



ROMEO Research Portal User Guide

Nova Scotia Health Authority
Research Ethics Board



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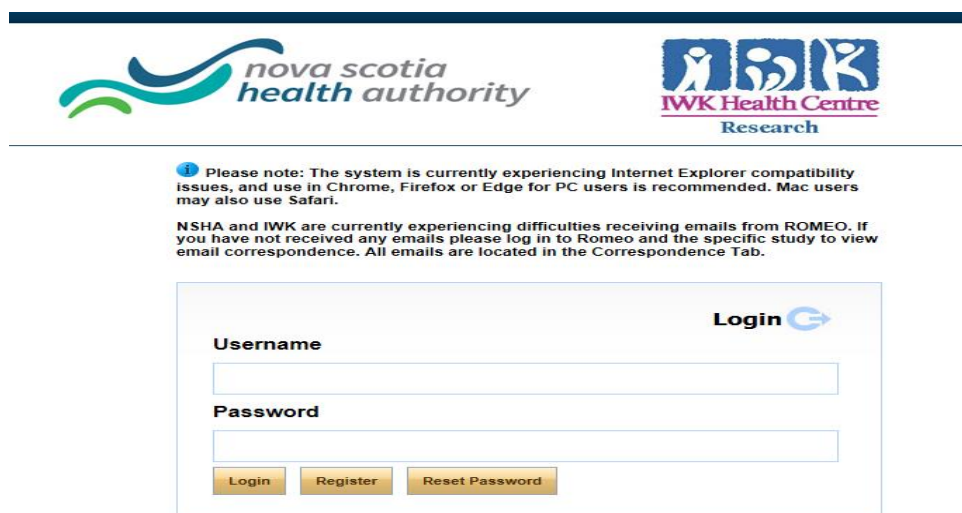
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[Need Help? Contact Us](#)

Accessing the Researcher's Portal

The Researcher's Portal is available through the Login at the following URL: <http://nshealthresearchservicesoffice.com/Romeo.Researcher/Login.aspx>

If you already have an account, login with your primary email address and password.



The screenshot shows the login page for the Researcher's Portal. At the top, there are logos for the Nova Scotia Health Authority and the IWK Health Centre Research. Below the logos, a message states: "Please note: The system is currently experiencing Internet Explorer compatibility issues, and use in Chrome, Firefox or Edge for PC users is recommended. Mac users may also use Safari." Another message follows: "NSHA and IWK are currently experiencing difficulties receiving emails from ROMEO. If you have not received any emails please log in to Romeo and the specific study to view email correspondence. All emails are located in the Correspondence Tab." The login form contains fields for "Username" and "Password", a "Login" button with a blue arrow icon, and three buttons at the bottom: "Login", "Register", and "Reset Password".

Many profiles already exist in Romeo as some were created before the existence of the Portal when only the REB used Romeo.

If you are a first time user of the Researcher's Portal, please contact the REB Office ResearchEthics@nshealth.ca to see if you already have a user profile in the system.

Researcher's Home Page

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



A screenshot of the Researcher's Home Page navigation bar. The bar is light blue and contains the following elements from left to right: a "BACK TO HOME" link, a "Search" button, a "File No" dropdown menu, a search input field, a magnifying glass icon, a red circle around the "APPLY NEW" link, a "News" link, and a yellow circle around the "Useful Links" link. Below the navigation bar, there are two role selection buttons: "Role: Principal Investigator" and "Role: Project Team Member". A yellow arrow points from the "Useful Links" link to a text box on the right.

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

All files in which your role is Principal Investigator (PI) will be under the heading "Role: Principal Investigator."

All files in which your role is anything other than the PI (coordinator, assistant, etc.) will be under the heading "Role: Project Team Member."



Interventional Study or Non-Interventional Study?

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

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

Because Romeo is a shared database with the IWK, you will see IWK application forms too.

To submit to the Nova Scotia Health REB ONLY select from NS Health options.

NSHA - Certifications (Human Ethics)

Application Name	Description	Status
<u>Nova Scotia Health INTERVENTIONAL STUDY - Ethics Application Form (EAF)</u>	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
<u>Nova Scotia Health NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)</u>	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

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.

Start Date: 2014/07/11

End Date: 2015/10/26

Keywords:

Add

Clear all

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 / Changing the PI

The applicant automatically defaults to the role of Principal Investigator (PI) on the application.

If you are not the PI of the study, you may transfer the PI Role to another researcher by clicking the “Change PI” button.

Important: DO NOT change PI’s “Last Name” and “First Name” manually – always use “Change PI” feature and search by name.

The screenshot shows the 'Project Team Info' tab selected in the application form. The 'Principal Investigator' section is active, displaying instructions and a form to change the PI. The 'Change PI' button is highlighted with a red circle. The form fields show the current PI's details: Prefix (Ms.), Last Name (Gillam), First Name (Nadine), Affiliation (Administration (NSHA)), Rank, and Institution (QEII Health Sciences Cent). Contact information includes Phone1 (902-473-2126), Email (nadine.gillam@nshealth.ca), and Primary Address (Rm. 118, CCR 5790 University Ave, Halifax, NS B3H 1V7). There are also fields for Phone2, Fax (902-473-5620), Alternate Address, Preferred Address (Primary Address selected), and Country (Canada).

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: Fax: 902-473-5620

Email*: nadine.gillam@nshealth.ca Alternate Address:

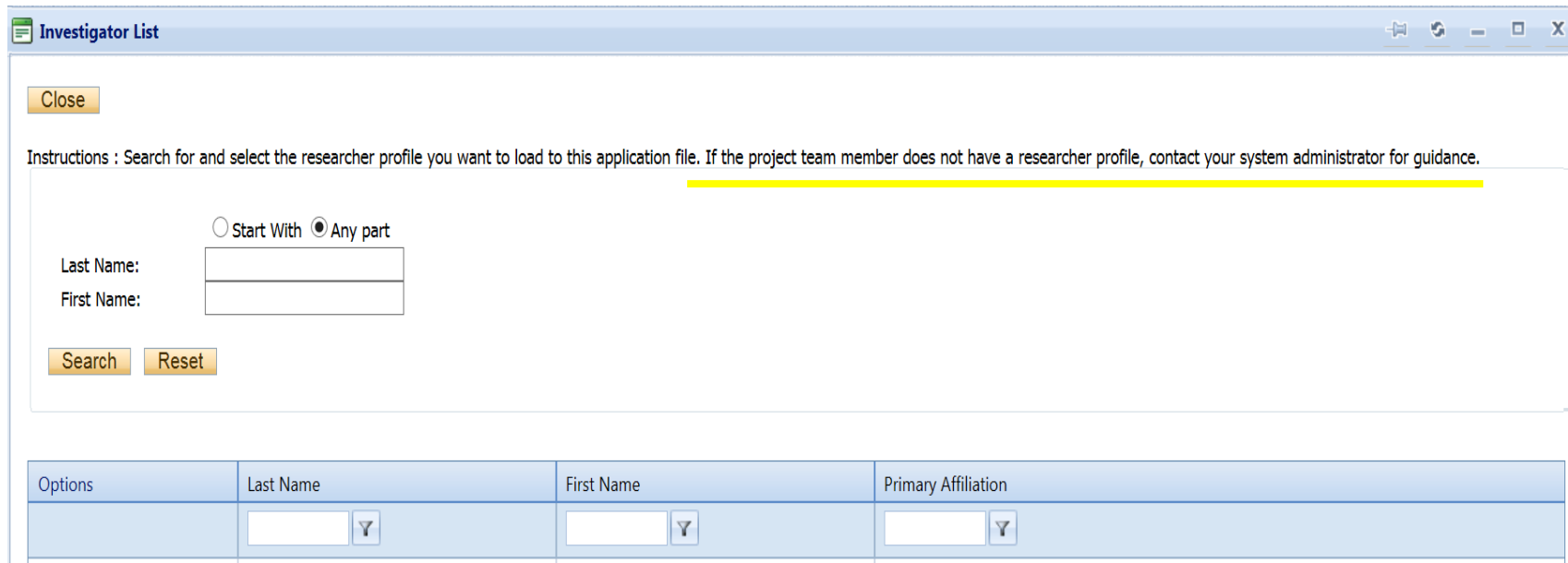
Primary Address: Rm. 118, CCR 5790 University Ave
Halifax, NS B3H 1V7

Preferred Address: ☒ Primary Address ☐ Alternate Address Country: Canada

Changing the PI cont'd

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.”



The screenshot shows a web application window titled "Investigator List". At the top left is a "Close" button. Below it is a line of instructions: "Instructions : Search for and select the researcher profile you want to load to this application file. If the project team member does not have a researcher profile, contact your system administrator for guidance." Below the instructions are two radio buttons: "Start With" (unselected) and "Any part" (selected). There are two text input fields labeled "Last Name:" and "First Name:". Below these fields are "Search" and "Reset" buttons. At the bottom of the window is a table with four columns: "Options", "Last Name", "First Name", and "Primary Affiliation". Each of the last three columns has a text input field with a dropdown arrow.

Options	Last Name	First Name	Primary Affiliation
	<input type="text"/>	<input type="text"/>	<input type="text"/>

Changing the PI cont'd

Once you've identified your PI – click on “select.” Project Team Info will automatically be updated with PI's information.

The “Submit” button is only visible to the PI; the PI is the only person who can submit the application once it has been completed.

Investigator List

Close

Instructions : Search for and select the researcher profile you want to load to this application file. If the project team member does not have a researcher profile, contact your system administrator for guidance.

☐ Start With ☒ Any part

Last Name: MacKnight

First Name:

Search Reset

Options	Last Name	First Name	Primary Affiliation
Select	MacKnight	Chris	

Close

If you are unable to identify the person you are looking for from the investigators list, please contact ResearchEthics@nshealth.ca

Important: Now that the PI role has been updated, the applicant must be added as a project team member. This must be done before you close the application. Failing to do so will result in you losing access to the application form once you exit the application form.

Adding Other 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.
- Continue to project add team members by clicking “Add New.”

Other Project Member Info:
Instructions : Do not hand type data for this section. To add more project team members to this application file, click the Add New button to search for and select from other researcher profiles.

Add New

Last Name	First Name	Role In Project
No records to display.		

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 contact ResearchEthics@nshealth.ca

Completing the Ethics Application Forms (EAF)

The Ethics Application 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 as seen in the screenshot below!

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

* Principal Investigator Attestation/Commitments * Administrative Information * Research Summary * Research Protocol Information * Compensation / Conflict of Interest

* Participant Identification and Informed Consent * Privacy and Confidentiality * Other Ethical Issues

i 2.1) PI's Institutional Affiliation(s)
Please list primary affiliation E.g. NSHA/IWK/DAL

i 2.2) PI'S NSHA Zone
-Select- ▼

i 2.3) * Is this research interdisciplinary (eg. Research is considered interdisciplinary if it is involving investigators/sub-investigators from two or more departments, divisions, programs or services)?
☐ Yes
☐ No

i 2.4) * Is this research:
☐ Investigator Driven (Sponsored)
☐ Industry Driven (Sponsored)

i 2.5) * If Investigator driven, is it led:
☐ Locally
☐ Externally
☐ N/A (Industry Driven)

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

Attachments

You should attach any relevant document(s) 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.

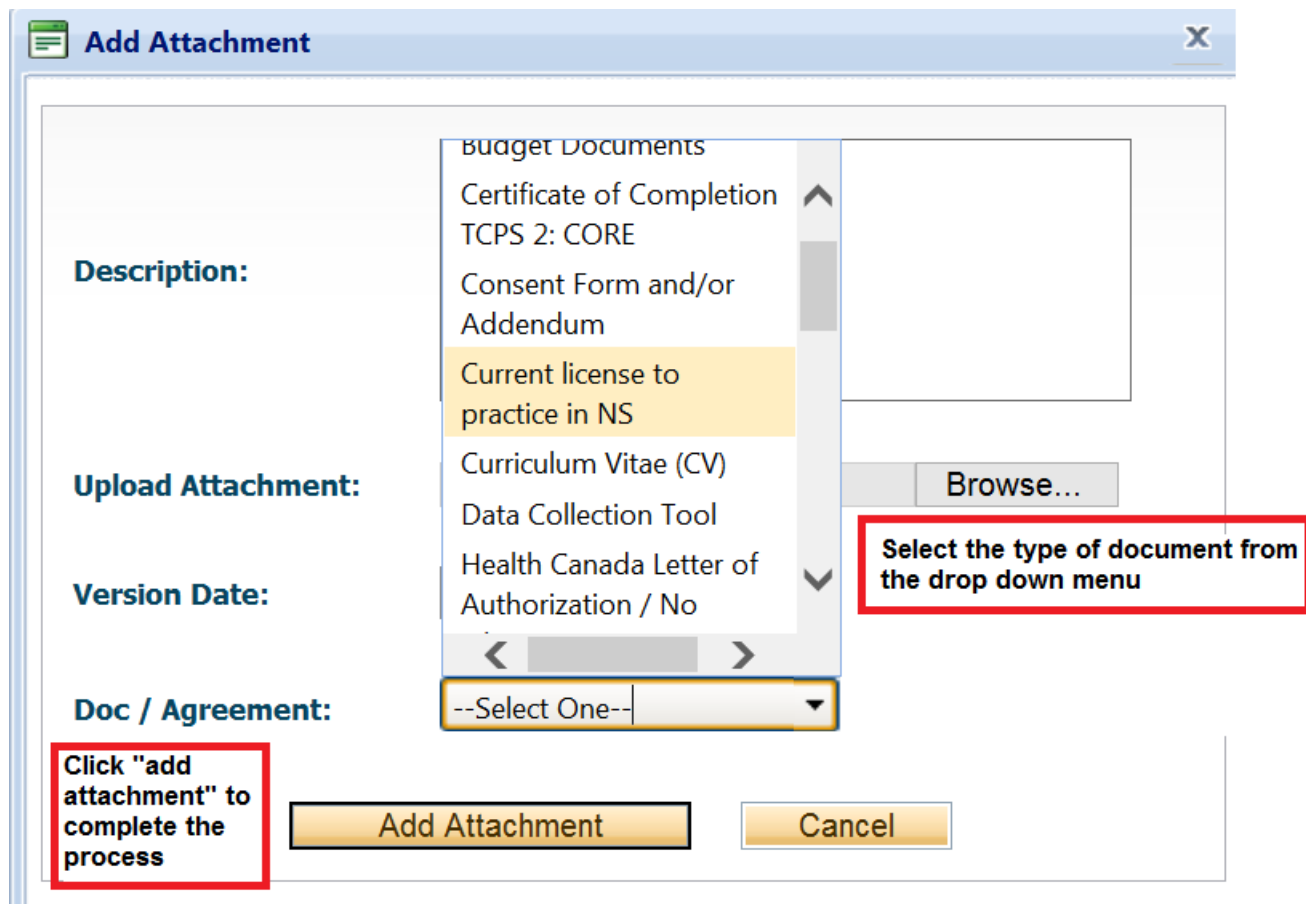
The screenshot shows a web-based 'Add Attachment' dialog box. It contains the following fields and controls:

- Description:** A large text area for describing the document.
- Upload Attachment:** A button labeled 'Browse...'.
- Version Date:** A date input field with a calendar icon.
- Doc / Agreement:** A dropdown menu currently showing '--Select One--'.
- Buttons:** 'Add Attachment' and 'Cancel' at the bottom.

Four red-bordered callout boxes provide instructions:

- Description:** Include a brief description of the document (e.g. Mood Questionnaire, Optional Sub-Study ICF, etc.) If your document has a version number, please list it in this box.
- Upload Attachment:** Click "browse" to select the document from your computer
- Version Date:** Enter the date as it appears on your document. If your document has no date, leave this blank.
- Doc / Agreement:** Doc / Agreement - see next slide

Attachments cont'd



The screenshot shows a web-based 'Add Attachment' dialog box. It has a title bar with a close button (X). The main area contains several labels on the left: 'Description:', 'Upload Attachment:', 'Version Date:', and 'Doc / Agreement:'. A large text area for the description is on the right. Below the 'Upload Attachment:' label is a 'Browse...' button. A dropdown menu is open, showing a list of document types: 'Budget Documents', 'Certificate of Completion TCPS 2: CORE', 'Consent Form and/or Addendum', 'Current license to practice in NS' (highlighted in yellow), 'Curriculum Vitae (CV)', 'Data Collection Tool', and 'Health Canada Letter of Authorization / No'. At the bottom, there is a '--Select One--' dropdown menu. Two buttons, 'Add Attachment' and 'Cancel', are at the bottom right. Three red boxes with black text provide instructions: one at the bottom left says 'Click "add attachment" to complete the process', one on the right says 'Select the type of document from the drop down menu', and one at the bottom left says 'Click "add attachment" to complete the process'.

Add Attachment

Description:

Upload Attachment:

Version Date:

Doc / Agreement:

Budget Documents
Certificate of Completion TCPS 2: CORE
Consent Form and/or Addendum
Current license to practice in NS
Curriculum Vitae (CV)
Data Collection Tool
Health Canada Letter of Authorization / No

Browse...

Select the type of document from the drop down menu

--Select One--

Click "add attachment" to complete the process

Add Attachment Cancel

Errors Tab

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



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Role: Principal Investigator

Applications: Drafts	(2)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(1)
Applications: Withdrawn	(0)
Events: Drafts	(1)
Events: Requiring Attention	(0)
Reminders	(0)

Role: Project Team Member

Applications: Drafts	(6)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(0)
Applications: Withdrawn	(0)
Events: Drafts	(0)
Events: Requiring Attention	(0)
Reminders	(0)

ROMEO has no automatic save feature! But it does have a time out feature so save often!



Submitting the Application

- Once the PI and team members are added 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.
- If applicable, 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, an automated email confirming the receipt of the application will be sent to all team members associated with the application.

Once an application has been submitted you are not able to edit it; although you may view it under the quick link, “Applications – Under Review”.



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Role: Principal Investigator

Applications: Drafts	(2)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(1)
Applications: Withdrawn	(0)
Events: Drafts	(1)
Events: Requiring Attention	(0)
Reminders	(0)

Role: Project Team Member

Applications: Drafts	(6)
Applications: Requiring Attention	(0)
Applications: Under Review	(0)
Applications: Post-Review	(0)
Applications: Withdrawn	(0)
Events: Drafts	(0)
Events: Requiring Attention	(0)
Reminders	(0)

Work Flow State of Applications Under Review

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

ORS – Office of Research Services

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y	All	<input type="text"/> Y	
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 returned to the research team. The PI and Coordinator(s) will receive notification by email that the file is being returned for clarifications/revisions.

At this stage, the application may be edited by clicking on the link: “Applications – Requiring Attention.” If you are making the revisions on behalf of the PI, you will need to notify them when the revisions are complete so they may re-submit the application.



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Role: Principal Investigator

Applications: Drafts (2)

Applications: Requiring Attention (0)

Applications: Under Review (0)

Applications: Post-Review (1)

Applications: Withdrawn (0)

Events: Drafts (1)

Events: Requiring Attention (0)

Reminders (0)

Role: Project Team Member

Applications: Drafts (6)

Applications: Requiring Attention (0)

Applications: Under Review (0)

Applications: Post-Review (0)

Applications: Withdrawn (0)

Events: Drafts (0)

Events: Requiring Attention (0)

Reminders (0)

Approved Applications

Once the application has been approved, the PI, Research Coordinator and Supervising Investigator (where applicable) will receive an automatic approval email.

A formal approval letter will be sent via email. After the application has been approved, it can no longer be modified. It can be viewed under “Applications –Post Review.”

All modifications will need to be requested by submitting the appropriate Event Form.



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Role: Principal Investigator

[Applications: Drafts](#)

(2)

[Applications: Requiring Attention](#)

(0)

[Applications: Under Review](#)

(0)

[Applications: Post-Review](#)

(1)

[Applications: Withdrawn](#)

(0)

[Events: Drafts](#)

(1)

[Events: Requiring Attention](#)

(0)

[Reminders](#)

(0)

Role: Project Team Member

[Applications: Drafts](#)

(6)

[Applications: Requiring Attention](#)

(0)

[Applications: Under Review](#)

(0)

[Applications: Post-Review](#)

(0)

[Applications: Withdrawn](#)

(0)

[Events: Drafts](#)

(0)

[Events: Requiring Attention](#)

(0)

[Reminders](#)

(0)

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
<input checked="" type="radio"/> Application Workflow Log <input type="radio"/> 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

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 are to be submitted for approved ethics application(s) only.
- 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.).
- **Romeo is a shared database with the IWK so IWK Event Forms are also visible. To submit an Event to the Nova Scotia Health REB, ensure you select the applicable NS Heath Event Form.**

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	

Accessing Event Forms

You can access Event Forms at any time either under the quick link, “Applications: Post Review” (PI or team member depending on your role in the project).

	Role: Principal Investigator	
	Applications: Drafts	(2)
	Applications: Requiring Attention	(0)
	Applications: Under Review	(0)
→	Applications: Post-Review	(0)
	Applications: Withdrawn	(0)
	Events: Drafts	(0)
	Events: Requiring Attention	(0)
	Reminders	(0)
	Role: Project Team Member	
	Applications: Drafts	(0)
	Applications: Requiring Attention	(0)
	Applications: Under Review	(0)
→	Applications: Post-Review	(8)
	Applications: Withdrawn	(0)
	Events: Drafts	(1)
	Events: Requiring Attention	(0)
	Reminders	(0)

Accessing Event Forms – Applications – Post Review

By clicking on “Applications – Post Review”, you may view all of your approved ethics applications.

To submit an Event Form (i.e. amendment form, a serious adverse event (SAE) or an annual approval (renewal) request), click on “Events.”

[My Files](#) | [APPLY NEW](#) | [News](#) | [Useful Links](#) | [Settings](#)

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
	<input type="text"/>	<input type="text"/>	<input type="text"/>	All	<input type="text"/>	
View Edit Events	Ref No :1184		Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification\Human Ethics)	Project Status: Pending Workflow Status: Pre Submission Last Saved: 2014/07/14	

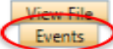

Accessing Event Forms – Reminders

From the “Reminders” quick link you will see the due date of the “Milestones” (milestones are set for initial letters and annual renewals).

Dates in yellow font are coming due, while dates in red font are past due. Click on “Events” to access the forms.

APPLY NEW | News | Useful Links | Settings

My Reminders

	File No	Title	Status	Application Form Name	Milestones
	<input type="text"/> <input type="button" value="Y"/>	<input type="text"/> <input type="button" value="Y"/>	<input type="text"/> <input type="button" value="Y"/>	<input type="text"/> <input type="button" value="Y"/>	
	6004436	Test-January 2, 2013	Active	(Certification\Human Ethics)	2011/11/27 - Renewal Due Send reminder 30 days before renewal dat...
	6005486	Test-January 17, 2013	Active	Application Form for Ethics Clearance - new (Certification\Human Ethics)	2013/02/08 - Renewal Due Testing

Event Info Tab

SaveClosePrintExport to WordExport to PDFSubmit

Event InfoNSHA Annual Renewal RequestAttachmentsLogs

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 – Example: Request for Annual Renewal

Please Note: The process for submitting any type of Event Form is the same as what is described on the next few slides.

Answer all of the questions!

Complete the all studies tab (Interventional and Non-Interventional Studies) and either the Interventional or Non-Interventional tab (as it pertains to your study).

Complete the Minor Study Deviation tab if applicable.

[Save](#) [Close](#) [Print](#) [Export to Word](#) [Export to PDF](#) [Submit](#)

Event Info

NSHA Annual Renewal Request

Attachments

Logs

All Studies (Interventional & Non-Interventional studies)

Interventional Study

Non-Interventional Study

Minor Study Deviation

Complete this form for ALL studies (Interventional & Non-Interventional Studies) IN ADDITION to either the Interventional OR the Non-Interventional request for annual renewal.

1.1 What is the status of the study (tick all that apply)?

☐ Enrolling participants

☐ Enrollment complete

☐ Study procedures ongoing

☐ Study procedures complete

☐ Data analysis phase

☐ Study has not yet started

1.2 How many participants signed an informed consent form in the past year?

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

- 1) Multiple attachments may be uploaded to the Event Form
- 2) Attachments may be Word documents, Excel spreadsheets, jpeg files, pdfs, etc.
- 3) The maximum size Romeo allows is 5MB. If your file is larger than that, try 'zipping' the file or saving it as a compressed PDF document. If this is not sufficient to meet the file size restriction, simply break the file into pieces equal to or less than the maximum size accepted by the Portal, clearly label each piece (e.g., 'Part 1 of 5 - IB') and upload.
- 4) To ensure successful uploads, please note the following:
 - ❖ Do not attach files that include the following characters in the file name: “ , # % & * : < > ? / { } | ~
 - ❖ Do not use the period character in the middle of a file name, or at either the start or end of a file name
 - ❖ File names should not exceed 128 characters

The screenshot shows a web-based 'Upload Attachment' dialog box. It contains a 'Description:' text area, an 'Upload Attachment:' section with a file input field and a 'Browse...' button, and two buttons at the bottom: 'Add Attachment' and 'Cancel'. Three red boxes with arrows point to specific elements: the first box points to the 'Description:' area with the text 'Include a brief description of the document and the date you are submitting the event form (i.e. current date).'; the second box points to the 'Add Attachment' button with the text 'Click "Add Attachment" to complete the process'; the third box points to the 'Browse...' button with the text 'Click on "Browse" to select the document from your computer'.

Submitting the Event Form

Assuming the PI has delegated this task, all members of the project team (i.e. PI, Sub-Investigator, Research Coordinator, etc.) are able to submit event forms by clicking the “Submit” button at the top of the form.

Romeo does not send automated emails confirming submission of Event Forms.

Request for Amendment

Save Close Print Export to Word Export to PDF Submit

Event Info * Request for Amendment Attachments Errors

Tip! Please note that incomplete applications will not submit successfully. If the "Errors" tab is still visible – as in this screen shot – then some of the required questions have been left unanswered and you will not be able to submit the application. Please check the "Errors" tab before hitting the submit button!

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.

Tracking the Event Form

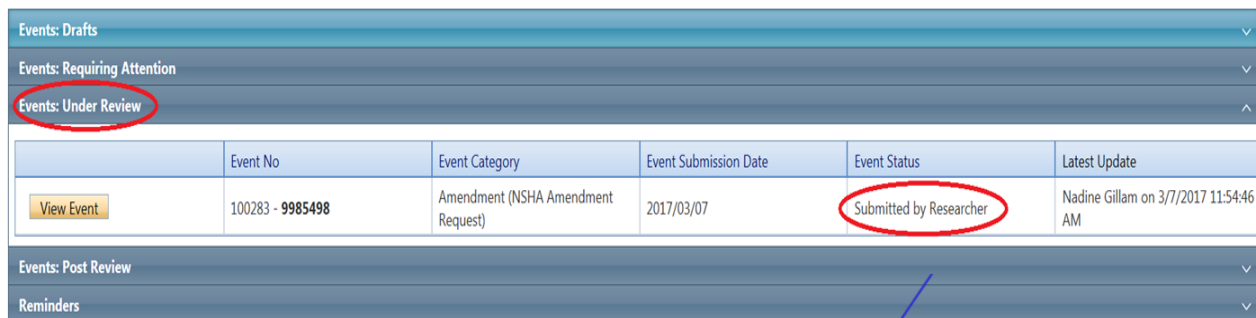
To check the status of the Event Form, click on “Applications – Post Review” and then click on “Events.”

Event forms that were started and saved, but not submitted will appear under “Events: Drafts.”



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

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.



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)

When the Event Status is “pending,” this means that the event has been reviewed by the Research Ethics Office and it awaiting approval from the Co-Chair.

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					

When the event form has been approved, it will move to the quick link, Events: Post Review and the event status will change from “Pending” to “Approved.” The project team will receive a confirmation email and a 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.

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 by the REB Office to the research team for clarifications/revisions.

Click the “Edit” button to access the form and make any corrections that have been indicated in a separate email that would have been sent to you from the REB office.

Events: Drafts					
Events: Requiring Attention					
	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	ngillam on 3/7/2017 12:22:34 PM
Edit					
Events: Under Review					
Events: Post Review					
Reminders					

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.

[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 the NS Health REB Office

ResearchEthics@nshealth.ca