



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 July 2017](#).

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 your mouse to see the information related to that section.

There are six 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. Declarations

While Section 1 Project Details always needs to be completed, Sections 2-5 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 6, 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 four 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.

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.

When all the mandatory fields have been completed click the 'Mark Complete' button, this will take you to Section 6 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'.

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 HREC or RG Office that the Safety Report and any related documents are to be submitted to. Once all the boxes have been selected, click the Submit button at the bottom of the screen. You will receive a submission confirmation email.