



Submitting a Clinical Trial Safety Report

Safety Reporting to the (REGIS) HREC

Significant Safety Issue (SSI) Form

SSIs are to be completed and sent to the HREC for all clinical trials (therapeutic goods and non-therapeutic goods).

SSIs that have been implemented as an urgent safety measure should be reported within **72 hours** of the sponsor becoming aware of the issue.

All other SSIs should be reported within **15 calendar days** of the sponsor becoming aware of the issue

An SSI is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial:

- ❖ Urgent Safety Measure: A measure required to be taken to eliminate an immediate hazard to a participant's health or safety
- ❖ Temporary Halt of a Trial for Safety Reasons
- ❖ Early Termination of a Trial for Safety Reasons
- ❖ Amendment (submit through the Notification of an Amendment to a Research Study form)

Serious Breach Notification form (third party)

Completed when the trial sponsor is reporting the serious breach to the Human Research Ethics Committee (HREC) and the Therapeutic Goods Administration (TGA) or when a sponsor is providing additional/follow up information following a third-party report of a serious breach.

Safety Reporting to the (REGIS) Site/Institution

Reporting Local Safety Events to the Institution Form (including SSI Notification to REGIS sites from another Jurisdiction)

The researcher can select which type of report they are submitting

- ❖ Providing a REGIS site notification of an SSI that has been reported to a HREC in another Jurisdiction
- ❖ Reporting a local safety event e.g. SUSAR, USADE, URSAE

Local Safety Event

To be completed for all clinical trials (therapeutic goods and non-therapeutic goods) and submitted to the RGO within **72 hours** of the site becoming aware of the event, when, in the opinion of the investigator, one of the following events has occurred at the site:

- ❖ A Suspected Unexpected Serious Adverse Event (SUSAR) in a medicines or biological trial
- ❖ An Unanticipated Serious Adverse Device Event (USADE) in a medical device trial
- ❖ An Unexpected and Related Serious Adverse Event (URSAE) in any other interventional trial

This form should be completed by the Principal Investigator or their delegate(s) and submitted as a notification to their local Research Governance Office (RGO)

ETH/STE Projects

An Ethics or Site Project is where you can manage all post approval activities such as amendments and safety reporting.

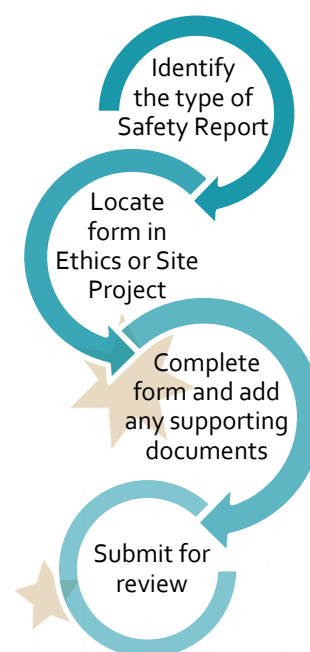
Who Can Submit?

The CPI or their delegate(s) can submit these forms.

Any person granted edit permissions during the application process (pre-approval) will continue to have access to the project (post-approval).

The form can be saved using the 'Save' icon at any time and completed later.

How does it work in REGIS?



Ethics/HREC Safety Reporting

Significant Safety Issue Notification

Complete & submit to the HREC (HREC within REGIS)

Step 1. Locate project

If the study does not appear in the 'Top 5 Projects' click the 'Projects' icon at the top of the page.



Projects

Click the Project Identifier (PID) and select the ETH identifier.

Step 2. Open a new Significant Safety Issue Notification Form

Select 'Forms', then 'New form' and then 'Significant Safety Issue Notification'.

Step 3. Complete the form

The **Project Details** section of the form will pull through information already available in the system.

Add the **date the SSI occurred** by selecting the calendar or manually typing in the date in the format DD/MM/YYYY

Date Significant safety Issue Occurred

dd/MM/yyyy

Sun	Mon	Tue	Wed	Thu	Fri	Sat
25	26	27	28	29	30	31
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31	1	2	3	4	5

Select the **Report Type** from the available options, 'Initial Report' or 'Follow-up Report'.

Select the **Form Type** from the dropdown menu: Urgent Safety Measure, Temporary Halt of a Trial for Safety Reasons and Early Termination of a Trial for Safety Reasons.

Depending on the answers provided the form will display additional questions or sections.

Answer each question and progress to the next section.

Step 4. Document Uploads

To add a document to the form select + Add Another

+ Add Another

Document Type: select the appropriate safety report from the dropdown menu.

Descriptor: Ensure to make the description clear and include the version and date if they exist.

Descriptor *

DO NOT upload study documents that have been amended and require review by the HREC, only reports are to be uploaded in this section. To submit amendments to study-wide documentation, complete the 'Notification of an Amendment Form' select 'General Amendment' and submit concurrently with this notification.

Step 5

The CPI or their delegate(s) can submit these forms.

Step 6

When the SSI has been acknowledged the status of the form changes to 'Approved', the CPI will be notified via a email and any PI's listed in REGIS will also be copied into that system email.

The SSI will also be automatically forwarded to all sites within REGIS

New Serious Breach Notification form (third party) (to a REGIS HREC)

Complete & submit to the HREC

Step 1. Locate project

If the study does not appear in the 'Top 5 Projects' click the 'Projects' icon to see all projects.



Projects

Click the required Project 'Identifier' (PID) and select the ETH identifier.

Step 2. Open a new Serious Breach Notification Form

Select 'Forms' then '+ New form' and then select 'Serious Breach Notification form (third party)'.

Step 3. Complete the form

The **Project Details** section of the form will pull through information already available in the system.

Select the **CTN/CTX Reference No.** and select who is reporting the breach; **sponsor** or **third party**.

Complete the Breach Details page.

Step 4. Document Uploads

To add a document to the form, select + Add Another

+ Add Another

Document Type: select the appropriate safety report from the dropdown menu.

Descriptor: Ensure to make the description clear and include the version and date if they exist.

Descriptor *

DO NOT upload study documents that have been amended and require review by the HREC, only reports are to be uploaded in this section. To submit amendments to study-wide documentation, complete the 'Notification of an Amendment Form' select 'General Amendment' and submit concurrently with this notification.

Step 5

The CPI, their delegate(s) and anyone with editor access to the ETH Project can submit the New Serious Breach Notification form (third party) by clicking 'Submit'.

Step 6



When the New Serious Breach Notification form (third party) has been acknowledged, the status of the form changes to 'Approved' and the CPI will be notified via email.

Governance/Site Safety Reporting

Reporting Local Safety Events to the Institution

Complete & submit to the RGO

Step 1. Locate project

If the study does not appear in the Top 5 Projects click the   Projects icon to see all projects.

Click the Project Identifier (PID) and select the STE identifier.

Step 2. Open a new Form

Select 'Forms' then '+ New form' and then select 'Reporting Local Safety Events to the Institution'.

Step 3. Complete the form

The **Project Details** section of the form will pull through information already available in the system.

Select the **Type of Safety Report**: Local Safety Event (SUSAR/USADE/URSAE)

Depending on the answers provided the form will display additional questions or sections.

Answer each question and progress to the next section.

Step 4. Document Uploads

Document Type: Select from the dropdown menu.

Descriptor: Ensure to make the description clear and include the version and date if they exist.

Descriptor *

DO NOT upload amended documents to be reviewed by the RGO. Complete the 'Site Amendment' select the 'General' option and submit concurrently with this notification.

Note: You can upload a single zip. File or an email with attachments in this section.

Step 5

The PI, their delegate(s) or anyone with editor access to the STE Project can

submit the Reporting Local Safety Events to the Institution form by clicking 'Submit'.



Step 6

When the Reporting Local Safety Events to the Institution form has been acknowledged, the status of the form changes from 'Submitted' to 'Approved'. The PI will be notified via email.

Significant Safety Issue Notification (to REGIS sites from another Jurisdiction)

Complete & submit to the RGO

Step 1. Locate project

If the study does not appear in the Top 5 Projects click the   Projects icon to see all projects.

Click the Project Identifier (PID) and select the STE identifier.

Step 2. Open a new Form

Select 'Forms' then '+ New form' and then select 'Reporting Local Safety Events to the Institution'.

Step 3. Complete the form

The **Project Details** section of the form will pull through information already available in the system.

Select the **Type of Safety Report**: SSI from approving HREC (external to REGIS).

Note: If you select this report and have Ethics in REGIS, the following warning message appears advising you that Ethics exists in REGIS and you cannot submit the SSI against the Site project, you must submit it against the Ethics project.

Ethics exists in REGIS.
Significant Safety Issues (SSI) must be submitted against the ETH project. On HREC acknowledgement the system will notify the CPI, PI's, Administration Contacts and all sites managed in REGIS.
For guidance please see: [Clinical Trial Safety Reporting](#)

This form can not be submitted against this STE.

Depending on the answers provided the form will display additional questions or sections.

Answer each question and progress to the next section.

Step 4. Document Uploads

Document Type: Select from the dropdown menu.

Descriptor: Ensure to make the description clear and include the version and date if they exist.

Descriptor *

DO NOT upload amended documents to be reviewed by the RGO. Complete the 'Site Amendment' select the 'General' option and submit concurrently with this notification.

Step 5

The PI, their delegate(s) or anyone with editor access to the STE Project can submit the Reporting Local Safety Events to the Institution form by clicking 'Submit'.

To reduce duplication of a notification of an SSI from an approving HREC (external to REGIS) this form is only required to be submitted by a single site. The system will notify each Research Office with a site in REGIS.

Step 6

When the Reporting Local Safety Events to the Institution form has been acknowledged the status of the form changes from 'Submitted' to 'Approved'.

The system will provide an automated acknowledgement of receipt notification.

This is the site acknowledgement, the Research Governance Office will not provide an individual response however, they may request further information.