Submitting safety reports in Research GEMS
Safety reporting, serious breaches, protocol deviations and local safety events

Safety reporting to the Human Research Ethics Committee (HREC)

Safety reporting form

A safety reporting form is to be completed and submitted to the HREC for all clinical trials (therapeutic goods and non-therapeutic goods). Changes 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 safety reports should be reported within **15 calendar days** of the sponsor becoming aware of the issue.

A safety report is required when a safety issue arises that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial:

❖ Urgent safety measure (**USM**): 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.

These actions may also require submission of an ethics amendment via the [Notification of an amendment to a research study form.](#)

Serious breach report form

This form can be completed by either the trial sponsor or a third-party when a serious breach has occurred. Both the HREC and the therapeutic goods

administration (TGA) need to be made aware of the breach, as per [the TGA guidelines](#).

Safety reporting to the (GEMS) site/institution

Reporting local safety events to the institution form (including safety reporting forms to GEMS sites from another jurisdiction)

The researcher can select which type of report they are submitting:

❖ Providing a SA Health site listed in GEMS of a significant safety issue (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 research governance officer (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 and submitted by the principal

investigator (PI) or an authorised delegate.

Who can submit?

The project owner (coordinating principal investigator for ethics and PI for sites), administration contacts and delegates have automatic access to the forms.

There are different levels of permissions available:

❖ **Share with view**: User can only view the application and forms.
❖ **Share with edit**: User can view and edit the application and forms.
❖ **Share with edit and submit:** User can view, edit, and submit applications and forms.

Permissions can be set initially within the project registration, or at any time using the share feature. For more information, refer to user guide [Sharing access to applications and projects.](#)

How does it work in GEMS?
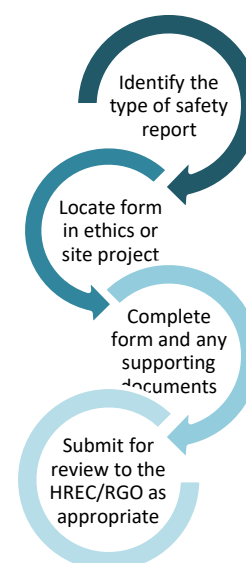
Safety Reporting to the HREC
Safety reporting form (GEMS)

Complete and submit to the HREC (within GEMS)

Step 1. Locate project

Click the 'Projects' icon to see all projects.

Click the required 'GEM Identifier' or 'Title' in the list of projects.

Step 2. Select the ethics project

Click on the ethics project identifier to be taken into the ethics project details. Only an approved study can have a safety notification form created.

Step 3. Create a new form
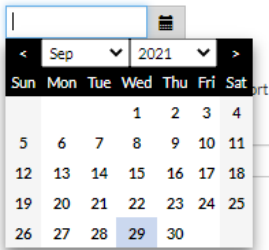
Select 'Forms' from the tabs on the top left.

Click the [+ New form] button, and then select 'Safety reporting form'.

Step 4. Complete the form

The project details section of the form will automatically populate information that is already available in the system.

Add the date the SSI occurred by selecting the calendar icon or manually enter the date in DD/MM/YYYY format.

Select the report type from the available

options: 'Initial report' or 'Follow-up report'.

Select the form type from the drop-down list:

❖ Urgent Safety Measure (USM).
❖ Temporary Halt of a Trial for Safety Reasons.
❖ 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 'Add row' button and to delete rows, select the red bin icon.

Document type: select the appropriate safety report from the drop-down list.

Document descriptor: ensure to make the description clear.

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

Only reports are to be uploaded in this section.

DO NOT upload study documents that have been amended and require HREC review. To submit amendments to study-wide documentation, complete an ethics Notification of an amendment form and select 'General amendment' to submit that form concurrently with this form.

Step 6.

If you are the CPI or an authorised

delegate, you will be able to submit the safety reporting form by clicking 'submit'.

Person/s with edit permission can save the form and notify the CPI or an authorised delegate that it is now ready to submit.

Step 7.

When the safety reporting form has been acknowledged, the status of the form will change to 'Approved.' The CPI and relevant team members will receive an email notification.
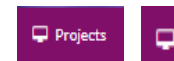
The safety reporting form will also be automatically forwarded to all associated sites within GEMS.

Serious breach report form (GEMS)

Complete and submit to the HREC (within GEMS)

Step 1. Locate project

Click the 'Projects' icon to see all projects.

Click the required 'GEM Identifier' or 'Title' in the list of projects.

Step 2. Select the ethics project

Click on the ethics project identifier to be taken into the ethics project details. Only an approved study can have a safety notification form created.

Step 3. Create a new form

Select 'Forms' from the tabs on the top left.

Click the [+ New form] button, and then

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Department for
Health and Wellbeing

select 'Serious breach report form'.

Step 4. Complete the form

The project details section of the form will automatically populate information that is already available in the system.

Select the CTN/CTX reference no**.** and select who is reporting the breach: sponsor or third party.

Step 5. Complete the breach details page.

Step 6. Document uploads

Document type: Select from the drop-down list.

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

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

DO NOT upload study documents that have been amended and require HREC review. To submit amendments to study-wide documentation, complete an ethics Notification of an amendment form and select 'General amendment' to submit that form concurrently with this form.

Step 7.

If you are the CPI or an authorised delegate, you will be able to submit the serious breach form by clicking 'submit'.

Person/s with edit permission can save the form and notify the CPI or an authorised delegate that it is now ready to submit.

Step 8.

When the serious breach report form has been acknowledged, the status of the form will change to 'Approved.' The CPI and relevant team members will receive an email notification.

Protocol deviation form (GEMS)

Complete and submit to the HREC (within GEMS)

Step 1. Locate project
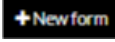
Click the 'Projects' icon to see all projects.

Step 2. Select the ethics project

Click on the ethics project identifier to be taken into the ethics project details. Only an approved study can have a protocol deviation form created.

Step 3. Create a new form

Select 'Forms' from the tabs on the top left.

Click the [+ New form] button, and then select 'Protocol deviation form'.

Step 4. Complete the form

The project details section of the form will automatically populate information that is already available in the system.

Step 5. Upload any relevant documents

Document type: Select from the drop-down list.

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

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

DO NOT upload study documents that have been amended and require HREC review. To submit amendments to study-wide documentation, complete an ethics Notification of an amendment form and select 'General amendment' to

submit that form concurrently with this form.

Step 6.

If you are the CPI or an authorised delegate, you will be able to submit the protocol deviation form by clicking 'submit'.

Person/s with edit permission can save the form and notify the CPI or an authorised delegate that it is now ready to submit.

Step 7.

When the protocol deviation form has been acknowledged, the status of the form will change to 'Approved.' The CPI and relevant team members will receive an email notification.

The protocol deviation form will also be automatically forwarded to all associated sites within GEMS.

Governance/site safety reporting

Reporting local safety events to the institution

Complete and submit to the RGO

Step 1. Locate project

Click the 'Projects' icon to see all projects.

Click the required 'GEM Identifier' or 'Title' in the list of projects.

Step 2. Select the site project

Click on the relevant site's project identifier to be taken to the site's project details. Only an approved study can have a safety notification form created.

Step 3. Create a new form

Select 'Forms' from the left-hand menu, select the **+New form** button and then select 'Reporting local safety events to the institution.'

Step 4. Complete the form

The project details section of the form will automatically populate information that is already available in the system.

Select the type of safety report: Local Safety Event (SUSAR/USADE/URSAE).

Note: If you select 'SSI from approving HREC (external to GEMS)' and have ethics in GEMS, the following warning message appears advising you that ethics exists in GEMS and you cannot submit the SSI against the site project, you must submit it against the ethics project.

> ⊘ **Ethics exists in GEMS.**
> 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 Research GEMS. For guidance please see: **Clinical Trial Safety Reporting**
>
> **This form can not be submitted against this SSA.**

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 drop-down list.

Document descriptor: Ensure to make the description clear.

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

DO NOT upload amended documents to be reviewed by the RGO. Complete a 'Site amendment' form and select the 'General' option to submit that form concurrently with this form.

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

Step 6.

If you are the CPI or an authorised delegate, you will be able to submit the reporting local safety events to the institution form by clicking 'Submit'.

Person/s with edit permission can save the form and notify the CPI or an authorised delegate that it is now ready to submit.
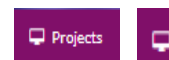
Step 7.

When the reporting local safety events to the institution form has been acknowledged the status of the form will change to 'Approved.' The CPI and relevant team members will receive an email notification.

Significant safety issue notification (to GEMS sites from another jurisdiction)

Complete and submit to the RGO

Step 1. Locate project

Click the 'Projects' icon to see all projects.

Click the required 'GEM Identifier' or 'Title' in the list of projects.

Step 2. Select the site project

Click on the relevant site's project identifier to be taken to the site's project details. Only an approved study can have a safety notification form created.

Step 3. Create a new form

Select 'Forms' from the left-hand menu.

Select the **+New form** button 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 GEMS).

To reduce duplication, a notification of an SSI from a HREC external to GEMS is only required to be submitted by a single site. The system will notify each research office that has an associated site in GEMS.

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

❶ **Ethics exists in GEMS.**
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 Research GEMS. For guidance please see: **Clinical Trial Safety Reporting**

This form can not be submitted against this SSA.

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 drop-down list.

Document descriptor: Ensure to make the description clear.

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

DO NOT upload amended documents to be reviewed by the RGO. Complete a 'Site amendment' form and select the 'General' option to submit that form concurrently with this form.

Step 6.

If you are the CPI or an authorised delegate, you will be able to submit the reporting local safety events to the institution form by clicking 'Submit.'

Person/s with edit permission can save the form and notify the CPI or an authorised delegate that it is now ready to submit.

The system will notify each research office that has an associated site in GEMS.

Step 7.

When the reporting local safety events to the institution form has been acknowledged, the status of the form will change 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.