Submitting a Clinical Trial Safety Report

Safety Reporting to the (REGIS) HREC

Significant Safety Issue Form

SSI's 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 in order 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 <u>in the opinion of the investigator</u> 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 delegate and submitted as notification to their local Research Governance Office (RGO)

Who can submit

The Project Owner (CPI for ETH, PI for STE) has full access to complete and is **the only person who can submit the Notification form**. The Owner can give edit and view permissions to others.

Any person granted edit permissions during the application process (pre-approval) will continue to have access to the project (post approval). **Editors can complete the notification form but cannot submit it.**

Form can be saved using the 'Save' icon at any time and completed.

How does it work in REGIS?

Identify the type of Safety Report

Locate form in Ethics or Site Project

Complete form and any supporating documents

Submit for review to the HREC/RGO as appropriate

Ethics/HREC Safety Reporting

Significant Safety Issue Notification

Complete & submit to the HREC (HREC within REGIS)

Step 1. Locate project 🖥 Projects 🖥

Click the 'Projects' icon to see all projects.

Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Ethics Project

This is where you can manage post approval activity (e.g. amendments and safety reporting). Only an approved study can have a safety notification created.

Click on the three dots ⋮ next to the identifier and then select 'Project Information'

Step 3. Open a new Form

Select 'Forms' from the left-hand menu.

Select '+ New form' and then select 'Significant Safety Issue Notification'.

Step 4. 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 three horizontal dots to pull up the calendar or manually typing in the date in the DD/MM/YYYY format.

Date Significant safety Issue Occurred
20/08/2020

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

Select the **Form Type** from the drop-down 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 5 Document Uploads

Note: You can add further rows by clicking the plus icon '+' and to delete rows, select the checkbox on that row and then click the minus icon '-'.

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

Document descriptor: Ensure to make the description clear.

Document version and Document Date: If there is no version or date, then add version 1 and the date the report is being submitted.

DO NOT upload study documents that have been amended and require to be 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 6

If you are the CPI you will be able to submit the SSI by clicking submit.

If you are not the CPI then save the form by selecting the save icon and notify the CPI that the SSI can now be submitted.

Step 7

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

The SSI will also be automatically be 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 🖥 Projects 🖥

Click the 'Projects' icon to see all projects.

Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Ethics Project

This is where you can manage post approval activity (e.g. amendments and safety reporting). Only an approved study can have a safety notification created.

Click on the three dots ⋮ next to the identifier and then select 'Project Information'

Step 3. Open a new Form

Select 'Forms' from the left-hand menu.

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

Step 4. 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 part**y.

Complete the Breach Details page.

Step 5 Document Uploads

Document Type: Select from the dropdown menu.

Document descriptor: Ensure to make the description clear and descriptive.

Document version and Document Date:). If there is no version or date,

NSW Health | ACT Government

then add version 1 and the date the report is being submitted.

DO NOT upload study documents that have been amended and require to be review by the HREC. Complete the 'Notification of an Amendment Form' select 'General Amendment' and submit concurrently with this notification.

Step 6

Anyone with editor access to the ETH Project can submit the New Serious Breach Notification form (third party) by clicking 'Submit'.

Step 7

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

Governance/Site Safety Reporting

Reporting Local Safety Events to the Institution

Complete & submit to the RGO

Step 1. Locate project `Projects`

Click the 'Projects' icon to see all projects.

Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Site Project

This is where you can manage post approval activity (e.g. site amendments and safety reporting). Only an approved study can have a safety notification created.

Click on the three dots next to the identifier and then select 'Project Information'

Step 3. Open a new Form

Select 'Forms' from the left-hand menu, select '+ New form' and then select 'Reporting Local Safety Events to the Institution'.

Step 4. 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)

If you select 'SSI from approving HREC (external to REGIS)' 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.

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

Answer each question and progress to the next section.

Step 5 Document Uploads

Document Type: Select from the dropdown menu.

Document descriptor: Ensure to make the description clear.

Document version and Document Date: If there is no version or date, then add version 1 and the date the report is being submitted.

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 6

Anyone with editor access to the STE Project can submit the Reporting Local Safety Events to the Institution form by clicking 'Submit'.

Step 7

When the Reporting Local Safety Events to the Institution form has been acknowledged the status of the form changes from 'Submitted' to 'Approved' and the PI will receive notification via email.

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

Complete & submit to the RGO

Step 1. Locate project `Projects`

Click the 'Projects' icon to see all projects.

Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Site Project

This is where you can manage post approval activity (e.g. site amendments

and safety reporting). Only an approved study can have a safety notification created.

Click on the three dots next to the identifier and then select 'Project Information'

Step 3. Open a new Form

Select 'Forms' from the left-hand menu.

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

Step 4. 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.

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

Answer each question and progress to the next section.

Step 5 Document Uploads

Document Type: Select from the dropdown menu.

Document descriptor: Ensure to make the description clear.

Document version and Document Date: If there is no version or date, then add version 1 and the date the report is being submitted.

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 6

Anyone with editor access to the STE Project will be able to 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 7

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 and the Research Governance Office will not provide an individual response however, they may request further information.