Government of Western Australia
Department of Health

All Researchers | User Guide Monitoring - Safety Reports

Add a Safety Report | Select the Section | Complete the Report | Submit the Report

When is a Safety Report required?

A Safety report is a requirement of the National Health and Medical Research Council's (NHMRC) Safety monitoring and reporting in clinical trials involving therapeutic goods. The Report should be created and submitted to a WA Health Human Research Ethics Committee (HREC), and/or a Research Governance (RG) Office in line with these reporting requirements. All supporting documents should be submitted with the report. For further guidance see WA's requirements in the WA Health Research Authorisation and Monitoring Forms Guidelines and the National Mutual Acceptance Monitoring and Reporting Tables May 2020.

Add a Safety Report

Any Project Member can add a Safety Report form to the project. Go to the Monitoring tab in the Project workspace.

Click 'Add' under the Forms section and select the Safety Report and click 'Add Selected Form to the Project'. The form will open in Edit mode. Clicking 'Save & Close' will take you out of Edit mode.

Select Section

The report is in sections, and you only need to complete the section relevant to the type of report you are submitting. Each section of the report has an information icon ⓘ which you can hover over with you mouse to see the information related to that section.

There are eight sections to the report:

1. Project Details
2. Serious Breach
3. Significant Safety Issue (SSI)
4. SUSAR or USADE
5. Annual Safety Report and/or Updated Investigator Brochure.
6. Supporting Documents
7. General Comment
8. Declaration

While Section 1 Project Details always needs to be completed, Sections 2-6 only need to be completed if you have answered 'Yes' to the first question in that section. Remember to select 'No' to the sections that are not relevant.

In Section 8, the declaration can be signed by either the Coordinating Principal Investigator (CPI), the CPI Delegate, Principal Investigator (PI) or PI Delegate.

Complete the Report

In Section 1 select the sites impacted by the report and add the sponsor (if applicable).

Select 'Yes' or 'No' to the first question in each of the next five sections. Selecting 'Yes' will open the section and the mandatory fields, that are denoted by a red asterix (*) next to the field title, which will have to be completed.

Serious Breach

Section 2 is to be completed if there has been a serious breach is a breach of the project protocol or Good Clinical Practice that is likely to affect to a significant degree:

- the safety or physical or mental integrity of the trial participant; or
- the reliability and robustness of the data generated in the project.

Significant Safety Issue

Section 3 should be completed if there has been a Significant Safety Issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial.

Local SUSAR or USADE

Section 4 is reported to the applicable RG Office for local

- Suspected Unexpected Serious Adverse Reaction (SUSAR) is an adverse reaction that is both serious and unexpected
- An Unanticipated Serious Adverse Device Effect (USADE) is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

Annual Safety Report and/or Updated Investigator Brochure (IB)

In Section 5 if the report requires the submission of an Annual Safety Report; Executive Summary of a Development Updated Safety Report; Updated/addenda or annual Investigator Brochure and/or product information; these will have to be added under the Documents section in the Monitoring tab.

Supporting Documents

A document can be added through the form or from the Document section of the Monitoring tab.

To add a document through the form, select 'Yes' in Section 6 Supporting Documentation and the 'Add' button will appear. The form will also show any documents that have been added under the Monitoring tab that are not associated with a form.

Click the 'Add' button and the Add Project Documents screen will appear. Complete the information for the mandatory fields. Once all the information is added, click the 'Add' button.

You will have to tick the box under the Select column for all the documents that you want to submit with the Safety Report Form even if you have added them within the form.

See User Guide Monitoring – Document for assistance with this.

When all the mandatory fields have been completed click the 'Mark Complete' button, this will take you to Section 8 Declarations, where the report can be signed and authorised ready for submission. You can also navigate to this section of the report through the form 'Index'.

General Comments

The general comments section allows you to enter any other pertinent information that can't be detailed anywhere else within the form.

Submit the Report

To submit the report, scroll to the bottom of the Monitoring tab and click the 'Submit' button.

The submit screen will appear and show all available forms and documents that can be submitted. Click the box under the relevant HREC and/or RG Office for that Safety Report, all documents associated with the form should be automatically ticked if they have been selected within the form. If they have then click the Submit button, you will get a message that the submission was successful and an automated email will be sent to you detailing what you have submitted.

If the documents have not been automatically ticked then click Cancel and go back to the Monitoring tab and open the form and click Unauthorise under the Declaration and then click Edit go to the first part of the form and scroll down to the Supporting Documents section and tick the documents that need to be connected with the form. Click the Mark Complete button and sign and submit the form.