nova scotia health authority

Research Ethics Board

ROMEO Research Portal User Guide

Nova Scotia Health Authority
Research Ethics Board

Researcher Coordinator's User Manual

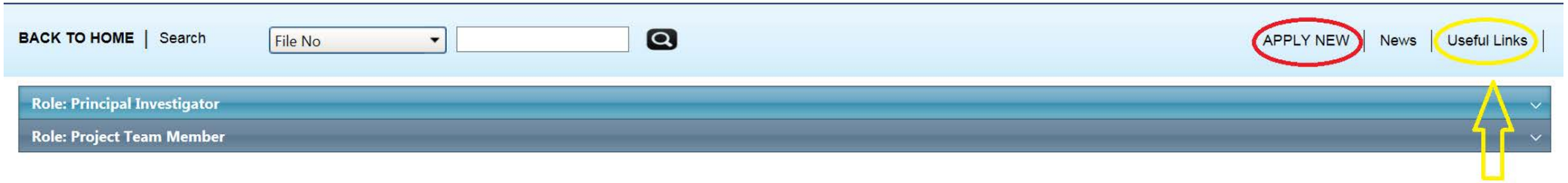
Accessing the Researcher's Portal

The Researcher's Portal is available through the Login at the following URL: http://nsha-iwk.researchservicesoffice.com/Romeo.Researcher/Login.aspx

If you are a first time user of the Researcher's Portal, you must click the 'register' button to create an account. Your username should be your primary email address. Once you have registered, you will receive an automatic email with instructions on setting up your password.

Researcher's Home Page

You are now in the Researcher's Home Page! To access the REB application forms, click on "APPLY NEW"



Researchers Should visit the "Useful Links" section every now & then for helpful tips & hints

Select the Proper Ethics Application Form (EAF)

nova scotia health authority

IWK Health Centre Research

BACK TO HOME | Search File No

APPLY NEW | News | Useful Links |

New Application Forms

All research projects being conducted in the Nova Scotia Health Authority (NSHA) and involving human participants, human biological materials (human embryos, fetuses, fetal tissue, reproductive materials, stem cells), NSHA patients, staff, resources or data are reviewed by the NSHA REB before the research begins. This applies to materials derived from living and deceased individuals.

Please read the descriptions below and select the appropriate ethics application form for your research submission.

IWK - Certifications (Human Ethics)

Application Name	Description	Status
IWK Interventional Study - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
IWK Non-Interventional Study - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open

NSHA - Certifications (Human Ethics)

Application Name	Description	Status
NSHA INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open

Project Info Tab

Application Ref No: 3549 **Project Title:** Test
Project Work Flow State: Pre-Submission

Application Form: NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)

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

Project Info | Project Team Info | * NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

Title *: Test

Start Date: 2014/07/11

End Date: 2015/10/26

Keywords: Add

Clear all

Enter your study title exactly as it appears on your research protocol.

Note: The start & end dates are used for administrative and reporting purposes and will be entered by the REB office staff.

IMPORTANT: Please note that all fields preceded by * are required. Failing to complete these fields will prevent the user from submitting the form.

Related Awards

If you are a student, please ignore this section and continue to the next tab.
If you are a non-student (e.g faculty, staff) and have applied for, or have been awarded, research funding, click **'Search'** to locate and attach the related research funding. If the related research funding is not found please ignore this section and continue to the next tab.

Search

		Award File No	Title	Award Status	PI Last Name	PI First Name	Sponsors Summary	Notes
No records to display.								

Project Team Info Tab

Project Info | Project Team Info | * NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

Change PI | Refresh

Prefix: Ms. **Last Name*:** Gillam **First Name*:** Nadine

Affiliation*: Administration (NSHA)

Project Team Info tab is automatically filled out with the logged in user's information

Rank:

Institution: QEII Health Sciences Cent

Phone1: 902-473-2126 **Phone2:**

Email*: nadine.gillam@nshealth.ca **Fax:** 902-473-5620

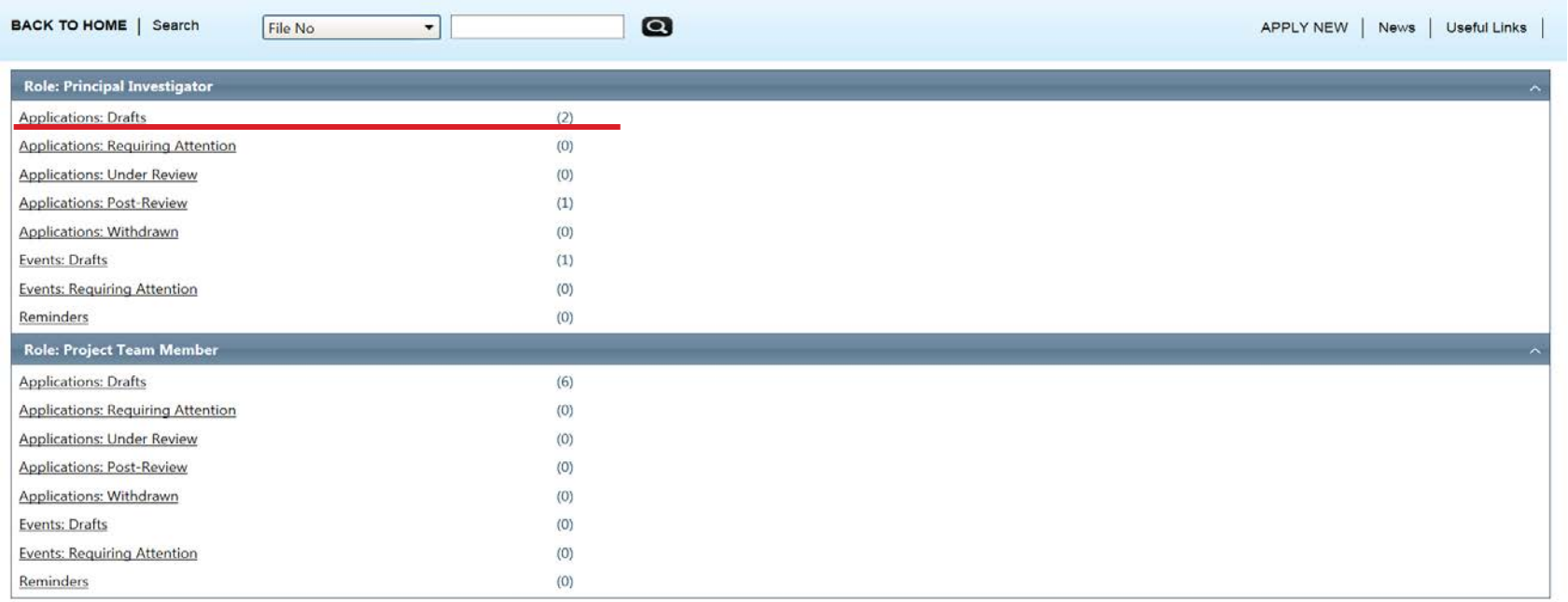
Primary Address: Rm. 118, CCR 5790 University Ave Halifax, NS B3H 1V7

Alternate Address:

Preferred Address: (•) Primary Address ( ) Alternate Address **Country:** Canada

PI Role Versus Project Team Member Role

- At this point, the applicant (person completing application on behalf of the PI) will automatically be designated as PI on the application.
- The role of the applicant from PI to Project Team Member will need to be modified to ensure the application will follow the proper process. This can be done at any point during the completion of the form.
- As long as the applicant remains PI the application will continue to be accessible from the Researcher's home page under "Role: Principal Investigator".



Project Team Info Tab

- Project Team Info tab is automatically filled out with applicant's info. To change the role of PI over to another researcher, click on "Change PI". Important: DO NOT change PI's "Last Name" and "First Name" manually – always use "Change PI" feature.

Project Info | Project Team Info | * NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

Change PI | Refresh

Prefix: Ms. **Last Name*:** Gillam **First Name*:** Nadine

Affiliation*: Administration (NSHA)

Rank:

Institution: QEII Health Sciences Cent

Phone1: 902-473-2126 **Phone2:**

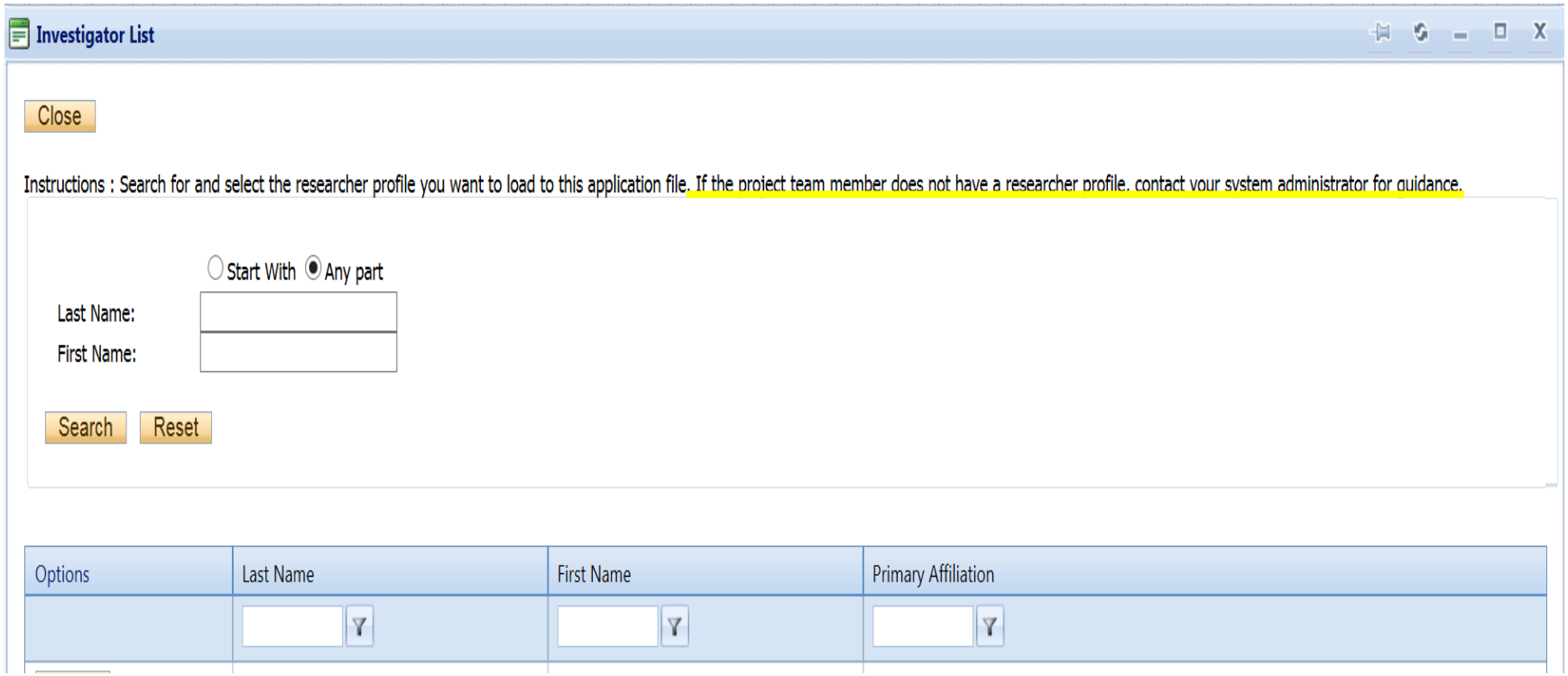
Email*: nadine.gillam@nshealth.ca **Fax:** 902-473-5620

Primary Address: Rm. 118, CCR 5790 University Ave Halifax, NS B3H 1V7 **Alternate Address:**

Preferred Address: Primary Address / Alternate Address **Country:** Canada

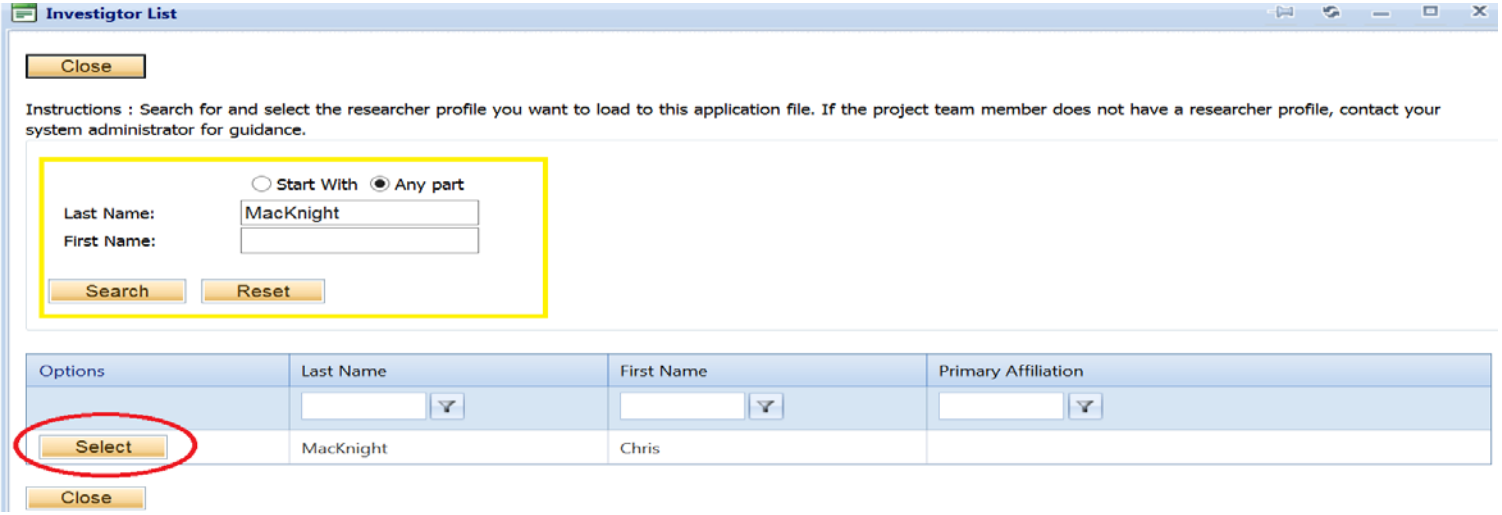
Transferring PI Role to Another Researcher

Once you click “Change PI”, you can search the Investigator List for the name of the person to be assigned as PI. The list can be searched in a variety of ways, i.e. type the last name of the person in the “Last Name” field, or use the filter to select search criteria such as “Start With” or “Any part.”



Transferring PI Role to Another Researcher

- Once you've identified your PI – click on "select".



If you are unable to identify the person you are looking for from the investigators list, please have that person register with the database by clicking on the register button on the login page. Once they have registered you will then be able to add them to the project team immediately.

Project Team Info will automatically be updated with PI's information.

Transferring PI Role to Another Researcher (cont'd)

At this point, you will also notice that the "Submit" button, previously located at the top of the form, has disappeared.

Important: the next step is to add yourself to the application as a team member. This must

Application Ref No: 3549 **Project Title:** Test
Project Work Flow State: Pre-Submission

Application Form: NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)

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

?

Project Info | Project Team Info | * NSHA NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

Change PI | Refresh

Prefix: Ms. **Last Name*:** Gillam **First Name*:** Nadine

Affiliation*: Administration (NSHA)

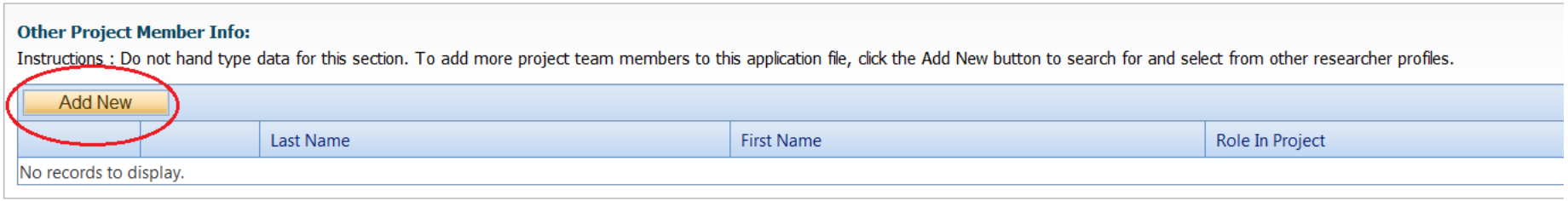
Rank:

Institution: QEII Health Sciences Cent

Phone1: 902-473-2126 **Phone2:**

Adding Team Members

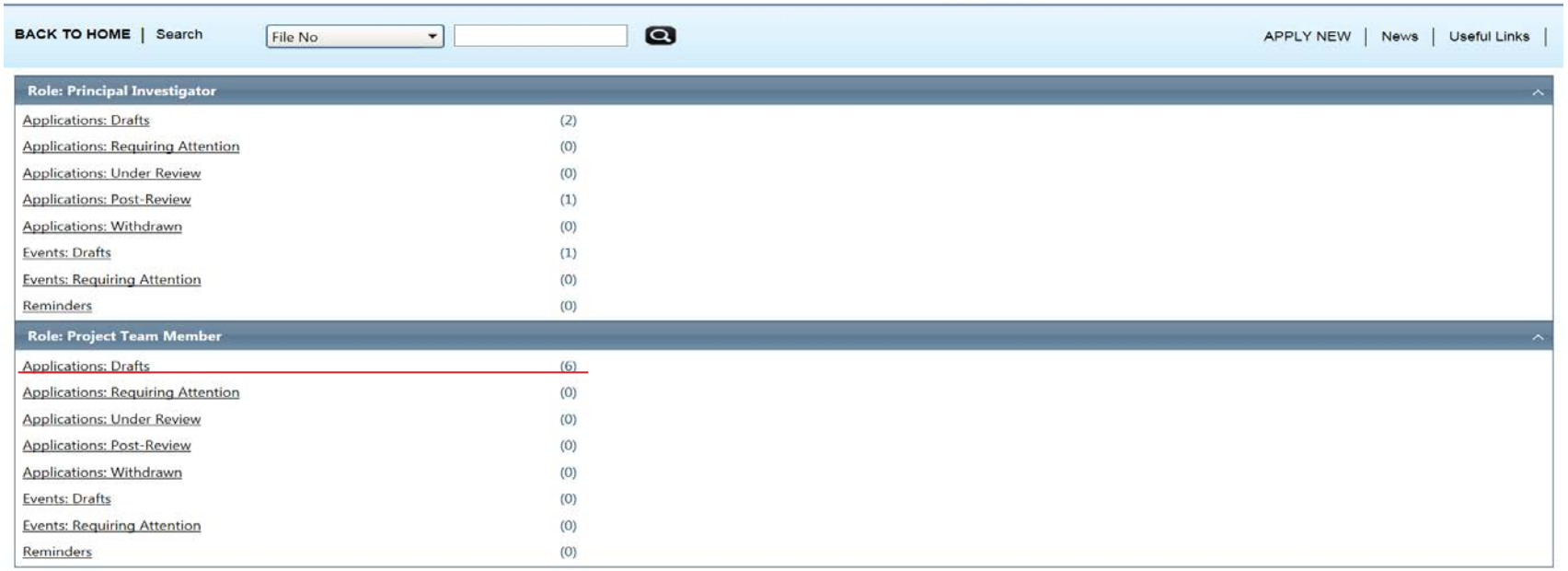
- From the Project Team Info tab, scroll down to “Other Project Member Info” and click “Add New”
- Repeat the search process, this time assigning yourself to the team and selecting your role in the study from the drop down menu under “Role In Project” data field.
- You may add as many team members as required by clicking “Add New.”



Do not hand type data for this section. Always use “Search Profiles.” If the person you are looking for is not in the list, please have that person register with the database .

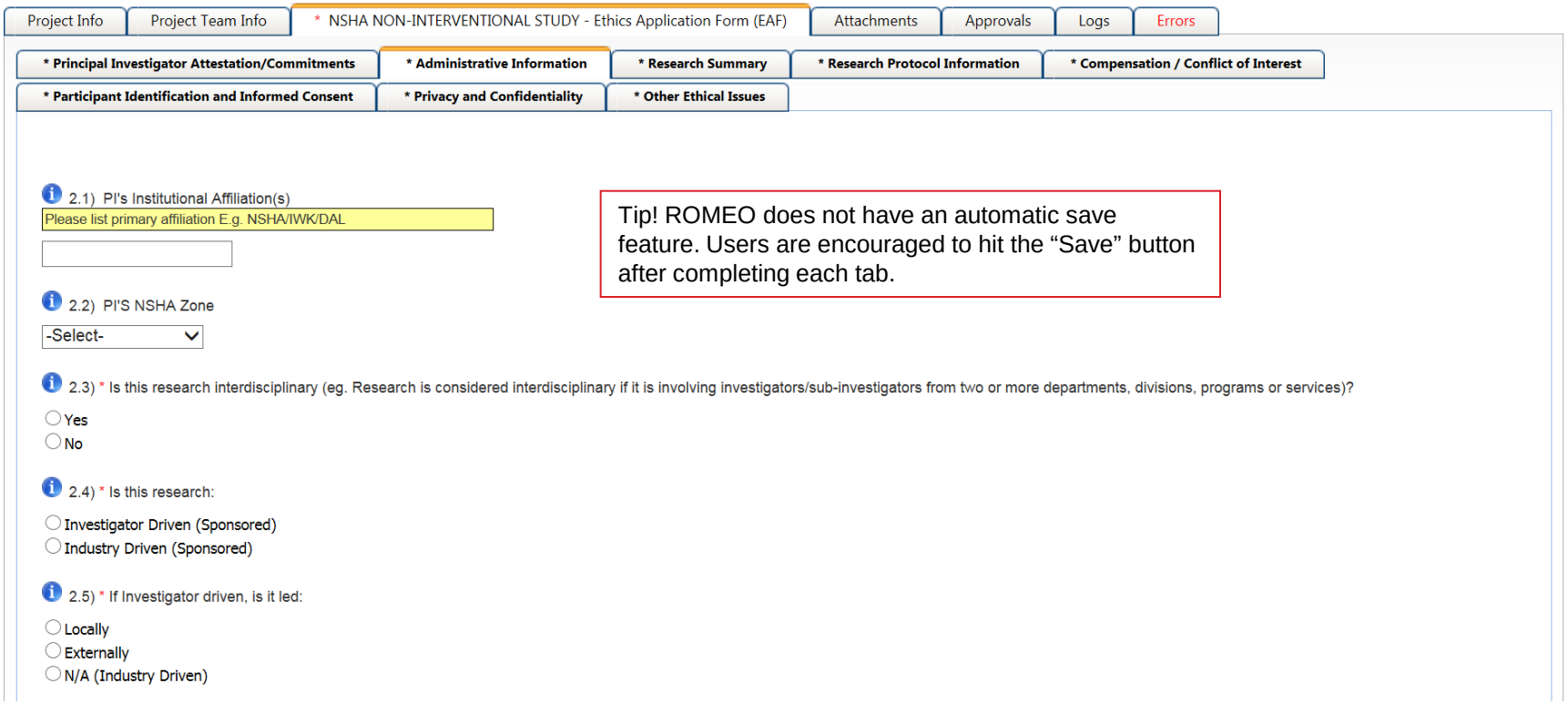
PI Role versus Project Team Member Role

- Once the change has been made on the “Project Team Info” tab, the application will be accessible to the Research Coordinator and to the other team members from the Researcher’s Home Page under “Role: Project Team Member”.
- **Important: The PI is the only person who can submit the application once it has been completed by the Research Coordinator.



Ethics Application Form (EAF) (Interventional and Non-Interventional Studies)

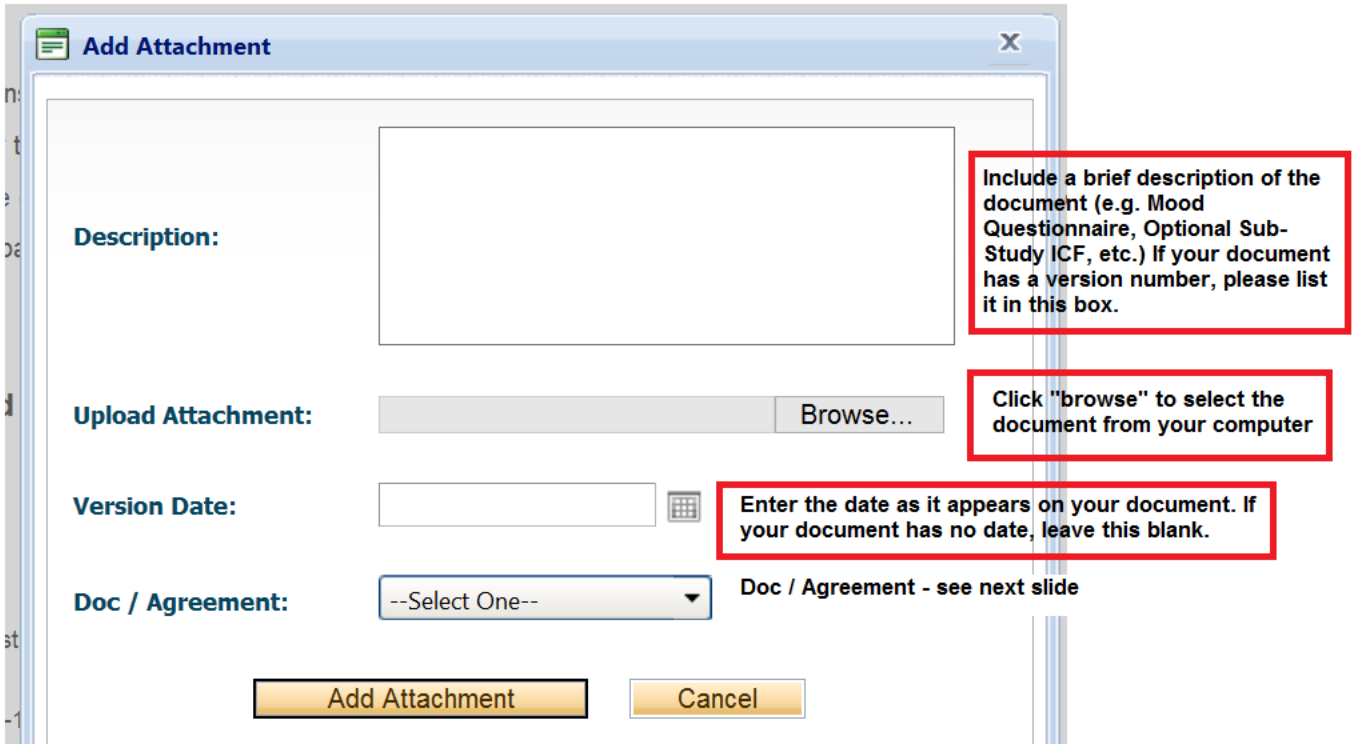
The Ethics Form(s) have several sub-tabs all of which contain required questions. If you are unsure how to answer a question, try clicking on additional information may be available as seen in the screenshot below!



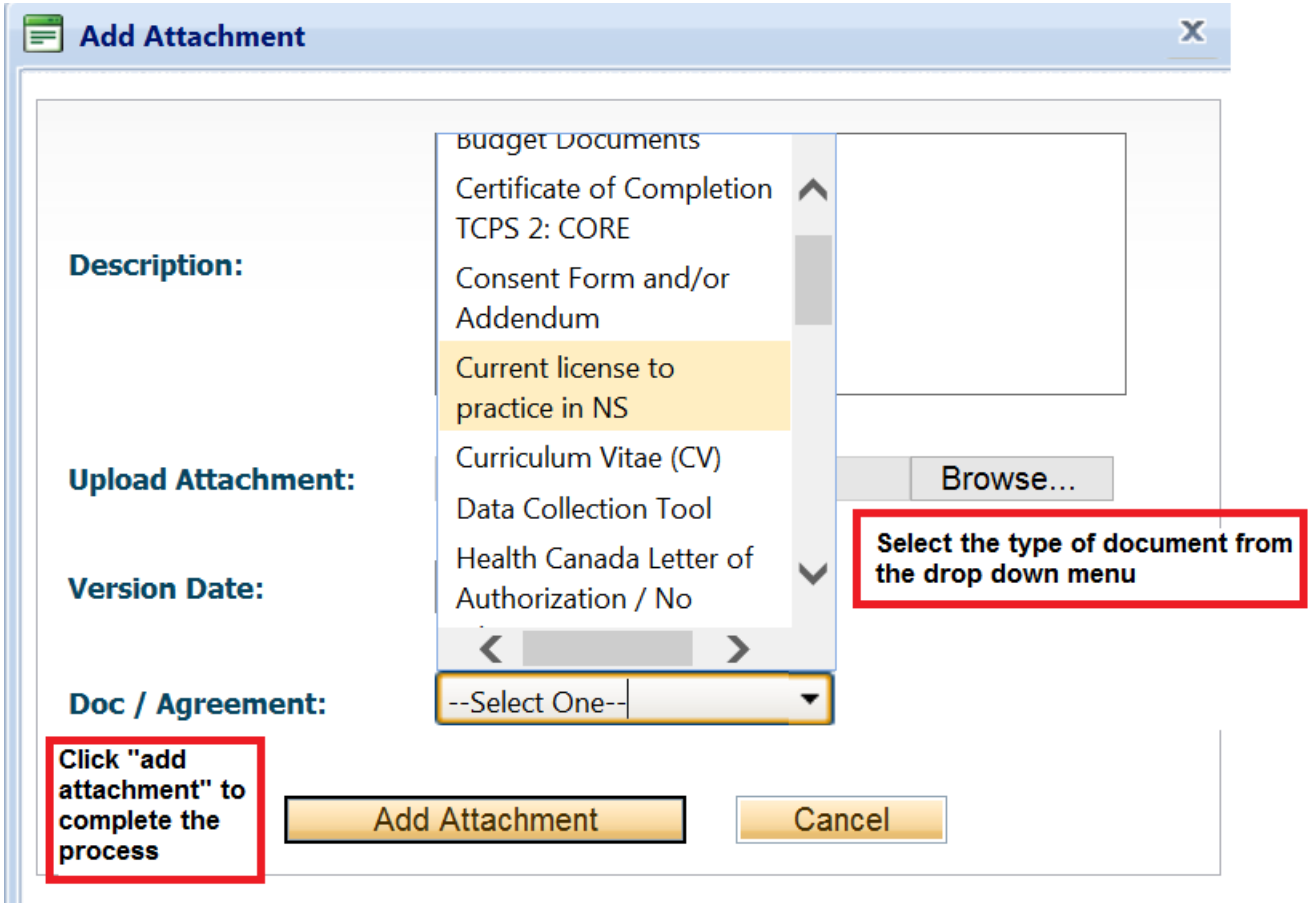
Tip! ROMEO does not have an automatic save feature. Users are encouraged to hit the “Save” button after completing each tab.

Attachments Tab

You should attach any relevant document(s) as listed on the “Attachments Tab.” Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be word files, spreadsheets, jpeg files, pdfs, etc.



Attachments Tab (cont'd)



Errors Tab

* Project Info | Project Team Info | * NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs | Errors

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions have been answered, the Errors tab will disappear from view.

Project Info ->Project Title is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.1 Is this a locally-initiated investigator-driven research study (e.g. the PI is the stud required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.3 Is the PI a trainee (e.g. student, resident, fellow)? A supervising investigator is re PI is a trainee and/or does not have a DHA/IWK affiliation. is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.4 Has funding been obtained for this study? is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.7 What does this study involve? (select all that apply) is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.8 Has this study been reviewed by a committee, department, or division of a partici institution? is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.9 Has this study been reviewed externally (e.g. by funding agencies or other acader institutions/organizations)? is required.

Save and Continue…

At any point in the process, you may “Save and Close” the application and complete it at a later date. The information entered will be saved and can be accessed again through the Researcher’s home page under “Applications: Drafts”. Important: Do not close that application by clicking the X at the top of your browser, doing so will result in the application being “locked” preventing other team members from accessing it.

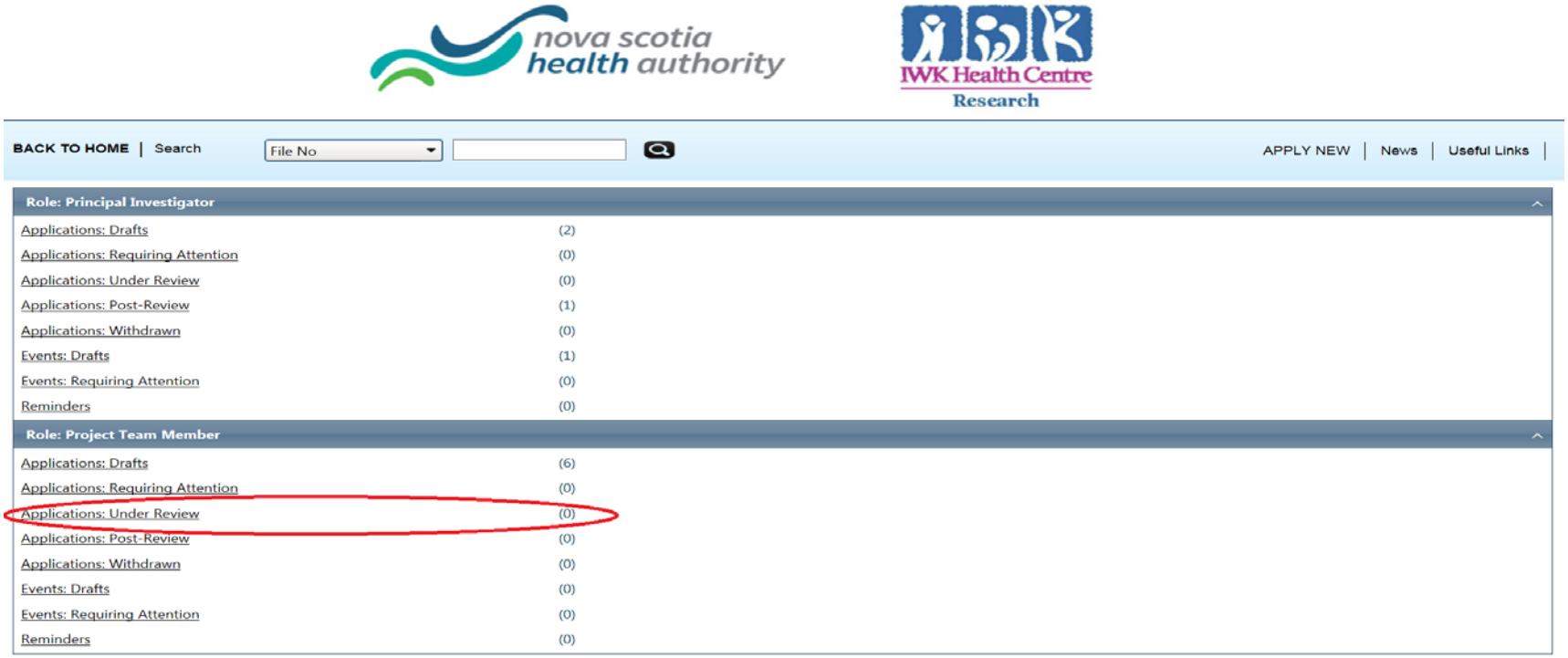
ROMEO has no automatic save feature! But it does have a time out feature! If you need to step away from your computer, always hit “Save and Close” as a precautionary measure. Failing to do so could result in information being lost or the application being “locked”. The user responsible for “locking” the application is able to “unlock” it by accessing it again and exiting properly. All other team members, who find themselves “locked out” of the application, can either contact the user who “locked” it or the system administrator for support (notifications@researchservicesoffice.com)

Submitting the Application

- From the moment you assign another PI and team members to the project, they will be able to view and edit the application.
- The PI is the only person who can submit the application, no other team member can do this on their behalf.
- The team member responsible for completing the application should notify the PI when the application is ready to be reviewed and submitted.
- Once the application has been submitted, the PI will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence.

Applications Under Review

Once the PI has submitted the application for review, you will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence. At this stage, you will not be allowed to make any changes to the application. However, it is still available for viewing under "Applications – Under Review".



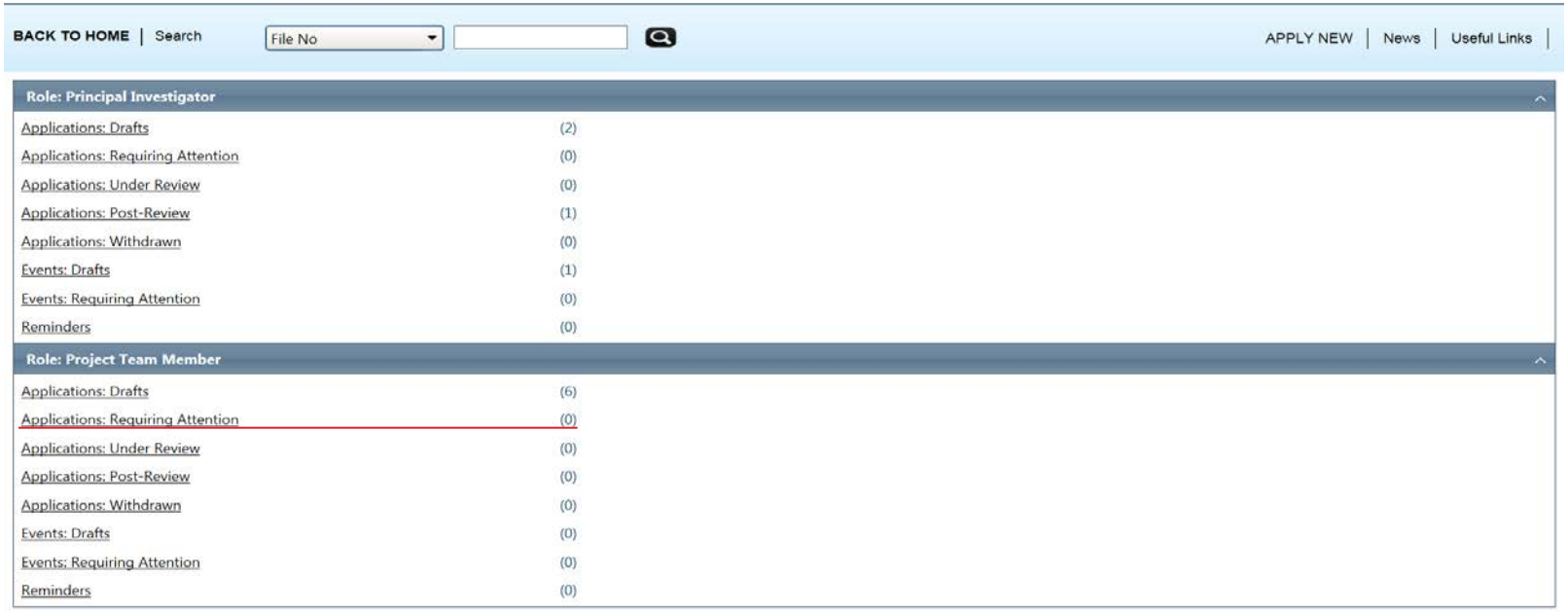
Work Flow State of Applications Under Review

Check the status of your application(s) under review under the “Work Flow State” column.

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
				All		
View Clone	**100239**	Test File	Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification\Human Ethics)	**Project Status**: Active **Workflow Status**: ORS Review	Test application being submitted for review [Acti... [See more, inside under Logs section]

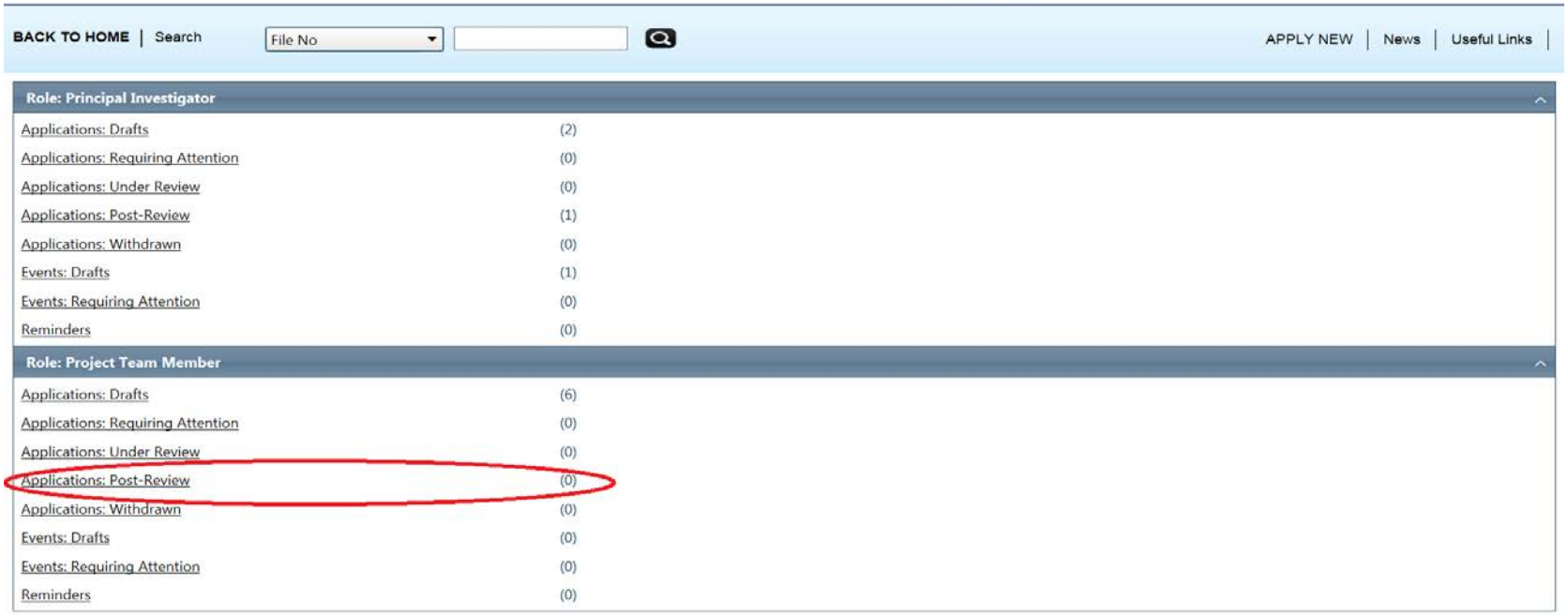
Applications Requiring Revisions

If the Board requires any revisions, the application will be pushed back to the researcher (applicant/PI). At this stage, you will be able to edit the application by clicking on this link: “Applications – Requiring Attention”. Remember that if you are making the revisions on behalf of the PI, you will need to let them know when the revisions are completed so that they may re-submit the application.



Approved Applications

Once the application has been approved, the PI, Research Coordinator and Supervising Investigator (where applicable) will receive an automatic email the study has been approved. A formal approval letter in the form of email will also be sent. The application can no longer be modified but is available for viewing under "Applications –Post Review"



Logs Tab – Workflow Logs

- The Logs tab is a useful tool that shows the history of the application. Text in blue font represents most recent updates
- The “Application Workflow Logs” tracks and time stamps approvals and messages

Close | Print | Export to Word | Export to PDF

View mode. Changes cannot be saved.

Project Info | Project Team Info | NSHA INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs

◉ Application Workflow Log ○ Application Log

Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
27/05/2015 11:50	Project Status has been changed from **Pending** to **Active** Project Work Flow State has been changed from **ORS Review** to **Approval Decision Made** **Pamela Trenholm** has been Added. (role is Research Coordinator)	**ORS Review** -> **Approval Decision Made**		ngillam	Office of Research Services/Office of Research Ethics
10/04/2015 08:52	New File Submitted By Researcher Project Work Flow State has been changed from **Pre Submission** to **ORS Review**	**Pre-Submission** -> **ORS Review**	Study Requesting REB Approval. [Action: Submit]	Nadine Gillam	Principal Investigator

Logs Tab – Project Logs

- The “Application Log” tracks and time stamps every action taken on the application.

Close | Print | Export to Word | Export to PDF

View mode. Changes cannot be saved.

Project Info | Project Team Info | NSHA INTERVENTIONAL STUDY - Ethics Application Form (EAF) | Attachments | Approvals | Logs

○ Application Workflow Log ◉ Application Log

Timestamp	Log Activity	User
2017/02/08 10:16	Project Status has been changed from **Active** to **Withdrawn**	ngillam
2017/02/08 10:13	Project Status has been changed from **Withdrawn** to **Active**	ngillam
2016/02/26 12:32	Renewal Event Submitted By Researcher	su
2015/10/19 11:07	Project Start date has been changed from **'0001/01/01'** to **'2015/05/25'**	ngillam
2015/09/30 14:26	Project Status has been changed from **Active** to **Withdrawn**	ngillam

Event Forms

- Event forms are: Amendments, Requests for Annual Approvals, Request for Acknowledgment, Serious Adverse Event (SAE) Reporting, Safety Updates and Study Completion.

- "Event Forms" allow researchers to make amendments to their approved ethics application(s).

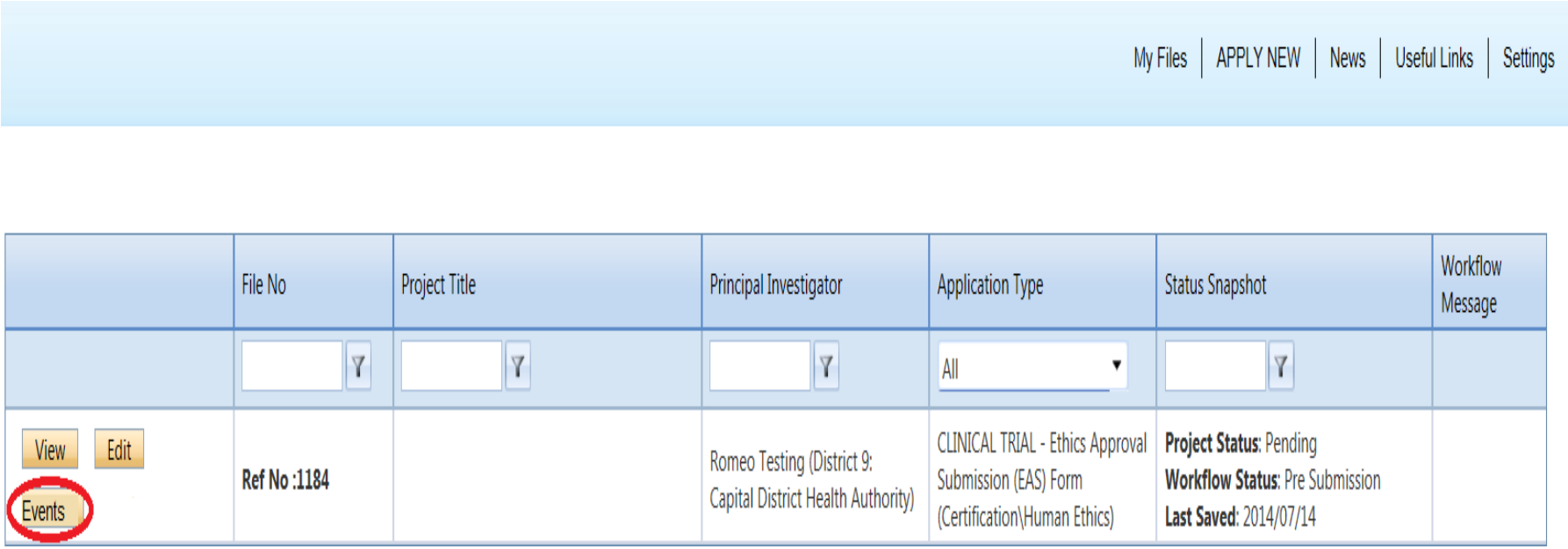
- Event Forms can be accessed, completed and submitted by any member of the project team (i.e. the PI, Sub-investigator(s), Research Coordinator, etc.) as opposed to the original ethics application which can only be submitted and re-submitted by the PI.

Accessing Event Forms

- You can access Event Forms at any time either under Role: Project Team Member by clicking on “Applications: Post Review”.
- Applications will also be available within 30 days of the ethics renewal due date by clicking on “Reminders”.

Accessing Event Forms – Applications – Post Review

- By clicking on “Applications – Post Review”, you may view all of your approved ethics applications. From there, if you wish to submit an amendment form, a serious adverse event (SAE) or an annual approval (renewal) request, you can access the event forms by clicking on “Events”.



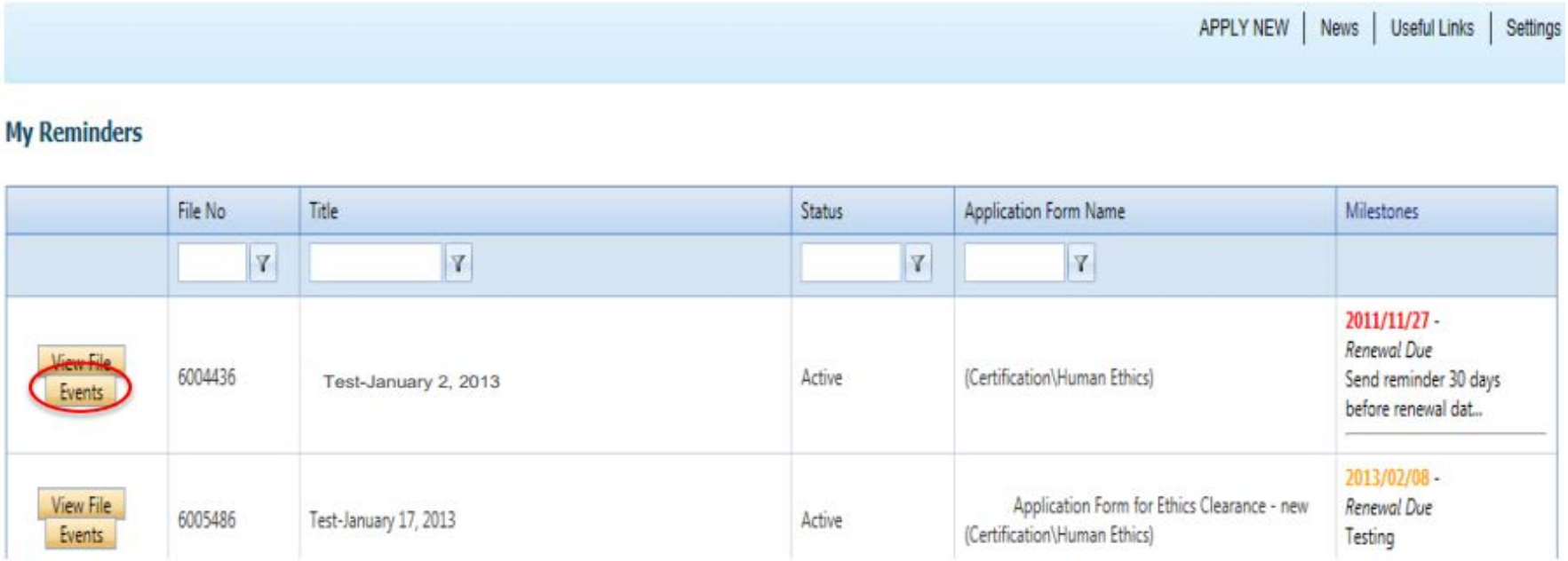
Accessing Event Forms

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.
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.
IWK Major Study Violation	Major study violations are deviations from regulatory requirements or REB-approved documents, policies, and/or processes that impact data integrity, participant safety, privacy/confidentiality or willingness to continue in the study. • Examples include: obtaining informed consent with an outdated or unapproved version of the consent; beginning study procedures before consent was obtained; enrolling participants who didn't meet eligibility criteria; omitting key protocol-required tests or procedures; medication errors, including prescribing a contraindicated medication; using the wrong survey instrument; or using or releasing personal information without the participant's consent. • CLINICAL TRIALS: Deviations that DO NOT meet the criteria of a Major Violation are to be submitted to the REB using the Minor Deviation Reporting Form as part of the Annual Renewal process. • Major study violations must be reported to the REB upon discovery.
IWK SAE/SUSAR - for local SAE/SUSAR Reporting	Adverse event: Any untoward medical occurrence experienced by a research participant. SAE: Serious Adverse Event. SUSAR: Suspected Unexpected Serious Adverse Reaction. An adverse event that is 'serious' and 'unexpected' and related or possibly related to participation in the research. Adverse events that do not meet all three of these criteria should not be reported to the REB.
IWK Safety Related Event Reporting (External SAEs, Minor Protocol Deviations, PSUR, DSMB, Safety Alerts)	External SAEs, Minor Protocol Deviation, PSUR: Periodic Safety Update Reports, DSMB: Data & Safety Monitoring Board updates, sponsor issued Safety Alerts or other sponsor provided safety information.
IWK Study Closure	If there are any unreported minor study deviations, please attach a completed report (see template)
IWK Study Personnel Change Notification	Use this form to notify the REB of changes to your project team for this study.
NSHA 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 hold, off hold; studies closed to accrual/enrollment, etc.
NSHA Amendment Request	This includes research protocols, ethics application forms, consent forms/addendums, research team contact pages, supporting materials, and product information.
NSHA Annual Renewal Request	REB approval for this study will expire on the last day of the specified approval period. To ensure continuing review, submit an Annual Approval Request 2-4 weeks prior to this date. If approval is not renewed on time, the Board will close your file and you must cease all study activities immediately.
NSHA Local Serious Unexpected Adverse Reaction Reporting Form	Adverse event: Any untoward medical occurrence experienced by a research participant. Serious unexpected adverse reaction (SUAR): An adverse event that is 'serious' and 'unexpected' and related or possibly related to participation in the research. Adverse events that do not meet all three of these criteria are not SUARs and should not be reported to the REB.
NSHA Major Study Violation	Major study violations are deviations from applicable regulatory requirements or REB approved documents, policies and/or processes that impact data integrity or participant safety, privacy/confidentiality, or willingness to continue in the study.
NSHA Notification of Change in Study Personnel.	Use this form to notify the REB of changes to your project team for this study.
NSHA Safety related events reporting (PSUR, DSMB, Safety Alerts)	(Periodic Safety Update Reporting (PSUR), Data & Safety Monitoring Board (DSMB) updates, sponsor issued safety alerts and/or sponsor provided safety information.
NSHA Study Closure	

Select the form you need to submit by clicking on the hyperlinks under "Event Form Name"

Accessing Event Forms – Reminders

- From the “Reminders” quick link you will see the due date of the “Milestones” –dates in yellow font are coming due, while dates in red font are past due. Click on “Events” to access the forms.



Event Info Tab

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

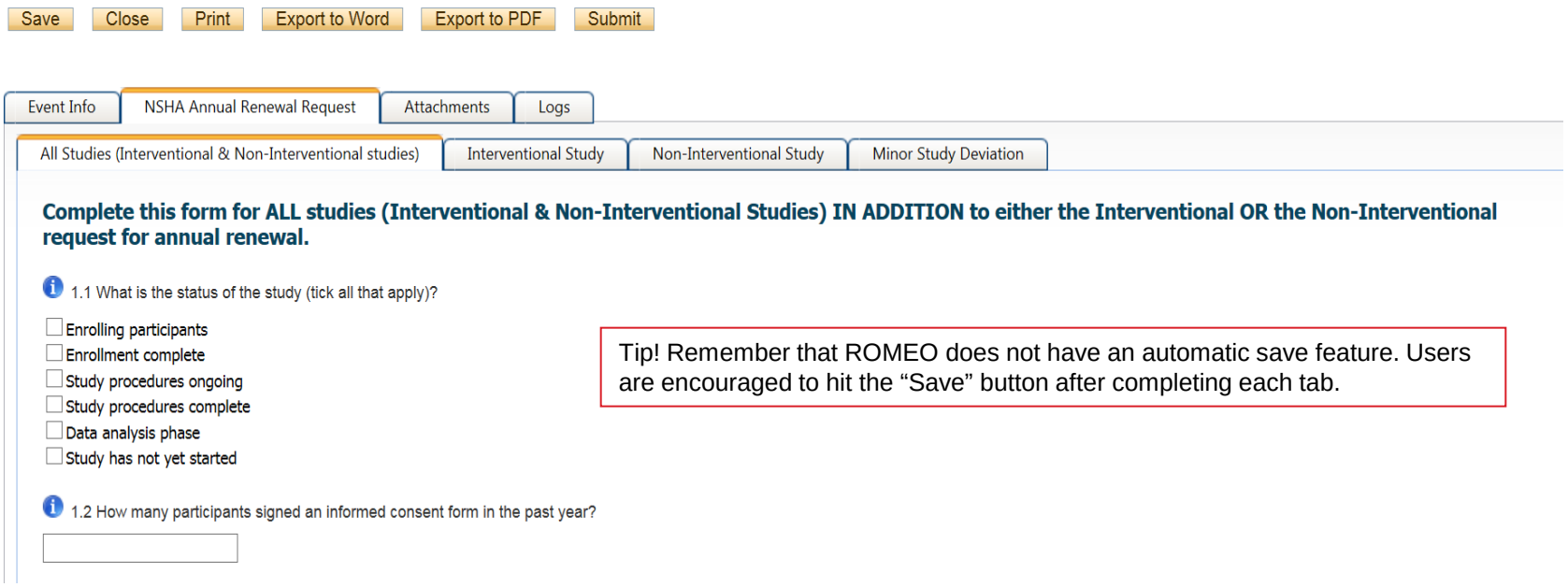
Event Info | NSHA Annual Renewal Request | Attachments | Logs

Note(s)

Researchers and Research Coordinators are invited to add comments if they wish. For example, if a study is being reports as closed to recruitment, insert a note.

Completing the Event Form

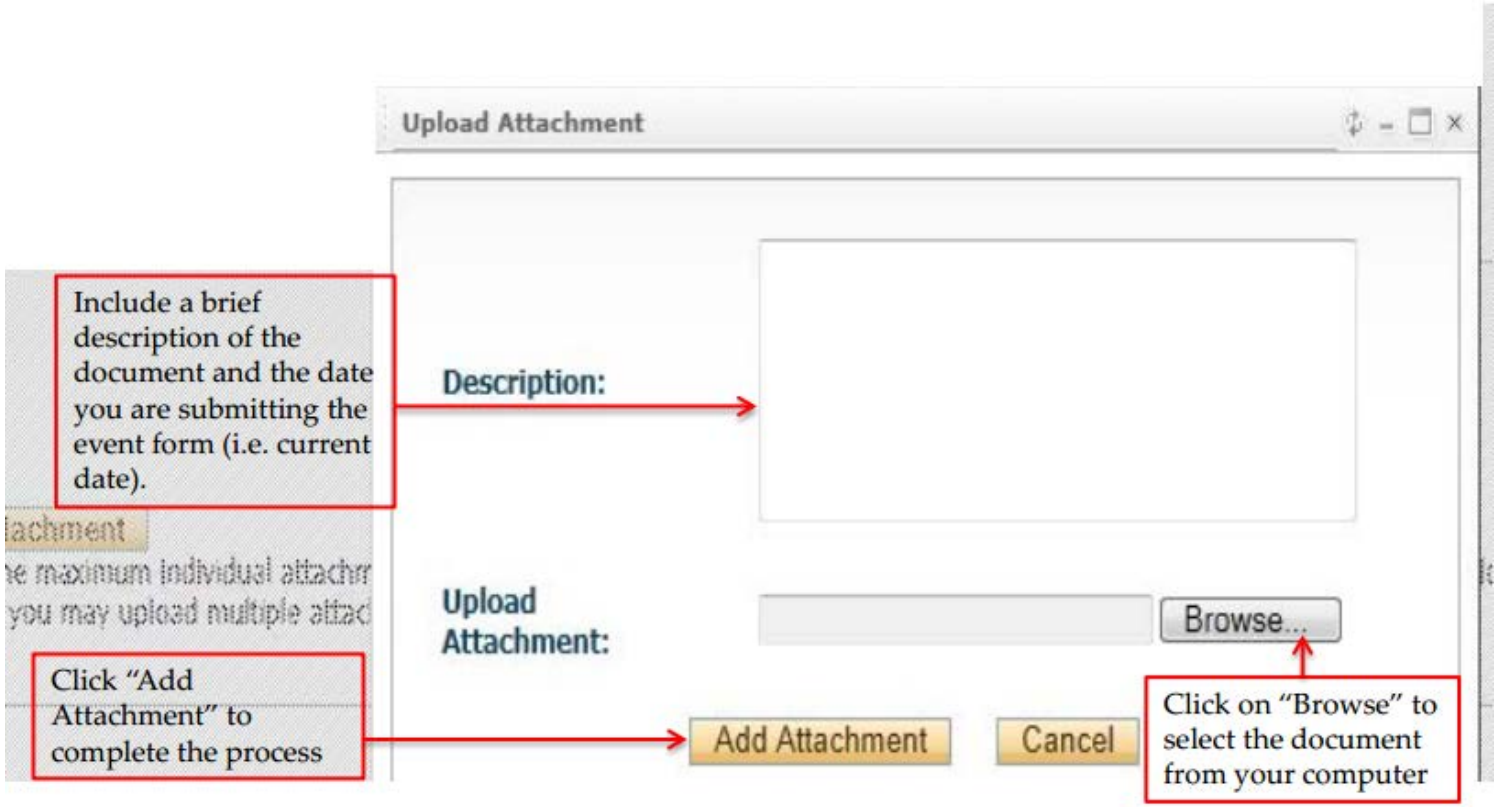
- Complete the form by answering all the questions of the Annual Renewal Form for All Studies (Interventional and Non-Interventional Studies). Once all of these questions have been answered, click on either the Interventional or Non-Interventional Studies sub-tab (as it applies to your study) and answer the remaining questions. Complete the Minor Study Deviation sub-tab as well if applicable.



Tip! Remember that ROMEO does not have an automatic save feature. Users are encouraged to hit the “Save” button after completing each tab.

Attachments Tab

- Researchers are able to attach document(s) to the event form through the Attachments tab. Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be Word documents, Excel spreadsheets, jpeg files, pdfs, etc.



Errors Tab

Request for Amendment

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

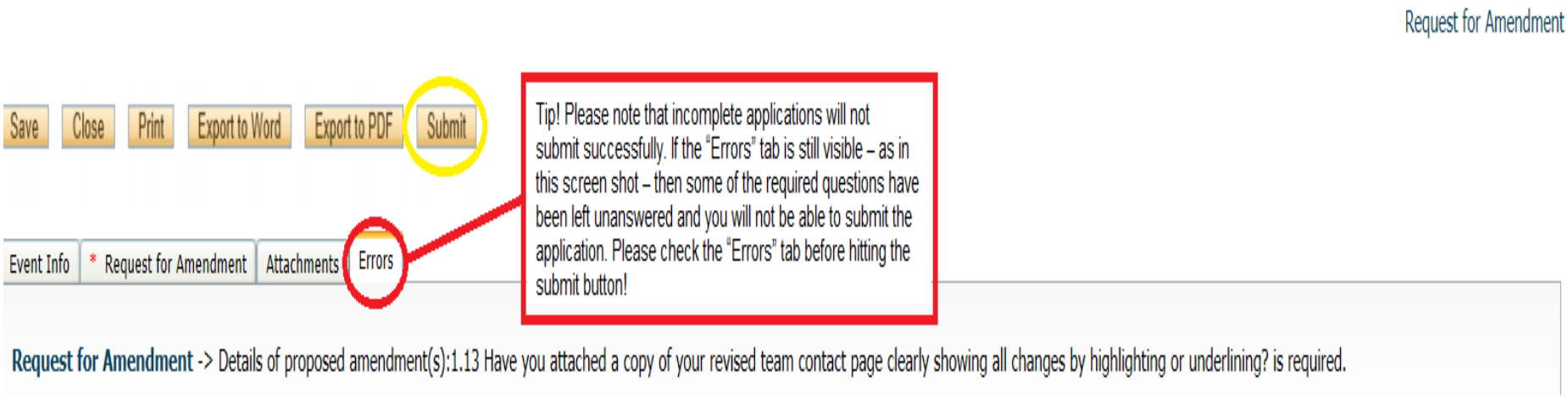
Event Info | * Request for Amendment | Attachments | Errors

Request for Amendment -> Details of proposed amendment(s):1.13 Have you attached a copy of your revised team contact page clearly showing all changes by highlighting or underlining? is required.

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions were answered, the Errors tab disappears.

Submitting the Event Form

- Remember that any member of the project team (i.e. PI, Sub-Investigator, Research Coordinator, etc.) is able to submit event forms by simply clicking the "Submit" button at the top of the form.



Tracking the Event Form

- The PI and other members of the project team will not receive a confirmation email after submitting an event form.
- However, they can still track whether or not their form was submitted by accessing the application for which you submitted an event form – either through "Applications – Post Review" or "Reminders" – and clicking on "Events". Event forms that were started and saved, but not submitted will appear under "Events: Drafts".

File No: 100283

Project Title: Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Events: Drafts

	Event No	Event Category	Event Form	Comments	Latest Update
View Event Edit Delete	100283 - **Ref No : 947**	Amendment	NSHA Amendment Request	This is a test Amendment Form ...	
View Event Edit Delete	100283 - **Ref No : 9037**	Amendment	NSHA Amendment Request		Nadine Gillam on 11/23/2016 7:56:37 AM

Events: Requiring Attention

Events: Under Review

Events: Post Review

Reminders

Tracking the Event Form (cont'd)

- Once the event form has been submitted, it will move down to "Events: Under Review". You will be able to view the event but will no longer be able to edit it.

File No: 100283

Project Title: Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Events: Drafts

Events: Requiring Attention

Events: Under Review

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event	100283 - **9985498**	Amendment (NSHA Amendment Request)	2017/03/07	Submitted by Researcher	Nadine Gillam on 3/7/2017 11:54:46 AM

Events: Post Review

Reminders

Note that the "Status" of the application indicates: "Submitted by Researcher".

Tracking the Event Form (cont'd)

- Once the event form has been assigned for review the "Status" of the application will change from "Submitted by Researcher " to "Pending".

File No: 100283

Project Title: Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Events: Drafts

Events: Requiring Attention

Events: Under Review

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event	100283 - **9985498**	Amendment (NSHA Amendment Request)	2017/03/07	Pending	ngillam on 3/7/2017 12:03:14 PM

Events: Post Review

Reminders

Event Form Approval

- Once the event form has been reviewed and approved, it will move down to Events: Post Review. The status of the event will change from “Pending” to “Approved.

- The PI , Research Coordinator and the Supervising Investigator (if applicable) will receive a confirmation email along with a copy of the formal approval letter. This letter has also been attached to the original application and can be viewed through the “Attachments” tab by any project team member.

- Please Note: The process for submitting any type of Event Form is the same as what has been described here.

File No: 100283

Project Title: Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Events: Drafts

Events: Requiring Attention

Events: Under Review

Events: Post Review

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event	100283 - **9985498**	Amendment (NSHA Amendment Request)	2017/03/07	Approved	ngillam on 3/7/2017 12:08:18 PM
View Event	100283 - **9948203**	Renewal (NSHA Annual Renewal Request)	2016/02/26	Approved	
View Event	100283 - **9927563**	Renewal (NSHA Annual Renewal Request)	2015/08/24	Approved	
View Event	100283 - **9921675**	Amendment (NSHA Amendment Request)	2015/05/28	Approved	

Reminders

Event Form – Requiring Attention

- Here you will find any event forms that have been returned for clarifications by the REB.
- Click the “Edit” button to access the form to make any corrections that have been indicated in a separate email that would have been sent to you from the REB office.

File No: 100283

Project Title: Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Events: Drafts

Events: Requiring Attention

	Event No	Event Category	Event Submission Date	Event Status	Latest Update
View Event Edit	100283 - **9985498**	Amendment (NSHA Amendment Request)	2017/03/07	Submitted by Researcher	ngillam on 3/7/2017 12:22:34 PM

Events: Under Review

Events: Post Review

Reminders

Event Form – Requiring Attention (Cont'd)

- Once the corrections have been made choose the re-submit button at the top of the screen to send the event back to the REB office for review and approval.

Event: Amendment **File No:** 100283 - **9985498**
PI : Gillam Nadine(Administration (NSHA))
Project Title : Test File: 18F- Sodium Fluoride PET Imaging as a Replacement for Bone Scintigraphy

Event Form: NSHA Amendment Request

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

Event Info | NSHA Amendment Request | Attachments | Logs

Details of proposed amendment(s)

1.1* Please list all documents including version # and date that are attached with the this amendment form.

PP support

1.2 If applicable, summarize the protocol changes.

PP support

Need assistance/have a question?

- Contact your system administrator
  - 902-473-2126
  - nadine.ransome@nshealth.ca