

## RESEARCHER MANUAL

### SUBMITTING A RESEARCH ETHICS UNANTICIPATED PROBLEM FORM

Please submit a Research Ethics Unanticipated Problem Form (Event Form) when you need to report an unanticipated problem that increased the level of risk to participants or has other ethical implications. Minor deviations from the approved research project do not require immediate reporting to the REB, and may be summarized and submitted through an Amendment Form at the time of Annual Renewal or Study Closure.

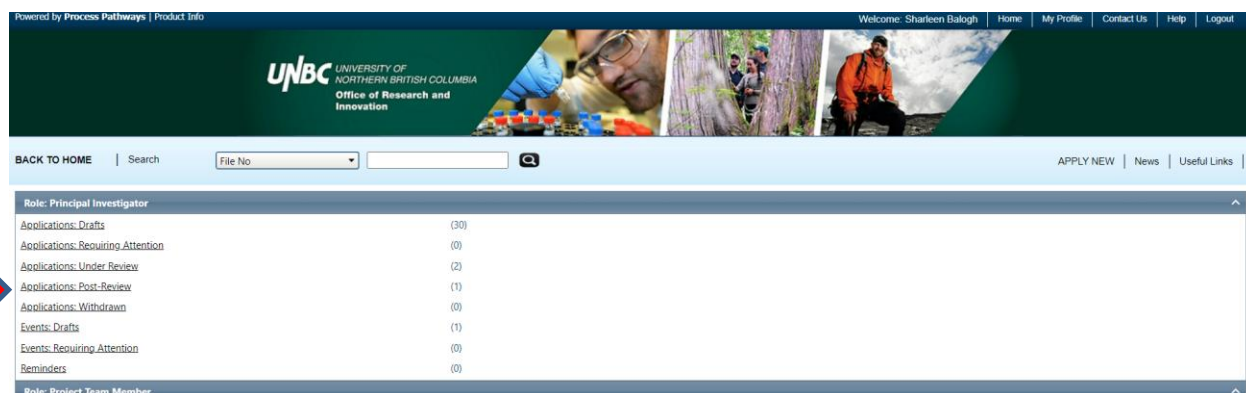
Please note: Romeo is compatible with Internet Explorer, Firefox, Microsoft Edge, Google Chrome and Safari. If you have any problems or questions, please contact the Office of Research and Innovation at [research@unbc.ca](mailto:research@unbc.ca).

1. To access Romeo, go to <https://unbc.researchservicesoffice.com> and click on “Research Portal” (see below). You will also find a link to ROMEO along with self-help and reference materials on the UNBC Office of Research and Innovation website ([https://www2.unbc.ca/office-research-and-innovation/romeo-research-portal#Romeo\\_Forms](https://www2.unbc.ca/office-research-and-innovation/romeo-research-portal#Romeo_Forms)). This link will take you directly to the login page (Step 2).



2. Login using your UNBC credentials (username@unbc.ca) and password. If you do not have a Romeo account, contact the Office of Research and Innovation at [research@unbc.ca](mailto:research@unbc.ca). You may be required to verify your identity with the mobile device “Authenticator” app or MFA Hardware Token issued by UNBC ITS to verify your identity, so please ensure that you have this available when you login.

3. The Research Ethics Unanticipated Problem Form can be accessed as an event form. To access event forms, click on the “**Applications: Post-Review**” link on your Romeo home page (see below).



You will be brought to a screen (similar to the one below), which lists your previous applications, and the options available for each application. Click on the “**Events**” button next to the relevant application.

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	File No	Project Title	Principal Investigator	Application Type	Status Snapshot
View   Clone   <b>Events</b>   Latest Workflow	[ ]	[ ]	[ ]	All	[ ]
		Test application	Ms. Sharleen Balogh (Office of Research and Innovation)	Research Ethics New Application Form (Certification)(Human Ethics)	<b>Project Status:</b> Pending Revisions by Researcher <b>Workflow Status:</b> Approval Decision Made

A screen will open (similar to the one below), which lists all of the available event forms for that application. Click on the “**Research Ethics Board Unanticipated Problem Form**” to open it.

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Create New Event

Event Form Name	Description
<a href="#">Research Ethics Board Amendment Form</a>	In cases where the nature and/or the extent of the proposed modifications are substantial, such that the changes result in a study that deviates substantially from the originally approved study or previous modified study, the REB reserves the right to require that a new application form be submitted.
<a href="#">Research Ethics Board Unanticipated Problem Form</a>	Any unanticipated problem that increases the level of risk to participants or has other ethical implications should be reported to the REB without delay. Changes that need to be made to reduce or eliminate immediate risk(s) to participants are to be implemented, followed by a report to the REB at the earliest opportunity. Minor deviations from the approved research project do not require immediate reporting to the REB, and may be summarized and submitted at the time of Annual Renewal, or Study Closure through an Amendment Form. If you would like to speak with a member of the board, or the board Chair regarding this problem please call 250-960-6735. Conversations can be of immediate support and assurance. The Form will still need to be completed in due course.
<a href="#">Research Ethics Board Annual Renewal and Study Progress Form</a>	This form must be submitted at least a week before the date of expiry listed on the latest approval letter. If your study is complete, please fill out the 'Study Closure Form' instead. If you have changes to be reviewed for this study, they will need to be recorded on an Amendment Form and submitted separate from the 'Annual Renewal and Study Progress Form'. The processes for a renewal or an amendment have been separated.
<a href="#">Research Ethics Board Study Closure Form</a>	This form must be submitted to close your REB approved study once it has concluded. If the date of expiry listed on your initial approval letter is approaching and your study is not yet complete, please submit an 'Annual Renewal and Study Progress Form'.

4. You will be brought to a screen similar to the one below. Under the “**Event Info**” tab, you can enter general comments and notes in the “**Note(s)**” text box (red arrow below). Click “**Save**” before moving to the next tab (blue arrow below). At any time, you can save your application and continue working on it at a later time. It is always good practice to save your application before changing tabs or leaving the application for an extended period of time.

Event: Unanticipated Problem | File No: 6009230 - Ref No: 2438  
PI: Wilson Tracy (Office of Research and Innovation)  
Project Title: Testing Romya

Event Form: Research Ethics Board Unanticipated Problem Form

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

Event Info | **Research Ethics Board Unanticipated Problem Form** | Attachments | Logs | Errors

Note(s)

[ ]

5. Proceed to the “**Research Ethics Board Unanticipated Problem Form**” tab. This tab includes event-specific questions to assess the nature of the unanticipated problem. Answer the questions on the “**Study State**”, “**Unanticipated Problem - Description**”, “**Unanticipated Problem – Occurrence(s)**”, and “**Unanticipated Problem - Mitigation**” sub-tabs (red rectangle below).

NOTE: fields marked with a red asterisk (\*) are mandatory, but please answer all questions relevant to your event form submission.

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 PI : Wilson Tracy(Office of Research and Innovation)  
 Project Title : Testing Romeo

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Event Info Research Ethics Board Unanticipated Problem Form Attachments Logs Errors

\* 1. Study Date \* 2. Unanticipated Problem - Description \* 3. Unanticipated Problem - Occurrence(s) \* 4. Unanticipated Problem - Mitigation

1.1\* What is the status of participant recruitment for this study?  
 (State if the Unanticipated Problem to be reported has caused, for example, Active recruitment to be paused, Recruitment is ongoing, Recruitment was complete, with participants engaged in another stage of the study, etc. Please describe.)

1.2\* Provide a brief summary of the progress of the study up to the time of the problem.  
 (Include whether the study was proceeding as planned and at what stage it has reached at the time of the problem. Maximum 200 Words.)

6. Proceed to the “**Attachments**” tab. This tab allows you to upload any related attachments. Click the “**Add Attachment**” button at the bottom of the page to attach documents (red arrow below).

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Add Attachment

NOTE : The maximum individual attachment size is 10MB. All attachments larger than 10MB will stall the system, and your data may be lost. However, you may upload multiple attachments, provided that each is no larger than 10MB.

A pop-up window will open. To upload an attachment, click the “**Browse**” button (red arrow below). Enter a **Description**, if applicable. Enter the date of submission as the “**Version Date**”. Under the “**Doc Agreement**” pull-down menu, select the type of document you are uploading (Information Letter, Consent Form, Research Proposal, etc.). Click on “**Add Attachment**” (blue arrow below).

Upload Attachment

Description:

Upload Attachment: Browse

Allowed File Types:  
 (png, jpg, png, doc, docx, xls, xlsx, txt, pdf, ppt, pptx, zip, epub, mobi)

Version Date:

Doc Agreement: --Select One--

Add Attachment Cancel

Click “**Save**” to save the information on this page.

7. **“Logs”** tab. There is no information to be entered in this section. You can toggle between **“Event Workflow Log”** and **“Event Log”** (red rectangle below) to see where your application is at in the approval process and to see any log activity.

Event: Unanticipated Problem    File No: 6099230 - Ref No : 2438  
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Project Title : Testing Romeo

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Event Info   \* Research Ethics Board Unanticipated Problem Form   Attachments   Logs   Errors

☒ Event Workflow Log   ☐ Event Log

Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
No records to display.					

8. **“Errors”** tab. This section will show you where there are errors in your application form. All errors must be corrected before you are able to submit your application.

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Research Ethics Board Unanticipated Problem Form -> 1. Study State:1.1 What is the status of participant recruitment for this study? is required.  
Research Ethics Board Unanticipated Problem Form -> 1. Study State:1.2 Provide a brief summary of the progress of the study up to the time of the problem. is required.  
Research Ethics Board Unanticipated Problem Form -> 2. Unanticipated Problem - Description:2.1 Is the problem unexpected in terms of nature, severity, or frequency? is required.  
Research Ethics Board Unanticipated Problem Form -> 2. Unanticipated Problem - Description:2.2 As PI, in your opinion is the unanticipated problem related to the study intervention? is required.  
Research Ethics Board Unanticipated Problem Form -> 2. Unanticipated Problem - Description:2.4 Has the type of unanticipated problem occurred in this or a related study, to your knowledge? is required.  
Research Ethics Board Unanticipated Problem Form -> 3. Unanticipated Problem - Occurrence(s):3.1 State when the unanticipated problem occurred. is required.  
Research Ethics Board Unanticipated Problem Form -> 3. Unanticipated Problem - Occurrence(s):3.3 State when the research team became aware of the problem. is required.  
Research Ethics Board Unanticipated Problem Form -> 3. Unanticipated Problem - Occurrence(s):3.4 How did the research team become aware of the problem is required.  
Research Ethics Board Unanticipated Problem Form -> 3. Unanticipated Problem - Occurrence(s):3.5 What action, if any, has been taken or is proposed to be taken by the research team (or others) to reduce any occurrences of future unanticipated problems of this nature? is required.  
Research Ethics Board Unanticipated Problem Form -> 3. Unanticipated Problem - Occurrence(s):3.6 What adverse outcome(s) has occurred, or is expected for the participant(s)? is required.  
Research Ethics Board Unanticipated Problem Form -> 4. Unanticipated Problem - Mitigation:4.1 Describe the current status of those affected by the unanticipated problem to your knowledge at the time. is required.  
Research Ethics Board Unanticipated Problem Form -> 4. Unanticipated Problem - Mitigation:4.2 Describe what follow-up mitigations you recommend for study participants? is required.  
Research Ethics Board Unanticipated Problem Form -> 4. Unanticipated Problem - Mitigation:4.3 Have any members of the research team been in communication with the participants since the research team has been aware of the unanticipated problem? is required.

9. **Final Processes.** Click to **“Save”** the information entered in your application. You can also choose to **“Print”**, **“Export to Word”**, or **“Export to PDF”** your application.

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10. When you are ready, click to **“Submit”** your Unanticipated Problem Form to the Office of Research and Innovation.

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Notes(s)