| Add an Amendment Form | Select the Section | Complete the Form | Submit the Form |

When is an Amendment required?

An amendment is required when there has been a change to the project. All supporting documents should be submitted with the amendment. There are two types of amendment forms, the Amendment Form and the Governance Only Amendment Form. The Amendment Form can be submitted to both the HREC and Research Governance (RG) Office (if there are no site specific documents related to the changes). The Governance Only Amendment Form is used when the changes are site specific. This form can have an Amendment Form attached to it if the update is related to that Governance Amendment.

For further guidance see WA Health Research Authorisation and Monitoring Forms Guidelines .

Add an Amendment Form

Any Project Member (PM) can add an Amendment Form to the project. Go to the Monitoring tab in the Project workspace.

Click 'Add' under the Forms section and select the Amendment Form 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 form is in sections and you only need to complete the section relevant to the type of amendment you are submitting. The form has information icons (i) which you can hover over with your mouse to see the information related to that section.

There are seven sections to the form:

1. Project Details
2. Change to Project Documentation
3. Change to Project Investigators
4. Addition of a Site
5. Extension of Approval
6. Department of Health Data Collections – Data and/or Linkage Update
7. Declarations

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.

Section 7, the declaration can be signed by either the Coordinating Principal Investigator (CPI), the CPI Delegate, Principal Investigator (PI) or PI Delegate.

Complete the Form

In Section 1 select the sites affected by the amendment e.g. all sites for a change to the protocol.

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.

Adding a Document

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 2 Change to Project 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 select all the documents that you want to submit with the Amendment Form even if you have added them in the form.

See User Guide Monitoring – Document for assistance with this.

Declaration

When all the mandatory fields have been completed click the 'Mark Complete' button, this will take you to Section 7 Declarations, where the form can be signed and authorised ready for submission. You can also navigate to this section of the report through the

form 'Index'. The form and documents can now be submitted. See Submit the Form.

Add the Governance Only Amendment Form

Any PM can add a Governance Only Amendment Form to the project. Go to the Monitoring tab in the Project workspace.

Click 'Add' under the Forms section and select the Governance Only Amendment Form 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.

PMs can only complete the form for sites that they are associated with and submit the form to the RG Office associated with those sites.

Select Section

The form is in sections and you only need to complete the section relevant to the type of amendment you are submitting. The form has information icons (i) which you can hover over with your mouse to see the information related to that section.

There are five sections to the form:

1. Project Details
2. Change to Project Documentation
3. Change to Budget Form
4. Attach an Amendment Form
5. Declarations

In Section 2 Change to Project Documentation add site specific documentation (e.g. insurance certificate) that is not required to be submitted to the HREC for review. Add and select the documents within the form as described previously under Adding a Document.

Amended Budget Form

If you select 'Yes' to Section 3 Change to Budget Form a copy of the last authorised Budget Form will be added to the Governance Only Amendment Form. Sponsors are unable to view the original or Amended Budget Form.

For more information when adding an Amended Budget Form to the Governance Only Amendment Form please refer to the User Guide Monitoring - Governance Only Amendment Form and Amended Budget Form or the Help Wiki for Monitoring Amendment.

Attach an Amendment Form

Once an Amendment Form has been approved by the HREC it can be submitted to the relevant RG Office/s. If there are additional site documents required that are related to the documents in the Amendment

Form, referencing the Amendment Form in this section will assist the RG Office when reviewing the site specific documents.

Declaration

When all the mandatory fields have been completed click the 'Mark Complete' button, this will take you to Section 5 Declarations, where the form can be signed and authorised ready for submission. You can also navigate to this section of the report through the form 'Index'.

Amendments approved under National Mutual Acceptance (NMA)

If the amendment has been approved by a Lead HREC outside of WA Health, then a Governance Only Amendment (GOA) Form will have to be created and submitted to all Research Governance (RG) Offices that have authorised sites in the project. The GOA Form can only have one RG Office and its sites included in section 1 but it can be submitted to all the RG Offices. This GOA Form should include the HREC's approval for the amendment.

If there are site specific documents that need to be provided to an RG Office as a result of the HREC approved amendment, this should be a separate Governance Only Amendment Form. The GOA Form with the HREC amendment should be referenced in Reason for change so that it can be associated by the RG Office.

Submit the Form

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

The Submit Project 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 form is to be submitted to, all documents associated with the form should be automatically ticked if they have been selected within the form. If they have been automatically selected then click the Submit button, you will get a message that the submission was successful, 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. Go to the Declarations page, click Un-authorise at the bottom of the page and then click Edit. Navigate to the first page of the form and scroll down to the Supporting Documents section, ensure that all documents that relate to the form are ticked. Click the Mark Complete button and sign and submit the form as described above.