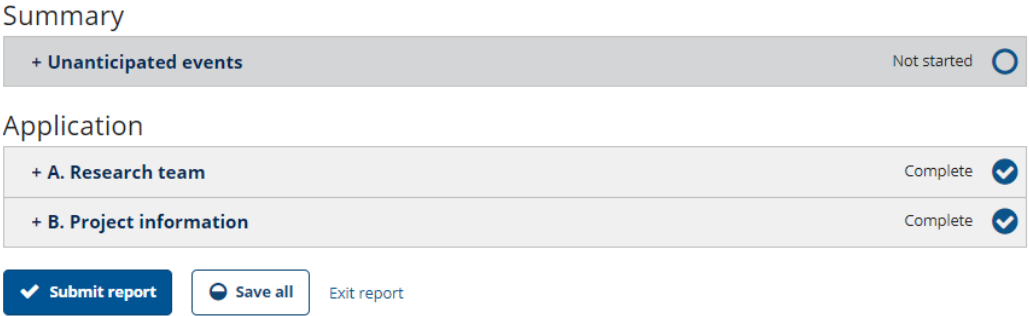
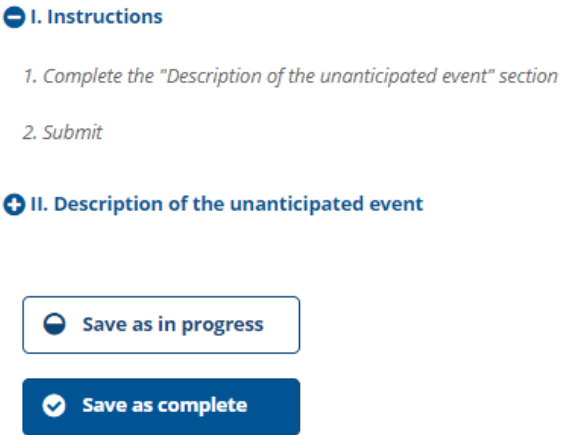
Submit Unanticipated Event Form for an approved application on RAIS

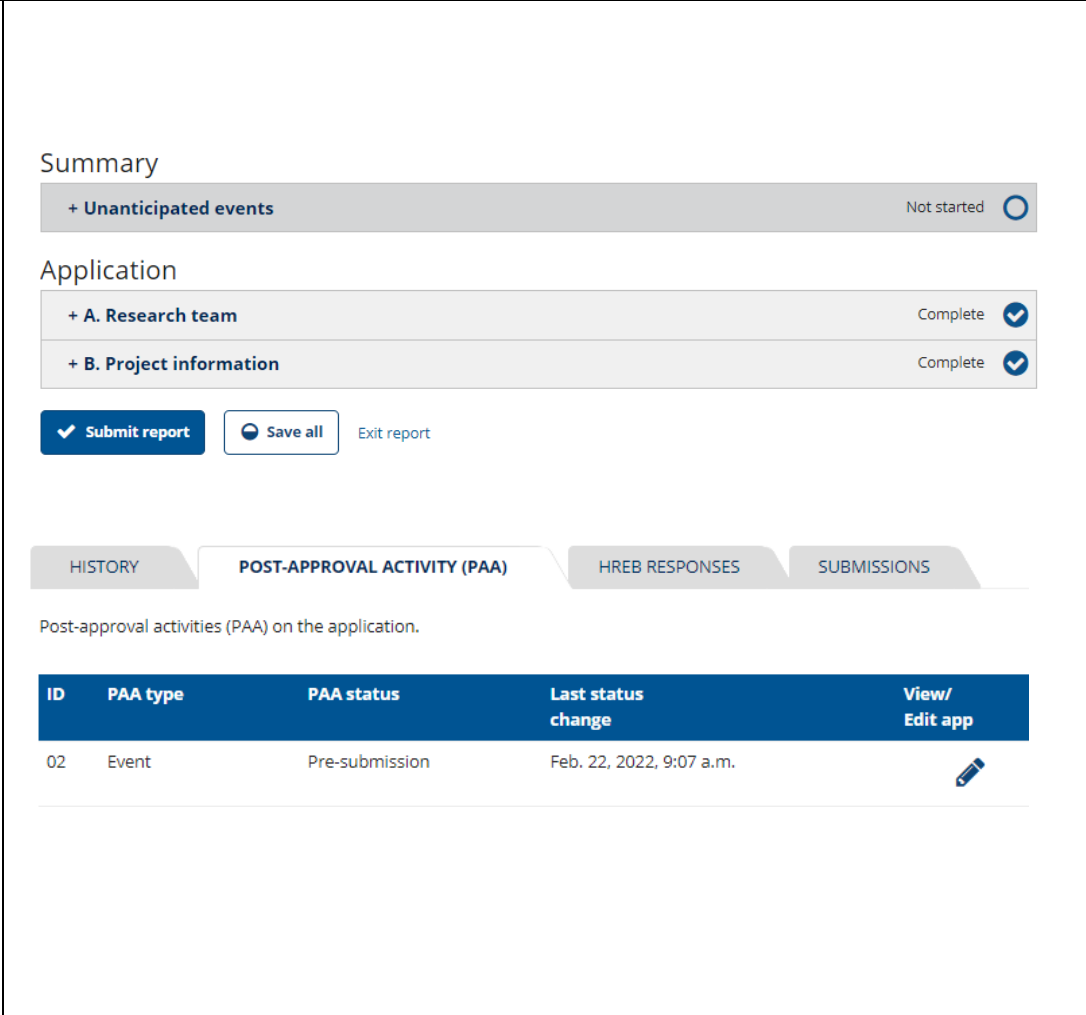
This quick guide describes basic navigation for users creating and submitting an unanticipated event form for research ethics application that was approved within the Research Administration Information System (RAIS). Additional resources for users are available at: www.uvic.ca/userais.

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

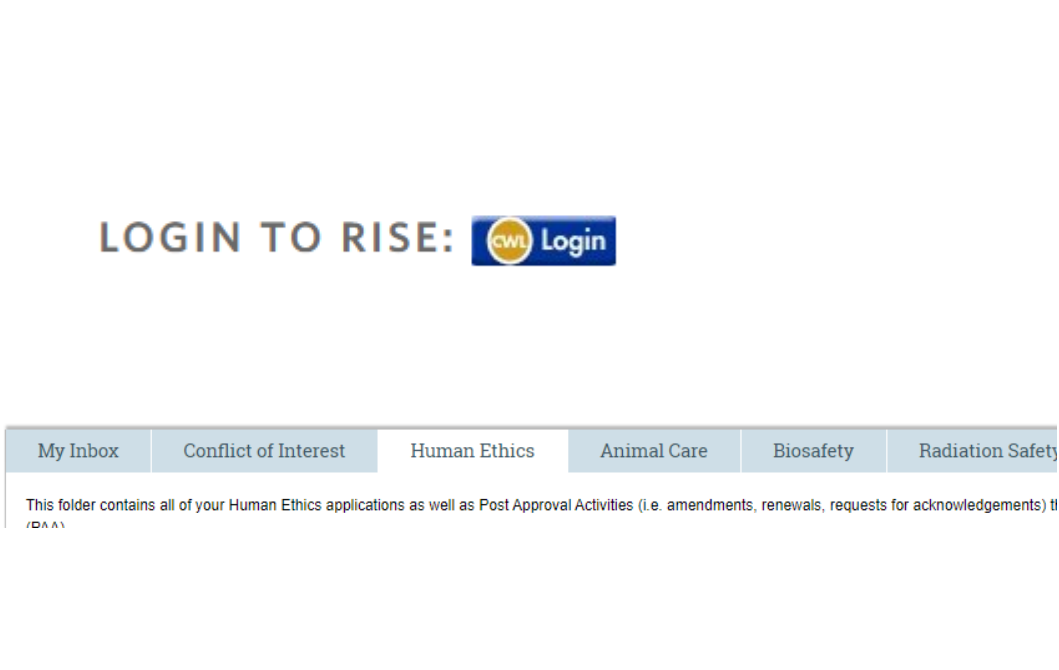

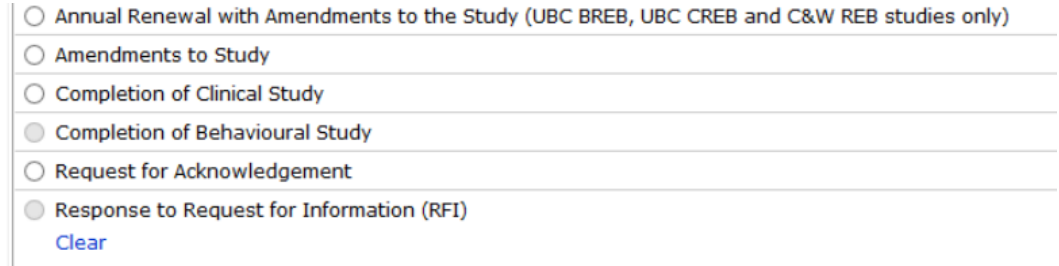
	Instructions	Screenshot
!	<p>Note for Faculty Supervisors of Student Researchers & Post-doctorial Fellows for <u>Capstone Projects, Theses & Dissertations</u>.</p> <p><i>Only faculty members, adjunct professors or sessional instructors as Principal Investigators (PI) can start an unanticipated event form.</i></p> <p><i>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.</i></p> <p><i>Only the PI has the option to submit the unanticipated form for review.</i></p> <p><u>VPN Requirements:</u></p> <p><i>If you are accessing RAIS off-campus make sure that your device is connected to Virtual Private Network (VPN). Otherwise, you will be taken to a white screen with an error message.</i></p>	

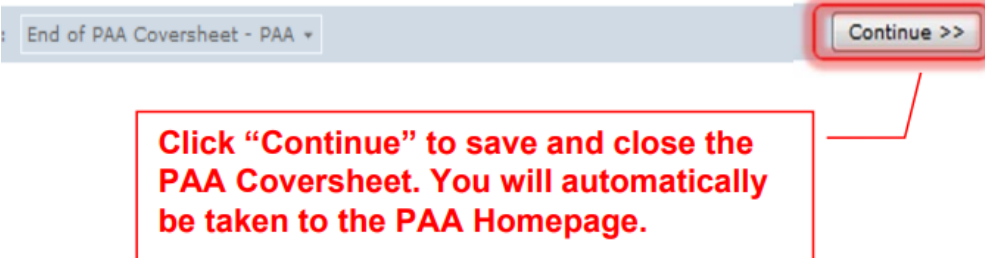
	Instructions	Screenshot									
1	<p>You can access UVic-RAIS through RAIS Support and Human Research Ethics websites.</p> <p>Click on the big blue button located in the right hand corner of the page.</p>										
2	<p>Log-in with your Netlink ID and password:</p> <p>From Home Page select the application you want to make changes to.</p>	<table border="1"> <thead> <tr> <th>ID</th> <th>Title</th> <th>Type</th> </tr> </thead> <tbody> <tr> <td>21-0063</td> <td>HREB orientation 2021</td> <td>Standard</td> </tr> <tr> <td>21-0061</td> <td>test</td> <td>Anonymized</td> </tr> </tbody> </table>	ID	Title	Type	21-0063	HREB orientation 2021	Standard	21-0061	test	Anonymized
ID	Title	Type									
21-0063	HREB orientation 2021	Standard									
21-0061	test	Anonymized									
3	<p>Once in the Project Page select the "Unanticipated event"</p>										

	Instructions	Screenshot
4	Start by completing the "Summary" first (see instructions at the top of the summary form).	 <p>Summary</p> <p>+ Unanticipated events Not started <input type="radio"/></p> <p>Application</p> <p>+ A. Research team Complete <input checked="" type="checkbox"/></p> <p>+ B. Project information Complete <input checked="" type="checkbox"/></p> <p><input checked="" type="button" value="Submit report"/> <input type="button" value="Save all"/> Exit report</p>
5	Remember to Save your work as needed.	 <p>I. Instructions</p> <p>1. Complete the "Description of the unanticipated event" section</p> <p>2. Submit</p> <p>II. Description of the unanticipated event</p> <p><input type="button" value="Save as in progress"/></p> <p><input checked="" type="button" value="Save as complete"/></p>

	Instructions	Screenshot										
6	<p>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.</p> <p>You can return to it later by going to the “Post-Approval Activity (PAA)” tab.</p> <p>NOTE: Post-Approval Activity (PAA) tab contains all actions related to your post-approval application (amendment, renewal, completion, etc.) such as View/Edit, Download PDF, Withdraw, etc.</p>	 <p>The screenshot displays the 'Post-Approval Activity (PAA)' tab of an application interface. At the top, there are sections for 'Summary' (with a '+ Unanticipated events' button and 'Not started' status) and 'Application' (with '+ A. Research team' and '+ B. Project information' buttons, both marked 'Complete'). Below these are buttons for 'Submit report', 'Save all', and 'Exit report'. A navigation bar shows 'HISTORY', 'POST-APPROVAL ACTIVITY (PAA)', 'HREB RESPONSES', and 'SUBMISSIONS'. The main content area is titled 'Post-approval activities (PAA) on the application.' and contains a table with the following data:</p> <table border="1"> <thead> <tr> <th>ID</th> <th>PAA type</th> <th>PAA status</th> <th>Last status change</th> <th>View/ Edit app</th> </tr> </thead> <tbody> <tr> <td>02</td> <td>Event</td> <td>Pre-submission</td> <td>Feb. 22, 2022, 9:07 a.m.</td> <td></td> </tr> </tbody> </table>	ID	PAA type	PAA status	Last status change	View/ Edit app	02	Event	Pre-submission	Feb. 22, 2022, 9:07 a.m.	
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Instructions for submitting the Unanticipated event report form on the Provincial Research Ethics Platform – PREP (harmonized studies)

	Instructions	Screenshot
1	<p>Go to PREP: https://www.rise.ubc.ca/ and login with your Campus Wide Login credentials.</p> <p>Select the application you want to submit the event form for.</p> <p>(The RISE/PREP guide will have more detailed instructions on starting the acknowledgement form on RISE/PREP)</p>	
2	<p>Click on the “New Post Approval Activity” action button to start the PAA.</p>	
2	<p>From the list of post-approval activities, select “Request for Acknowledgment” option to start completing the form.</p>	

	Instructions	Screenshot		
3	Under the "Nickname" field make sure you put the following: "Unanticipated event report"	<p>* Nickname</p> <p>Enter a nickname for this PAA. What would you like this PAA to be known as to the Principal Investigator and study team?</p> <p>(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)</p> <input data-bbox="500 470 1179 512" type="text" value="Unanticipated event report"/>		
4	In the meantime, complete UVic's " Unanticipated event form " in MS Word format and add it as an attachment to section 1.b of the "Request for Acknowledgement"	<p>1.B. DOCUMENTS</p> <p>Attach documents for this submission. The filenames you enter when attaching documents will appear "AS IS" on the REB Acknowledgement Certificate.</p> <div data-bbox="500 758 1511 877"> <input type="button" value="+ Add"/> <table border="1"> <thead> <tr> <th>Title</th> </tr> </thead> <tbody> <tr> <td>There are no items to display</td> </tr> </tbody> </table> </div>	Title	There are no items to display
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.			
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.	