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

When is an Amendment required?

An amendment is a required when there has been a changed 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 ⓘ which you can hover over with you 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.

Amendments approved under National Mutual Acceptance (NMA)

If the amendment has been approved by a Lead HREC outside of WA Health an Amendment Form is still completed and the HREC approval letter and all approved documents are attached to the form and

these are then submitted to a RG Office for validation. This is to allow all WA Health RG Offices involved with the project access to the ethically approved documentation.

The Governance Only Amendment Form is then completed for each site that has site specific documentation related to the amendment and the Amendment Form is attached under section 4 of that form.

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 ⓘ which you can hover over with you 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 and can be opened in the form. Sponsors are unable to view the original or Amended Budget Form.

To change the Budget Form click on the name either within the form or on the Monitoring tab. The Amended Budget Form when opened will still retain all previous authorisations. Only the sections edited will require reauthorisation.

Unauthorise the form and then click 'Edit'; the form will be locked out to you until you click 'Save & Close'. Go to Section 2 and click the 'Unlock' button to edit the department that requires changes. Click 'Save' to save the changes. Next go to Section 3 and update the funding and click 'Save'. Go to Section 1 and invite the person responsible for authorising that department (their invitation status will have reverted to pending). You can also at this point change the person you are inviting. Click 'Invite to quote/authorise' button. The person will then receive and email and a task for your project. The PI/PI Delegate will receive an email once they have signed. The PI or PI Delegate can then go to the Amended Budget Form and click 'Authorise'.

The Governance Only Amendment Form should be opened to complete the form.

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'.

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 and any related documents are to be submitted to. Any documents associated with the form will automatically be selected.

If the documents are not selected click 'Cancel' and then go back to the form and unauthorise it and edit it to select the associated documents.

Once all the boxes have been selected, click the 'Submit' button at the bottom of the screen. You will receive a submission confirmation email.