



## IWK Research & Innovation Advancement Research Ethics

### ROMEO Researcher Portal – Amendments

Amendments should now be submitted electronically to the REB via the ROMEO Research Portal.

If you have not already logged in the ROMEO Research Portal, please refer to the '*Registering in the ROMEO Researcher Portal & Introduction to Managing Study Review Activities*' document on our [Research Ethics page](#).

To login into the ROMEO Researcher Portal [click here](#).

Tips to ensure your amendment is reviewed efficiently:

- Ensure proper logos are in place on relevant documents
- Ensure version dates are correct on updated documents
- Ensure page numbers are on documents
- Ensure the correct Investigator name is on consent forms
- Include Principal Investigator (PI) approval for the amendment
- Include a check box on consent forms for participants to indicate whether they want study results
- Provide enough information describing the amendment

Amendments can be submitted by any team member of the study. Depending on your role in the study active studies will be found under 'Applications (Submitted- Post Review)' in either 'Role: Principal Investigator' or 'Role: Project Team Member'.

The screenshot shows the ROMEO Researcher Portal interface. At the top, there is a navigation bar with the text "Welcome: Joanne Street" and links for "Home", "My Profile", "Contact Us", "Help", and "Logout". Below this, the logos for "nova scotia health authority" and "IWK Health Centre Research" are displayed. A secondary navigation bar includes "APPLY NEW", "News", "Useful Links", and "Settings".

The main content area is divided into three sections based on the user's role:

- Role : Principal Investigator**
  - Applications (Saved - Not Submitted) (8)
  - Applications (Submitted - Requiring My Attention) (1)
  - My Reminders (1)
  - Applications (Submitted - Under Review) [Click here...]
  - Applications (Submitted - Post Review) [Click here...]** (circled in red)
  - Applications (Withdrawn) [Click here...]
- Role: Project Team Member**
  - Applications (Saved - Not Submitted) (1)
  - Applications (Submitted - Requiring My Attention) (0)
  - My Reminders (0)
  - Applications (Submitted - Under Review) [Click here...]
  - Applications (Submitted - Post Review) [Click here...]** (circled in red)
  - Applications (Withdrawn) [Click here...]
- Role: Reviewer**
  - Applications Requiring Your Review as a Chair (0)

Once found, click “Events” in the first column.

The screenshot shows the ROMEO Researcher Portal interface. At the top, there are logos for Nova Scotia Health Authority and IWK Health Centre Research. Below the logos, there are navigation links: APPLY NEW, News, Useful Links, and Settings. A table of applications is displayed with columns: File No, Project Title, Principal Investigator, Application Type, Status Snapshot, and Workflow Message. The first row contains the following data: File No: 1020172, Project Title: Test Run, Principal Investigator: Dr. Joanne Street (Administration (IWK)), Application Type: IWK NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) (Certification)Human Ethics, Status Snapshot: Project Status: Active, Workflow Status: Approval Decision Made. In the first column, there are three buttons: View, Clone, and Events. The Events button is circled in red.

Once clicked it opens to the ‘Event’ page. To create a new amendment, select the ‘IWK Amendment Request’ form from the table.

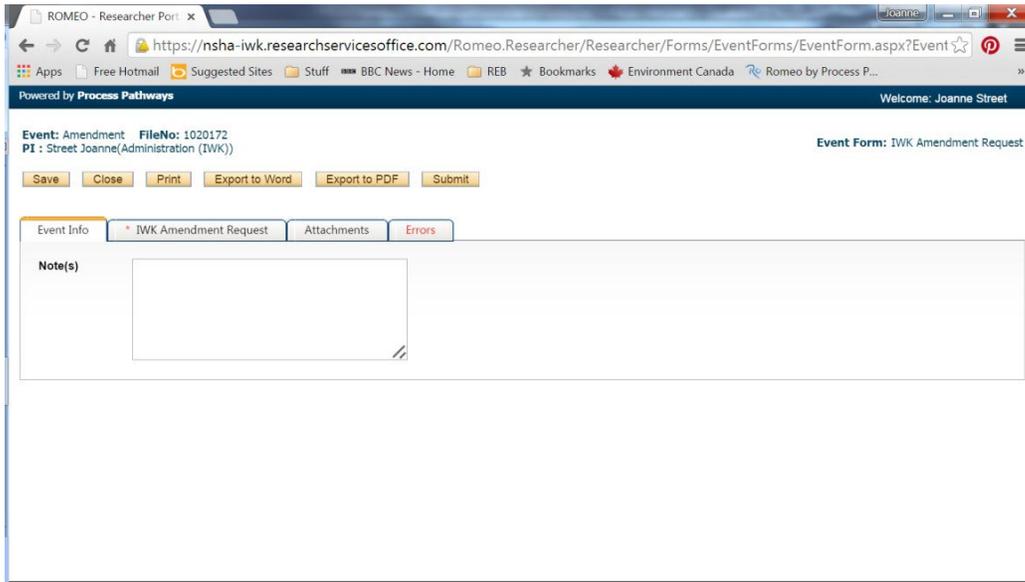
The screenshot shows the 'Create New Event' page in the ROMEO Researcher Portal. The page title is 'Create New Event'. Below the title, there is a table with two columns: Event Form Name and Description. The table contains three rows of data:

Event Form Name	Description
IWK Acknowledgement Request	Letters/notifications from the study team, sponsor, etc. that require an acknowledgement that the REB has received specific information. Examples would include: studies on placed hold, or reactivated; studies closed to accrual/enrollment, status updates, etc. Can also be used to submit external SAE Summary Tables.
IWK Amendment Request	This includes amendments to research protocols, consent forms, supporting materials and product information
IWK Annual Renewal Request	REB approval will expire on the last day of the specified approval period, normally effective for 1 year. To ensure continuing approval, an Annual Approval Request is required 4-6 weeks prior to the expiry date. If approval expires all study activities must cease immediately, and the REB may close your file.

The 'IWK Amendment Request' row is circled in red. At the bottom of the page, there is a small note: 'Minor study deviations are deviations from regulatory requirements.'

You will see four tabs to be completed.

- Event Info Tab – The note field is provided to record a brief outline of the changes made relevant to the amendment
- IWK Amendment Request Tab – This is the main application forms. All questions with a red asterisk \* must be completed
- Attachments Tab – upload any documents relevant to the amendment, for example, revised consents, protocol or other revised documents
- Errors Tab – Errors in the application will prevent Submission, click here for incomplete asterisk \* items



The electronic “form” may be created and Saved by any member of the research team. Final submission (Click “Submit”) should be done by the Principal Investigator as this serves as the PI’s electronic “signature”. If the PI is unable to complete the final “Submit” step, you may include an attachment of the PI Letter or PI supporting email indicating PI approval of the renewal request (in lieu of signature).

Once saved or submitted the amendment will be visible in the ‘Submitted Events’ (or ‘Saved Events’ as applicable). A traditional Approval Letter will be provided by mail. A copy will be scanned and uploaded, available in the attachments tab when selecting View. The Event status will then be set to “Approved”.

