

## RESEARCHER MANUAL

### SUBMITTING A RESEARCH ETHICS AMENDMENT FORM

Please submit a Research Ethics Amendment Form (Event Form) when you need to make changes to an approved Research Ethics application.

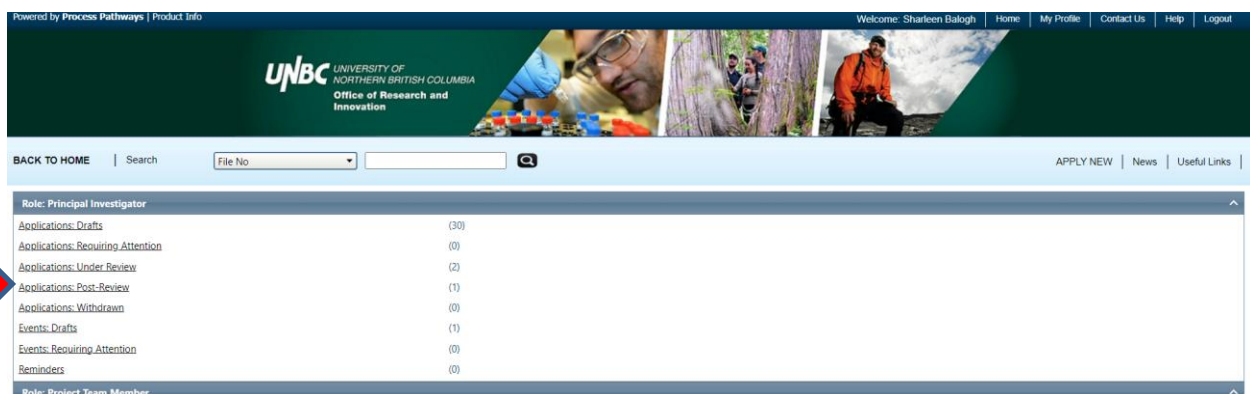
Please note: Romeo is compatible with Internet Explorer, Firefox, Microsoft Edge, Google Chrome and Safari. If you have any problems or questions, please contact the Office of Research and Innovation at [research@unbc.ca](mailto:research@unbc.ca).

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).

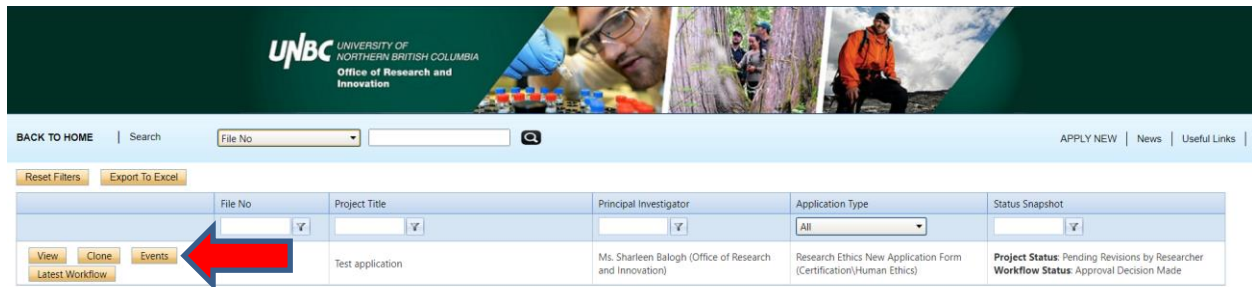


2. Login using your UNBC credentials (username@unbc.ca) and password. If you do not have a Romeo account, contact the Office of Research and Innovation at [research@unbc.ca](mailto:research@unbc.ca). You may be required to verify your identity with the mobile device “Authenticator” app or MFA Hardware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

3. The Research Ethics Amendment 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.



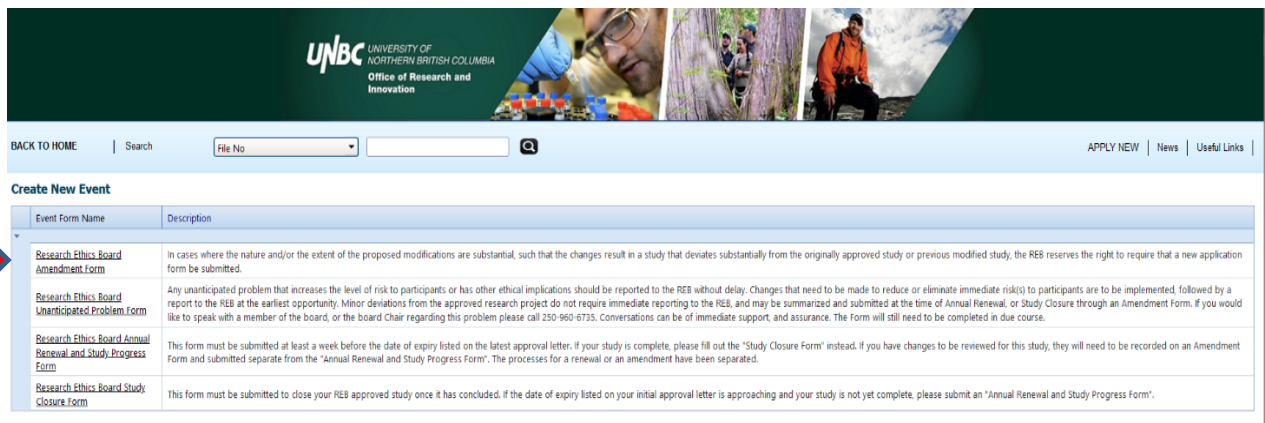
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Reset Filters | Export To Excel

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



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Create New Event

Event Form Name	Description
<b>Research Ethics Board Amendment Form</b>	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.
Research Ethics Board Unanticipated Problem Form	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.
Research Ethics Board Annual Renewal and Study Progress Form	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.
Research Ethics Board Study Closure Form	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: Amendment | File No: 6009230 | Ref No: 2426  
PI: Wilson Tracy (Office of Research and Innovation)  
Project Title: Testing Romeo

Event Form: Research Ethics Board Amendment Form

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

Event Info | **Research Ethics Board Amendment Form** | Attachments | Logs | Errors

Note(s)

[ ]

5. Proceed to the “Research Ethics Board Amendment Form” tab. This tab includes event-specific questions to assess the nature of amendment request. Answer the questions on the “Research Team”, “Project Funding”, “Project Information and Progress”, and “Requested Study Modifications” 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.

Event: Amendment File No: 6009230 - Ref No: 2426  
 PI: Wilson Tracy (Office of Research and Innovation)  
 Project Title: Testing Tumor

Event Form: Research Ethics Board Amendment Form

Save Close Print Export to Word Export to PDF Submit

Event Info \* Research Ethics Board Amendment Form Attachments Logs Errors

\* 1. Research Team \* 2. Project Funding \* 3. Project Information and Progress \* 4. Requested Study Modifications

1.1 If there is or will be a new Principal Investigator, or the Principal Investigator's contact information has changed, please provide the name and all contact information below

1.2 Have there been, or are there changes to be made to the members of the research team, or to their primary contact information since the last REB approval?  
 Please ensure all changes to the Research Team made since the last REB approval, or to be made through this Amendment Form, are outlined in this Tab's responses.

☐ Yes  
☐ No

6. Proceed to the “**Attachments**” tab. This tab allows you to upload all required attachments. Support documents that are modified from the originally approved version need to have all modifications identified by **highlighting** and **underlining** new text, and using **strike through** for text that is to be removed. Document footers are to be updated with the new document creation date, and version number, that corresponds to the version number of the document file name. Ensure that all documents are named using a consistent and informative naming convention. Please also "check" all that apply from the document list on the tab. Click the "**Add Attachment**" button at the bottom of the page to attach all updated support documents (red arrow below).

Event: Amendment File No: 6009230 - Ref No: 2426  
 PI: Wilson Tracy (Office of Research and Innovation)  
 Project Title: Testing Tumor

Event Form: Research Ethics Board Amendment Form

Save Close Print Export to Word Export to PDF Submit

Event Info \* Research Ethics Board Amendment Form Attachments Logs Errors

Please use "Add Attachment" button at the bottom of this page to attach all necessary support documents for your Research Ethics Amendment Form application. Support documents that are modified from the originally approved version need to have all modifications identified by **highlighting** and **underlining** new text, and using strike through for text that is to be removed. Document footers are to be updated with the new document creation date, and version number, that corresponds to the version number of the document file name. Ensure to use a consistent and informative naming convention for each document file name.

**Documents that pertain to your study may include:**  
 TCPS2 CORE Certificate (required for all undergraduate and graduate student researchers engaged in human participant research); Other REB approvals; Consents from Aboriginal groups or organizations; Other required consents; Safe Research Plan for In-Person Research involving populations that may face increased risk of COVID-19, or communities where local policies and protocols are in place regarding the pandemic; Participant recruitment materials (e.g., posters, letters, email scripts, and media advertisements); Participant information letter(s); Participant consent form(s); Interview protocols, questionnaires, survey instruments (As per TCPS2, Article 10.5, in studies using emergent design in data collection final versions of questionnaires or interview schedules must be submitted to the REB as soon as they become available); Research assistants/transcriber confidentiality agreement(s); Research contract(s); Research proposal; Any other applicable documents.

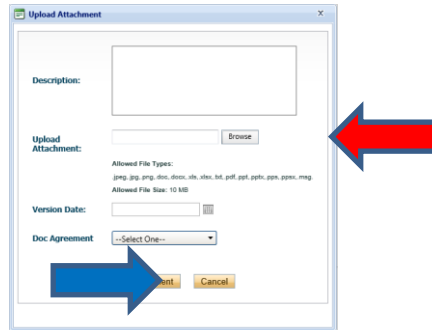
**Please refer to these Guidelines and Templates in preparing supporting documents:**

Research Risk Assessment Guidelines.pdf  
 Information Letter and Consent Form Guidelines.docx  
 Confidentiality and Non-Disclosure Agreement template.docx  
 REB Template for Amendment Application Development.docx  
 Recruitment\_Poster\_Template.docx

**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).

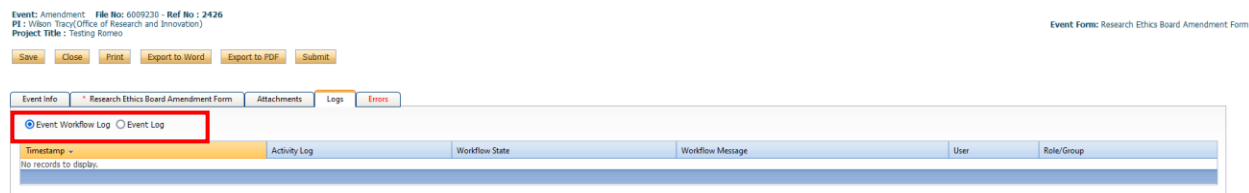


The 'Upload Attachment' window contains the following fields and buttons:

- Description:** A text area for entering a description.
- Upload Attachment:** A text input field with a **Browse** button next to it.
- Allowed File Types:** jpg, png, mp3, doc, docx, xls, xlsx, htd, pdf, ppt, pptx, docm, pptm, mpeg
- Allowed File Size:** 10 MB
- Version Date:** A date picker.
- Doc Agreement:** A dropdown menu with a **--Select One--** placeholder.
- Buttons:** **Add** (blue) and **Cancel** (orange).

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

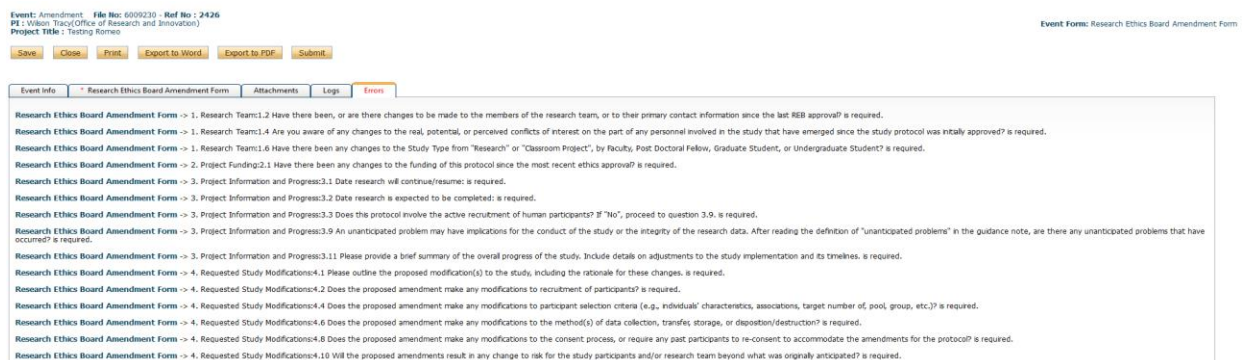
7. **“Logs”** tab. There is no information to be entered in this section. You can toggle between **“Event Workflow Log”** and **“Event Log”** (red rectangle below) to see where your application is at in the approval process and to see any log activity.



The 'Logs' tab shows the following interface:

- Event Info:** Amendment File No: 6009230 - Ref No: 2426  
PI: Wilson Tracy (Office of Research and Innovation)  
Project Title: Testing Romeo
- Event Form:** Research Ethics Board Amendment Form
- Buttons:** Save, Close, Print, Export to Word, Export to PDF, Submit
- Tabs:** Event Info, Research Ethics Board Amendment Form, Attachments, **Logs**, Errors
- Log Selection:** ☒ Event Workflow Log, ☐ Event Log
- Table:** A table with columns: Timestamp, Activity Log, Workflow State, Workflow Message, User, Role/Group. It currently shows 'No records to display.'

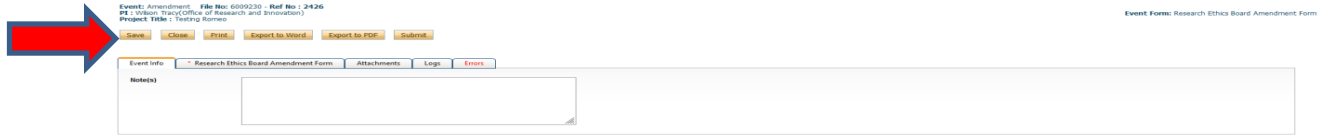
8. **“Errors”** tab. This section will show you where there are errors in your application form. All errors must be corrected before you are able to submit your application.



The 'Errors' tab displays a list of errors for the Research Ethics Board Amendment Form:

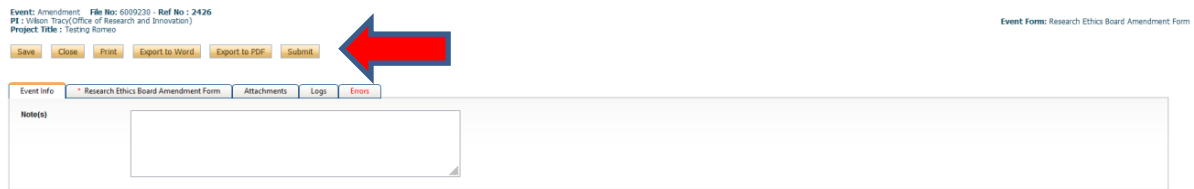
- Research Ethics Board Amendment Form -> 1. Research Team:2 Have there been, or are there changes to be made to the members of the research team, or to their primary contact information since the last REB approval? is required.
- Research Ethics Board Amendment Form -> 1. Research Team:4 Are you aware of any changes to the real, potential, or perceived conflicts of interest on the part of any personnel involved in the study that have emerged since the study protocol was initially approved? is required.
- Research Ethics Board Amendment Form -> 1. Research Team:6 Have there been any changes to the Study Type from "Research" or "Classroom Project", by Faculty, Post Doctoral Fellow, Graduate Student, or Undergraduate Student? is required.
- Research Ethics Board Amendment Form -> 2. Project Funding:2.1 Have there been any changes to the funding of this protocol since the most recent ethics approval? is required.
- Research Ethics Board Amendment Form -> 3. Project Information and Progress:3.1 Date research will continue/resume: is required.
- Research Ethics Board Amendment Form -> 3. Project Information and Progress:3.2 Date research is expected to be completed: is required.
- Research Ethics Board Amendment Form -> 3. Project Information and Progress:3.3 Does the protocol involve the active recruitment of human participants? If "No", proceed to question 3.9. is required.
- Research Ethics Board Amendment Form -> 3. Project Information and Progress:3.9 An unanticipated problem may have implications for the conduct of the study or the integrity of the research data. After reading the definition of "unanticipated problems" in the guidance note, are there any unanticipated problems that have occurred? is required.
- Research Ethics Board Amendment Form -> 3. Project Information and Progress:3.11 Please provide a brief summary of the overall progress of the study. Include details on adjustments to the study implementation and its timelines. is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.1 Please outline the proposed modification(s) to the study, including the rationale for these changes. is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.2 Does the proposed amendment make any modifications to recruitment of participants? is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.4 Does the proposed amendment make any modifications to participant selection criteria (e.g., individuals' characteristics, associations, target number of pool, group, etc.)? is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.6 Does the proposed amendment make any modifications to the method(s) of data collection, transfer, storage, or disposition/destruction? is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.8 Does the proposed amendment make any modifications to the consent process, or require any past participants to re-consent to accommodate the amendments for the protocol? is required.
- Research Ethics Board Amendment Form -> 4. Requested Study Modifications:4.10 Will the proposed amendments result in any change to risk for the study participants and/or research team beyond what was originally anticipated? 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.



The screenshot shows the top of the 'Research Ethics Board Amendment Form'. At the top left, it displays 'Event: Amendment', 'File No: 6009230', 'Ref No: 2426', 'PI: Wilson Tracy (Office of Research and Innovation)', and 'Project Title: Testing Romeo'. Below this is a row of buttons: 'Save', 'Close', 'Print', 'Export to Word', 'Export to PDF', and 'Submit'. A large red arrow points to the 'Save' button. To the right of the buttons is the text 'Event Form: Research Ethics Board Amendment Form'. Below the buttons is a tabbed interface with 'Event Info' selected, showing 'Research Ethics Board Amendment Form', 'Attachments', 'Logs', and 'Errors'. Below the tabs is a large text area labeled 'Note(s)'.

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



The screenshot shows the same form as above, but with a red arrow pointing to the 'Submit' button. The 'Event Info' tab is still selected, and the 'Note(s)' text area is visible below it.