

How To Submit Events in ROMEO

Events 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’.

1. [NS Health Acknowledgment Request](#)
2. [NS Health Amendment Request](#)
3. [NS Health Annual Renewal Request](#)
4. [NS Health Local Suspected Unexpected Adverse Reaction \(SUSAR\)](#)
5. [NS Health Major Study Violation](#)
6. [NS Health Change in Principal/Supervising Investigator \(PI/SI\)](#)
7. [NS Health Change in Personnel](#)
8. [NS Health Safety Related Events reporting](#)
9. [NS Health Study Closure](#)

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 • Examples include: obtaining informed consent with an outdated or unapproved version of the consent; beginning study procedures before consent was obtained; enrolling participants who didn't meet eligibility criteria;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.
NS Health Research Ethics	
Nova Scotia Health 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.
Nova Scotia Health Amendment Request	This includes research protocols, consent forms/addendums, research team contact pages, supporting materials, and product information.
Nova Scotia Health 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.
Nova Scotia Health Local Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Form	Adverse event: Any untoward medical occurrence experienced by a research participant. Suspected Unexpected Serious Adverse Reaction (SUSAR): 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 SUSARs and should not be reported to the REB.
Nova Scotia Health 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.
Nova Scotia Health Change in Principal/Supervising Investigator (PI/SI) form	Use this form to submit a change in PI/SI only (changes to team members are to be submitted using the 'change in study personnel form.'"
Nova Scotia Health Change in Study Personnel	Use this form to notify the REB of changes to your project team for this study. New team members must already have a master profile before being added to the REB file.
Nova Scotia Health 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.
Nova Scotia Health Study Closure	

1. NS Health Acknowledgment Request

Letters/notifications that require an acknowledgement from the REB (do not use this to make changes to a study)

Examples: studies on hold, off hold; studies closed to accrual/enrollment; Dear Investigator Letters from sponsor, etc.

Save Close Print Export to Word Export to PDF Submit

Event Info * Nova Scotia Health Acknowledgement Request Attachments Logs Errors

Note(s)

1. Enter description of event here...

2. Click on this tab

Save Close Print Export to Word Export to PDF Submit

Event Info * Nova Scotia Health Acknowledgement Request Attachments Logs Errors

* Details of Request for Acknowledgement

3. Fill out form

1.1* Have you provided a brief description of the document/item you are attaching for approval/acknowledgment by the REB in the 'event info' tab?
The REB requires a brief description be included in the 'event info' tab.

Yes - A brief description has been provided in the 'event info' tab.

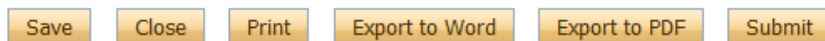
1.2* Have you attached one copy of each item requiring review (e.g. letter from sponsor indicating accrual is complete, etc.)?
This form should NOT be used to submit amendments, deviations, SUAR's

Yes - Document/item requiring acknowledgement is attached.
 Not applicable - There is no document/item to attach

4. Click here to add attachments

5. Click submit

2. NS Health Amendment Request (Protocols, Consents, Supporting Materials and Product information)



Event Info * Nova Scotia Health Amendment Request Attachments Logs Errors

Note(s)

1. Optional: Enter brief description of event here...

2. Click on this tab

3. Fill out form and add attachments.

Common Mistakes:

i 1.3* Has this protocol amendment(s) already been implemented to eliminate an immediate hazard to study participants?
ICH GCP 4.5.2

Yes
 No
 Not applicable; no changes to the protocol

Unless a protocol has already been implemented to prevent harm coming to participants, click "no" or "NA"

Please make sure to summarize your changes in the appropriate spots:

1.2- Protocol changes

1.6- Consent changes

1.14- Supporting document changes

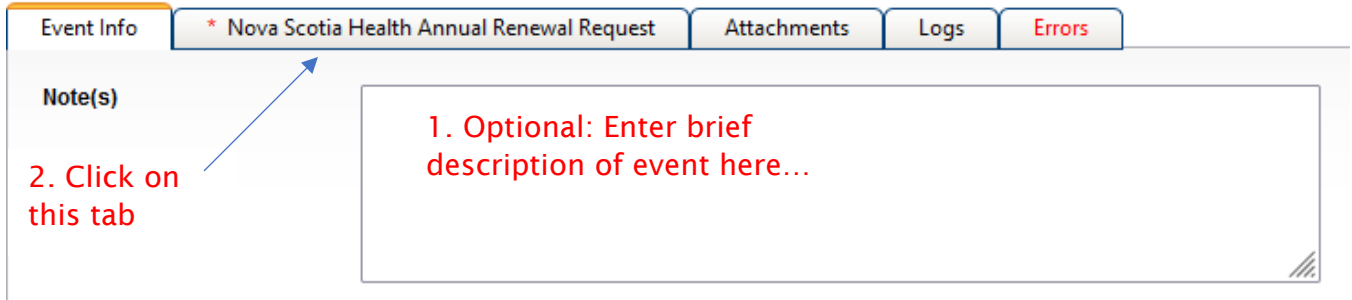
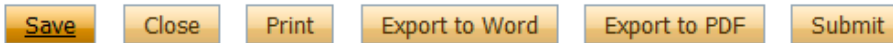
****IMPORTANT****

- Submit documents with changes **highlighted**.
- Tracked changes will **only** be accepted in Industry Sponsor provided Protocols.
- You do not need to submit a highlighted version and a clean version.

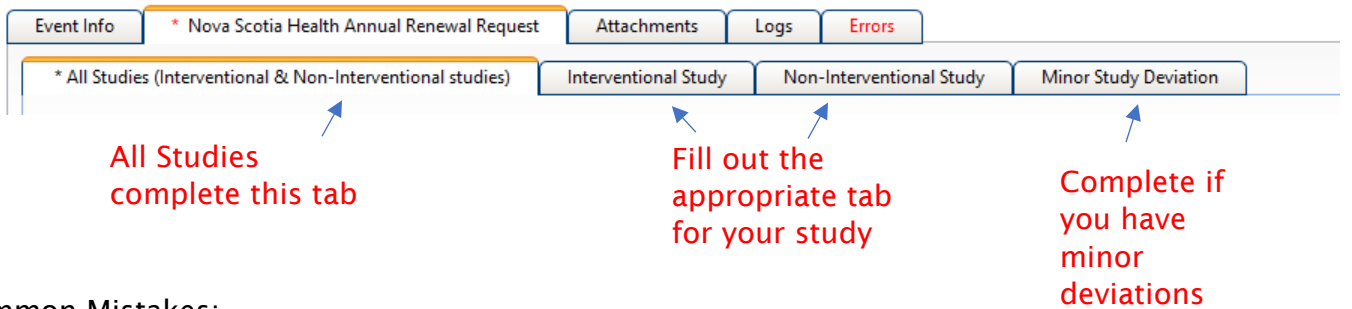
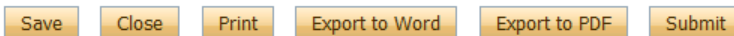
If your amendment has been returned by the Research Ethics Office and changes have been requested to a document:

- Remove the document and replace with a corrected document
- Make sure to update the amendment form to account for changes
- Click the re-submit button

3. NS Health Annual Renewal Request (Submit 2-4 weeks prior to your study expiry date)



3. Fill out form and add attachments (Make sure to fill out all appropriate tabs)



Common Mistakes:

Questions 1.4 and 1.5- the most common mistake is to put the same number for these two questions. 1.4 asks for the number completed while 1.5 asks how many are still participating.

i 1.4 What is the total number of participants who completed the study to date?

i 1.5 How many participants are currently participating in the study? (Receiving Treatment, Long Term Follow-Up etc.)

Question 1.7- Make sure the numbers from 1.2-1.6 add up to 1.7

i 1.7 What is your target enrollment (ensure this number corresponds with your consent form, protocol, etc.)?

Ensure this number is the most recent number based on either your original target or an amended target

Interventional Studies:

- Complete Tab 1
- Complete Tab 2
- Leave Tab 3 blank
- Complete Tab 4 if necessary

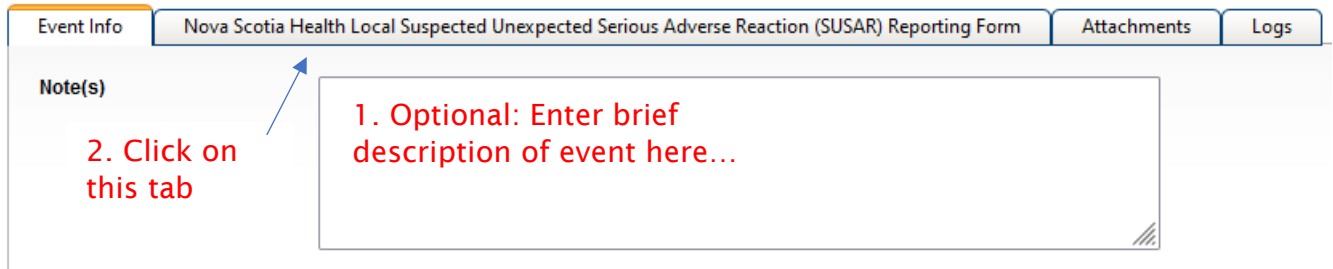
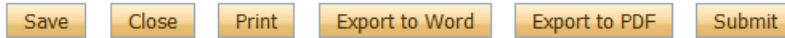
Non-Interventional Studies (including Chart Reviews and Secondary use of Data):

- Complete Tab 1
 - 0 or N/A is an acceptable response (i.e., no participants signed consent if you have a waiver of consent)
- Leave Tab 2 blank
- Complete Tab 3
- Complete Tab 4 if necessary

4. NS Health Local Suspected Unexpected Adverse Reaction (SUSAR)

Adverse events must meet 3 criteria to be reported to the REB:

- It must be **serious**
- It must be **unexpected**
- It must be **related or possibly related** to participation in the research



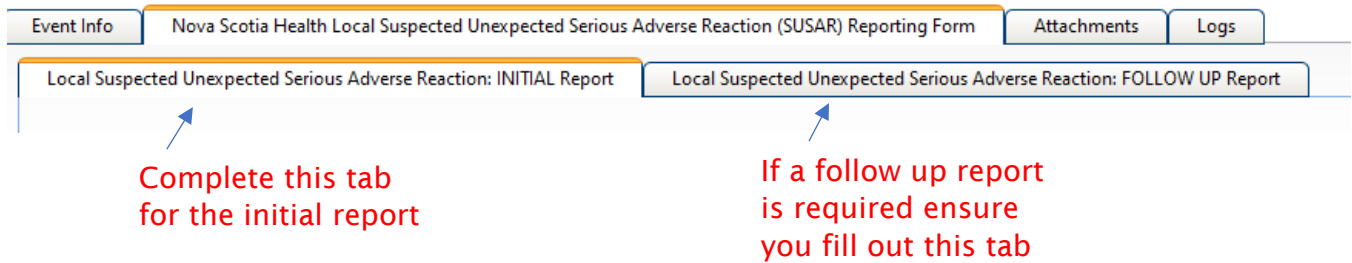
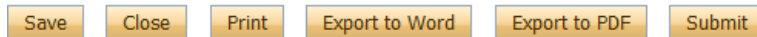
Event Info Nova Scotia Health Local Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Form Attachments Logs

Note(s)

2. Click on this tab

1. Optional: Enter brief description of event here...

3. Fill out form and add attachments as necessary.



Event Info Nova Scotia Health Local Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting Form Attachments Logs

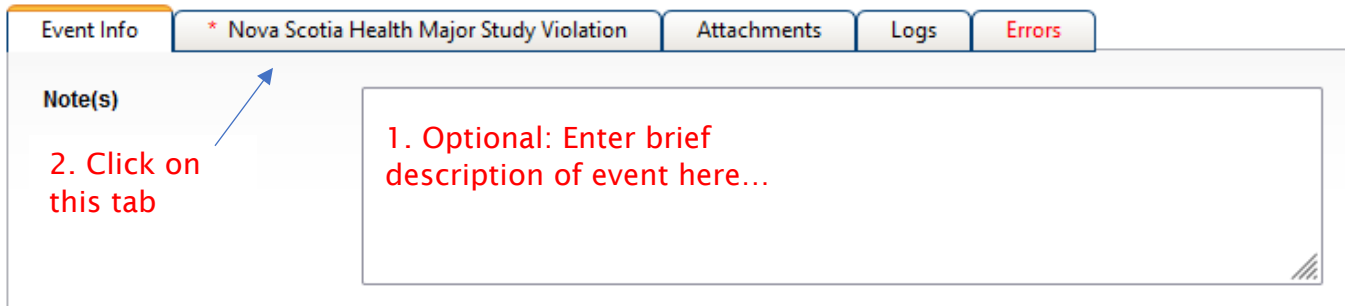
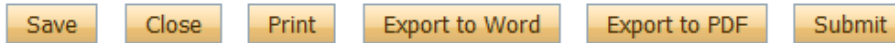
Local Suspected Unexpected Serious Adverse Reaction: INITIAL Report Local Suspected Unexpected Serious Adverse Reaction: FOLLOW UP Report

Complete this tab for the initial report

If a follow up report is required ensure you fill out this tab

5. NS Health Major Study Violation

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.



3. Fill out form and add attachments as necessary.

****Important****

i 1.3* Which aspect(s) of the study did the violation impact? Tick all that apply.

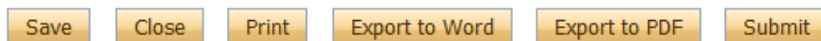
For clinical trials, if the violation does not affect data integrity or participant safety, privacy/confidentiality, or willingness to continue in the study are to be submitted as minor deviations (once per year) with either your annual renewal or study closure.

- Participant safety
- Participant willingness to continue in the study
- Participant privacy/confidentiality
- Data integrity
- Other

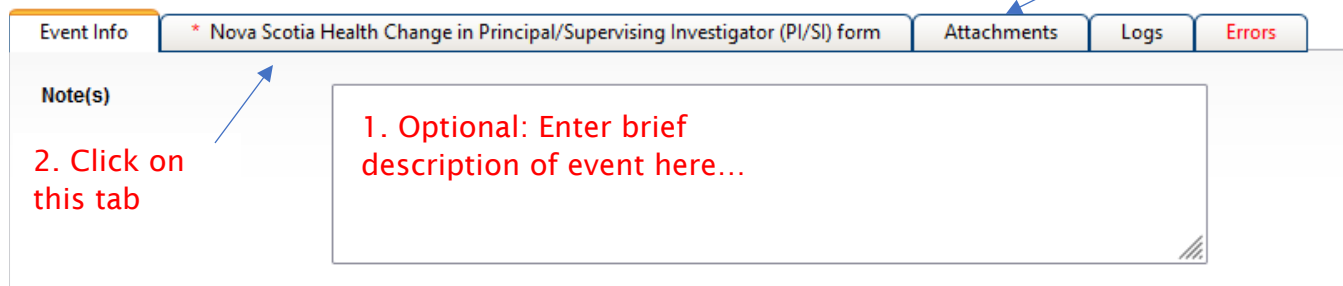
If you choose either “participant safety” or “participant privacy/confidentiality” the event must be reported in the Safety Improvement & Management System (SIMS):

[Login \(nshealth.ca\)](https://nshealth.ca)

6. NS Health Change in Principal/Supervising Investigator (PI/SI)



Required attachments
can be found on this



Event Info * Nova Scotia Health Change in Principal/Supervising Investigator (PI/SI) form Attachments Logs Errors

Note(s)

2. Click on this tab

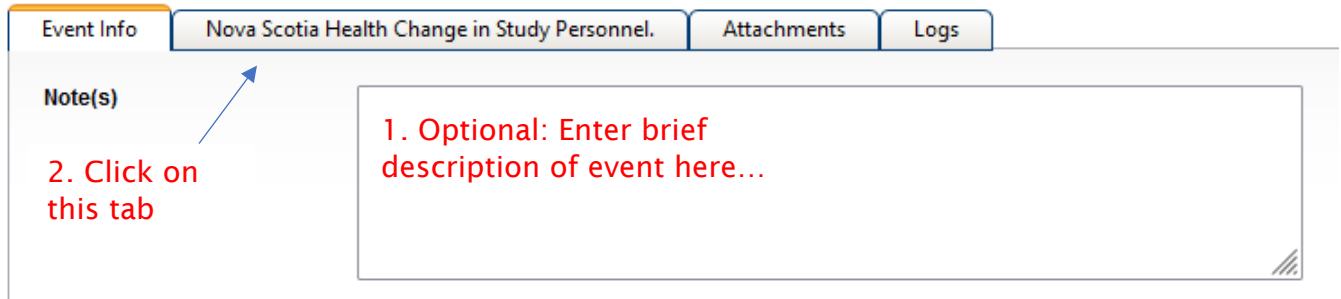
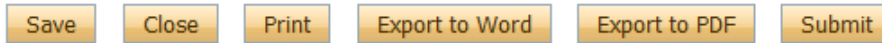
1. Optional: Enter brief description of event here...

3. Fill out form and add attachments

****Important****

- The new PI/SI must have an active & up to date ROMEO master profile before being added to the REB file.
- If they do not already have a ROMEO profile, please complete the [ROMEIO New User Profile form 2023](#) form.
- 5 documents are required from the incoming PI/SI:
 - Attestation form
 - TCPS2
 - CV
 - Letter of Support
 - Copy of medical license (for Interventional trials)

7. NS Health Change in Personnel (add or remove project team members)



Event Info Nova Scotia Health Change in Study Personnel. Attachments Logs

Note(s)

2. Click on this tab

1. Optional: Enter brief description of event here...

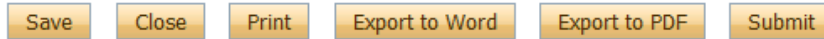
3. Fill out form

****Important****

- The new team member must have an active & up to date ROMEO master profile before being added to the REB file.
- If they do not already have a ROMEO profile, please complete the [ROMEo New User Profile form 2023](#) form.

8. NS Health Safety Related Events reporting

Periodic Safety Update Reporting (PSUR), Data & Safety Monitoring Board (DSMB) updates, sponsor issued safety alerts and/or sponsor provided safety information

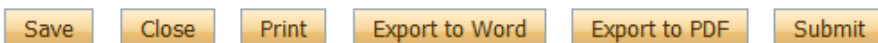


Event Info	* Nova Scotia Health Safety related events reporting (PSUR, DSMB, Safety Alerts)	Attachments	Logs	Errors
Note(s)	<div data-bbox="506 548 1385 730"><p>1. Optional: Enter brief description of event here...</p></div>			

2. Click on this tab

3. Fill out form and add attachments

9. NS Health Study Closure



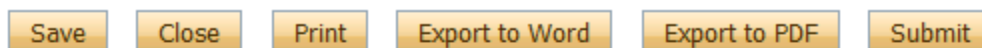
Event Info **Nova Scotia Health Study Closure** Attachments Logs

Note(s)

2. Click on this tab

1. Optional: Enter brief description of event here...

If your study is closing prematurely complete Tab 1, otherwise, leave it blank:



Event Info **Nova Scotia Health Study Closure** Attachments Logs

Premature Study Termination (Interventional Trials & Non-Interventional Studies)

If your study has terminated prematurely but the study has not yet closed, fill out this tab leaving the rest of the form blank.

Once the study closes complete another study closure form.

If your study has terminated prematurely and the study has closed, fill out all appropriate tabs.

All studies must complete Tab 2:

Logs

lies) **Study Closure Form: ALL STUDIES (Interventional Trials & Non-Interventional Studies)** Stud

Interventional studies must complete Tab 3 Non-Interventional studies must complete Tab 4:

s) **Study Closure: INTERVENTIONAL TRIALS** **Study Closure: NON-INTERVENTIONAL STUDY** Minor Study Deviation

Complete as required