

When is a Governance Only Amendment and Amendment Budget Form is required?

An amendment is a required when there has been a changed to the project. The Governance Only Amendment (GOA) Form is used when the changes are site specific. This guide is specifically when a Governance Only Amendment Form **and** Amended Budget Form (ABF) is required (an ABF can't be created for a migrated project). These forms will only be submitted to a Research Governance (RG) Office. This form can have an Amendment Form attached to it if the update is related to that GOA.

Add the Governance Only Amendment(GOA) Form

Any Project Member (PM) can add a GOA 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, closing the form and taking you back to the Monitoring tab.

PMs can only complete the form for sites that they are associated with. The form has to be signed/authorised and submitted by the PI or PI Delegate for that site.

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, research agreement, site specific Participant Information Sheet and Consent Forms) that is not required to be submitted to the HREC for review. Add and select the documents within the form.

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 (by ticking the box to the right of the document) that you want to submit with the GOA even if you have added them within the form.

See <u>User Guide Monitoring – Document</u> for assistance with this.

Add an Amended Budget Form (ABF)

If you select 'Yes' to Section 3 Change to Budget Form you will have to select the last authorised budget form that you want to make changes to. Once this is selected you will have to click 'Save & Close' to go back to the

Monitoring tab to access the new ABF. It should be sitting under the GOA. You can only access the ABF from the Monitoring tab.

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. Once the GOA has been marked complete you can also navigate to this section through the form 'Index'.

Amended Budget Form

To change the ABF, click on the name in the Monitoring tab. The ABF when opened will still retain all previous authorisations. You only need to make unlock the department/s where a change needs to be made the rest of the departments will retain their previous authorisation.

Click the Unauthorise button at the bottom of the page 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, this will also revert the Head of Department's invitation and authorisation status to pending. Make the required changes in that section of the ABF. Click 'Save' to save the changes. Next go to Section 3 and update the funding and click 'Save'.

Then go to Section 1 to invite the person responsible for authorising that department. You can also at this point change the person you are inviting. To change the person, tick the box under the Select column at the far right. Click the Edit button under the Departments and in the pop up window delete the person and add the new person. Click Save to save the changes.

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 ABF has to be authorised by the PI or PI Delegate before it is ready for submission. The PI or PI Delegate can then go to the Amended Budget Form and click Edit and then click 'Authorise'.

Submit the Form

The GOA and ABF have to be submitted together. Before submitting these forms please check that both forms have been authorised. To do this click on the three dot under the RGO that you are submitting to circled below.

Form Name	DoH HREC	SCGOPHCG RGO		
Governance Only Amendment Form 004	N/A	—		
Amended Budget Form 004	N/A	—		

This will open a pop-up window and you will be able to see the status. Both forms must have the status of Signed and Authorised before they can be submitted together.

View History for Amended Budget Form 004

Form Name	Version	Status	Locked By	Updated By	Submitted Date	Validation Date	Review Completion Date	Authorisation Decision Date
Amended Budget Fe 004	orm 1	Signed & Authorised		Henry Amberley				

When they have both have the Status of Signed & Authorised click the Submit button in the Monitoring tab.

The Submit Project pop-up screen will appear and show all available forms and documents that can be submitted. If the ABF is not listed then it has not been authorised and you will have to go back to the Monitoring tab to do this. RGS will not allow you to submit a GOA without the ABF or the ABF without the GOA. If both forms are listed, click the box under the relevant RG Office for each of the forms. Any documents associated with the form will automatically be selected.

If the documents are not selected click 'Cancel' and then go back to the GOA and unauthorise it and edit it to select the associated documents, make sure to Mark Complete and Sign & Authorise.

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