Government of **Western Australia**
Department of **Health**

Research Governance Service (RGS)

Researcher User Guide

Part B: Document Preparation and Submission

Version 4.0

January 2018

Suggested Citation

Department of Health. (2018). *Research Governance Service (RGS) Researcher User Guide (Part B)*, Research Development Unit, Department of Health, Perth.

Contents

1. Fill Out and Authorise Project Details 1
1.1 Fill Out the Project Details Tab (General Information) 1
1.2 Complete the Project Header Information 4
1.3 Complete Project Header for National Mutual Acceptance (NMA) 5
1.3.1 WA Health is the Lead HREC (With a WA Health Specialist HREC) 5
1.3.2 WA Health is the Lead HREC (Without a WA Health Specialist HREC) 6
1.3.3 External Lead HREC (With a WA Health Specialist HREC) 6
1.3.4 External Lead HREC Only 6
1.4 Add the Funder Details in the Governance Information 7
1.5 Authorise or Unauthorise a Section of the Project Details Tab 8
1.6 Systematic Unauthorisation of the Project Details Tab 9
2. Add, Fill Out and Authorise an Ethics Form 10
2.1 RGS Ethics Forms 10
2.2 NMA Ethics Forms 10
2.2.1 WA Health Lead HREC (With or Without Specialist HREC) 10
2.2.2 External Lead HREC (With a WA Health Specialist HREC) 10
2.2.3 External Lead HREC Only 11
2.3 Add an Ethics Form 12
2.4 Fill Out an Ethics Form 13
2.5 Sign, Authorise and Unauthorise an Ethics Form 16
2.6 Systematic Unauthorisation of the Ethics Forms 18
3. Add, Fill Out and Authorise a Governance Form 19
3.1 RGS Governance Forms 19
3.2 Add a Governance Form 20
3.3 Fill Out a Governance Form 23
3.4 Sign, Authorise and Unauthorise a Governance Form 23
3.4.1 Sign and Authorise a Site Specific Assessment Form 23
3.4.2 Sign and Authorise an Access Request Form 26
3.4.3 Unauthorise a Site Specific Assessment Form 27
3.4.4 Unauthorise an Access Request Form 28
3.5 Systematic Unauthorisation of the Governance Forms 29
4. Add, Fill Out and Authorise a Budget Form 30
4.1 Add Information to Project Details Tab for a Budget Form 30
4.2 Add a Budget Form 30
4.3 Fill Out and Authorise a Budget Form 31
4.3.1 SECTION 1: DEPARTMENT(S) SELECTION 32
4.3.1.1 Add a Department 32
4.3.1.2 Add an Internal Department 33
4.3.1.3 Add a Third Party Agency 35
4.3.1.4 Edit and Remove a Department or Head of Department 35
4.3.1.5 Next Steps 36
4.3.2 SECTION 1: INVITE A HOD TO AUTHORISE OR HOSD TO QUOTE AND AUTHORISE 37
4.3.2.1 Un-invite a User 38
4.3.2.2 Edit an Authorised or Declined Section 39
4.3.3 SECTION 2: SITE PROJECT BUDGET 39

4.3.3.1 Research Department Default Items 40
4.3.3.2 Complete the Research Department and Third Party Agency Costs 40
4.3.3.3 Remove a Service or Support Item 42
4.3.3.4 Authorise the Third Party Agency Costs 43
4.3.4 SECTION 3: SITE PROJECT FUNDING / SUPPORT 43
4.3.4.1 Complete the Site Project Funding / Support 43
4.3.4.2 Calculation of Costs and Funding 44
4.3.4.3 General Comments (mandatory in cases of shortfall) 45
4.3.5 SECTION 3: PI AUTHORISATION WHEN BUDGET FORM COMPLETE 45
5. Upload Supporting Documents 46
5.1 RGS Supporting Document Templates 46
5.2 Upload a Supporting Document 46
5.3 Authorise a Supporting Document 48
5.4 Edit a Supporting Document 48
5.5 Sort Documents 49
6. Add a Comment 49
7. View or Add a Declaration 50
8. Print and PDF an Application Form 51
8.1 Print a Form 51
8.2 PDF a Form 51
9. Ethics Submission, Validation and Review Assessment 52
9.1 Submission 52
9.1.1 WA Health Lead HREC (With a WA Health Specialist HREC) 53
9.1.2 External Lead HREC (With a WA Health Specialist HREC) 54
9.1.3 External Lead HREC Only 55
9.2 Validation 56
9.3 Review Assessment 58
10. Governance Submission, Validation and Review Assessment 61
10.1 Submission 61
10.2 Validation 62
10.3 Review Assessment 64
11. View Letters 66
12. Track a Project through the Review Process 67
12.1 Timeline 67
12.2 Summary 68

1. Fill Out and Authorise Project Details

After setting up the Sites and Members of your project (refer to Researcher Guide Part A) you should complete the Project Details tab. Project Details has been created to reduce Project Members duplicating data entry. The Project Details' information feeds into the ethics and governance application forms and allows the CPI or CPI Delegate to submit the ethics forms, and the PI or PI Delegate to submit the governance forms independently of each other (i.e. in parallel, ethics before governance or vice versa). This ability aligns with the NHMRC's Good Practice Process to assist with assessing the feasibility of a project (through the Budget Form) prior to submitting an application for ethical review.

The 'Project Details' tab has four sections that must have all mandatory fields or questions completed and authorised before the related application form can be added to the project and completed. The sections and their related forms are:

Project Details Section	Forms that Data Populates
1. Project Header	Ethics & Governance
2. Ethics Information	Ethics & Governance
3. Governance Information	Governance only
4. Investigator Contact Information	Ethics & Governance

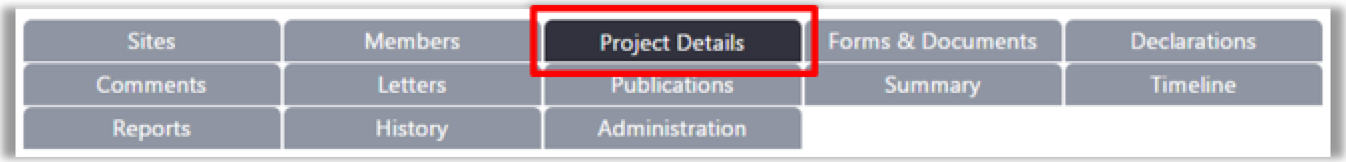
All Project Members (including Sponsors) can edit, mark complete and unlock all four sections. However, only certain project roles are allowed to authorise and unauthorise a specific section, this is to ensure the Project Details' information is correct prior to populating the forms.

Project Member Role to Authorise / Unauthorise Project Details:

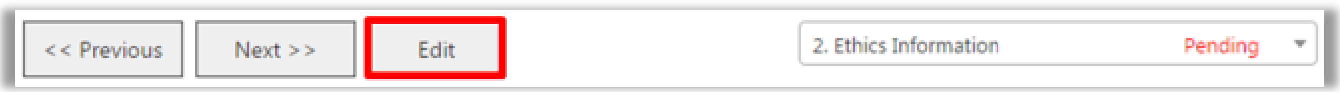
Project Details Section	Project Member Role
1. Project Header	CPI, CPI Delegate, PI, or PI Delegate
2. Ethics Information	CPI or CPI Delegate
3. Governance Information	PI or PI Delegate
4. Investigator Contact Information	CPI, CPI Delegate, PI or PI Delegate.

1.1 Fill Out the Project Details Tab (General Information)

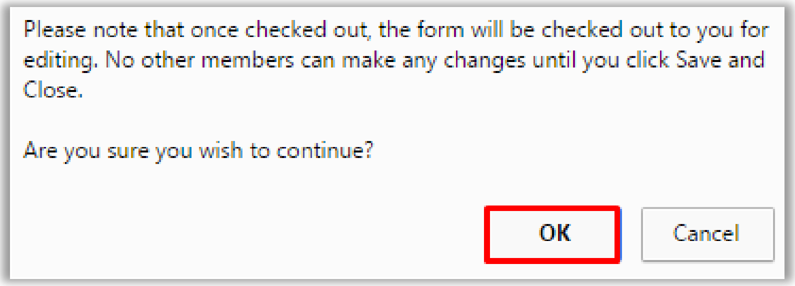
1. In the project's workspace, click on the 'Project Details' tab.



2. Select a section in the index at the top right of the screen, and click Edit. You can toggle between the different sections in the tab using the 'Index' or click '<<Previous' or 'Next >>'. You need to select 'Edit' for each section of the Project Details as they operate independently.



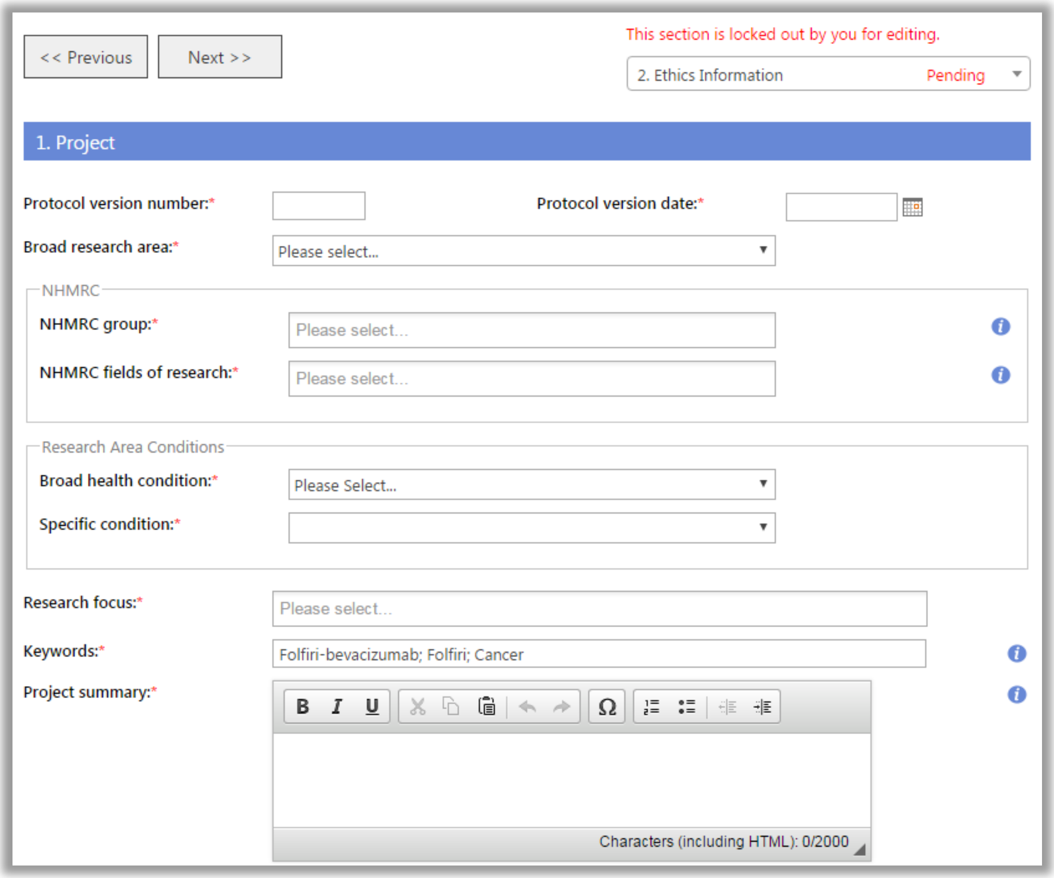
You will receive a warning that the Project Details will be checkout to you. Click ‘OK’.



You are only allowed to edit the section when its status is **'Pending'**. If you wish to edit the section and it has a different status, the following with apply:

- **If the status is 'In Use':** you may need to contact the Project Member who is editing the form. The other Project Member must click 'Cancel' or 'Save & Close' to release the lock on the form. If the Project Member is away for an extended period the CPI, CPI Delegate, PI or PI Delegate can 'Force Check-in the form. Alternatively, you may contact the RGS Administrator to 'Force Check-in' the form.
- **If the status is already 'Completed':** the form must be unlocked first by clicking 'Unlock'. This can be done by any Project Member.
- **If the status is already 'Authorised':** the section must be unauthorised first by clicking 'Unauthorise'. Only the CPI, CPI Delegate, PI or PI delegate can unauthorise their relevant sections.

3. Update the relevant fields. All mandatory fields have a red asterisk (*) next to them. Placing your pointer over the information icon on the right-hand side of the screen will provide you with tool tips and information about the section or field to be completed. A subsection within Ethics Information is shown below:

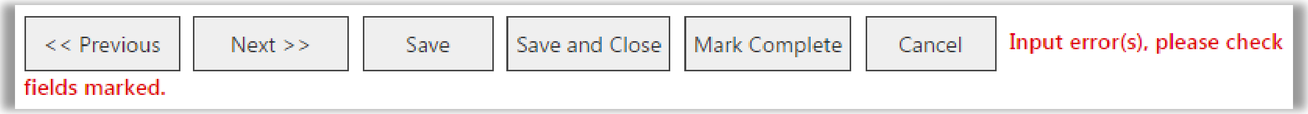


4. Click 'Save' to save changes, 'Save & Close' to save changes and exit 'Edit' mode, or 'Cancel' to discard any changes made. Changes will not be made to the Project Header until it is authorised by the CPI or CPI Delegate.

User tip: Click 'Save' every 5-10 minutes to ensure entered data is saved. You can click 'Save and Close' at any time and log out of the RGS and then return to the form later.

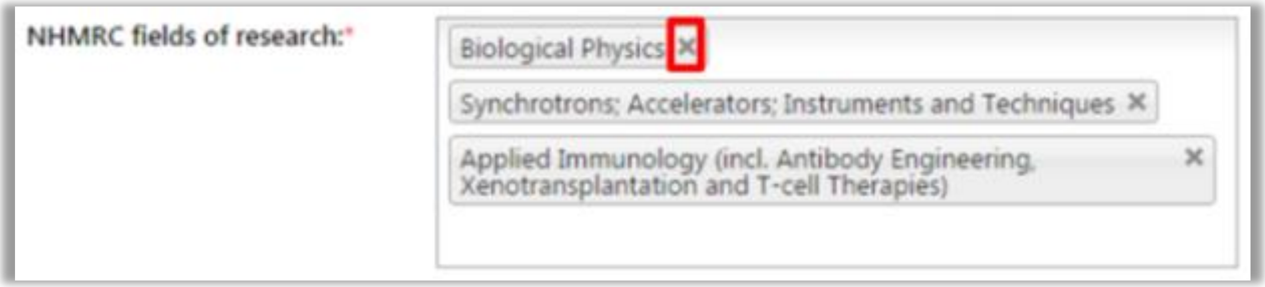
Mandatory Fields

If a mandatory field is left blank when you 'Mark Complete', you will receive a notification error and the RGS will automatically highlight fields that require mandatory information entered.



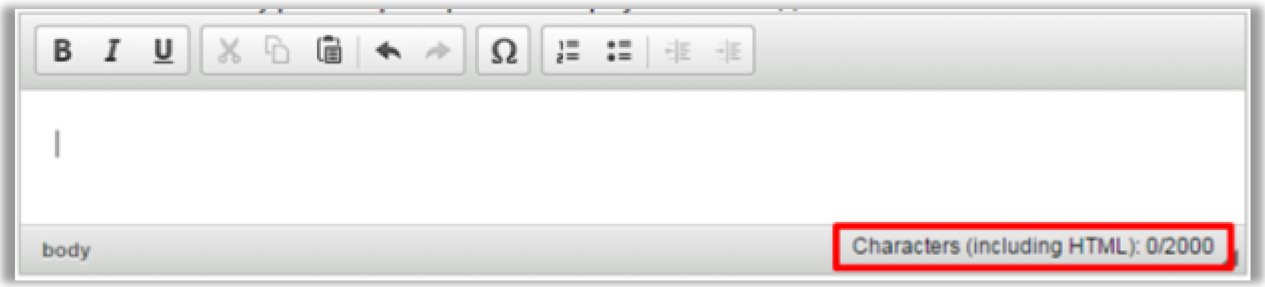
Entering Data in Multi-select Fields

If a field allows multiple selections, click on the desired option to add it into the list. If you have selected an option in error and wish to remove it, click on the X beside the option. **Note: Clinical Trial Phase is multi-select, nominate multiple phases if required.**

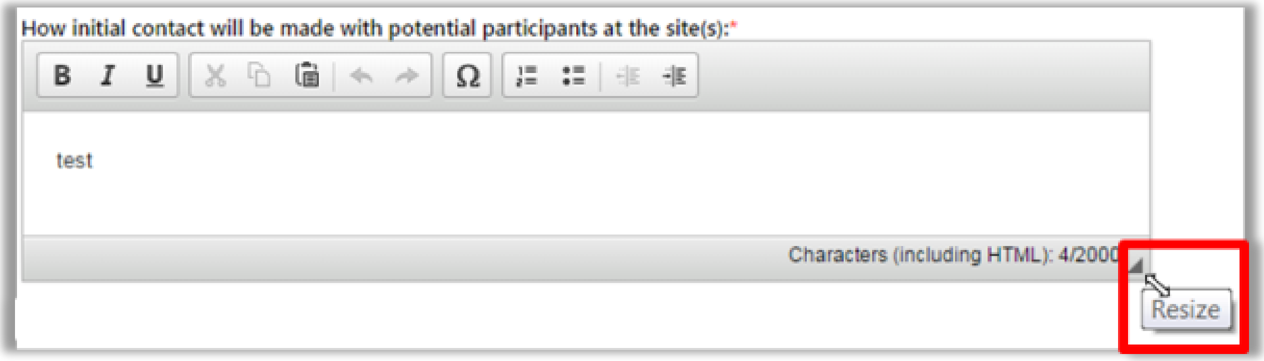


Entering Data in Rich Text Fields

Rich text fields show a character or word count on the bottom left-hand corner of the box. Use this as guide to ensure you do not go beyond the limit; otherwise, you will be prompted with an error.



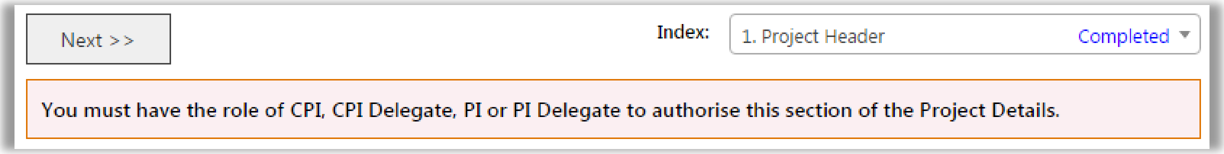
You may also drag the border of the box to extend its length.



5. Click '**Mark Complete'** when all information in that section has been entered. The status of the section will update to 'Completed' to inform other Project Members that this section is now final and ready for authorisation. Any Project Member who is currently editing the section may click 'Mark Complete'.

Any Project Member can edit a section with the 'Completed' status by clicking 'Unlock'.

6. If the status is 'Completed', the section is ready for authorisation by the CPI, CPI Delegate, PI or PI Delegate (refer to 'Project Member Role to Authorise / Unauthorise Project Details'). If a section of Project Details is not authorised an alert at the top of the page will be present if your role in the project doesn't allow you to authorise

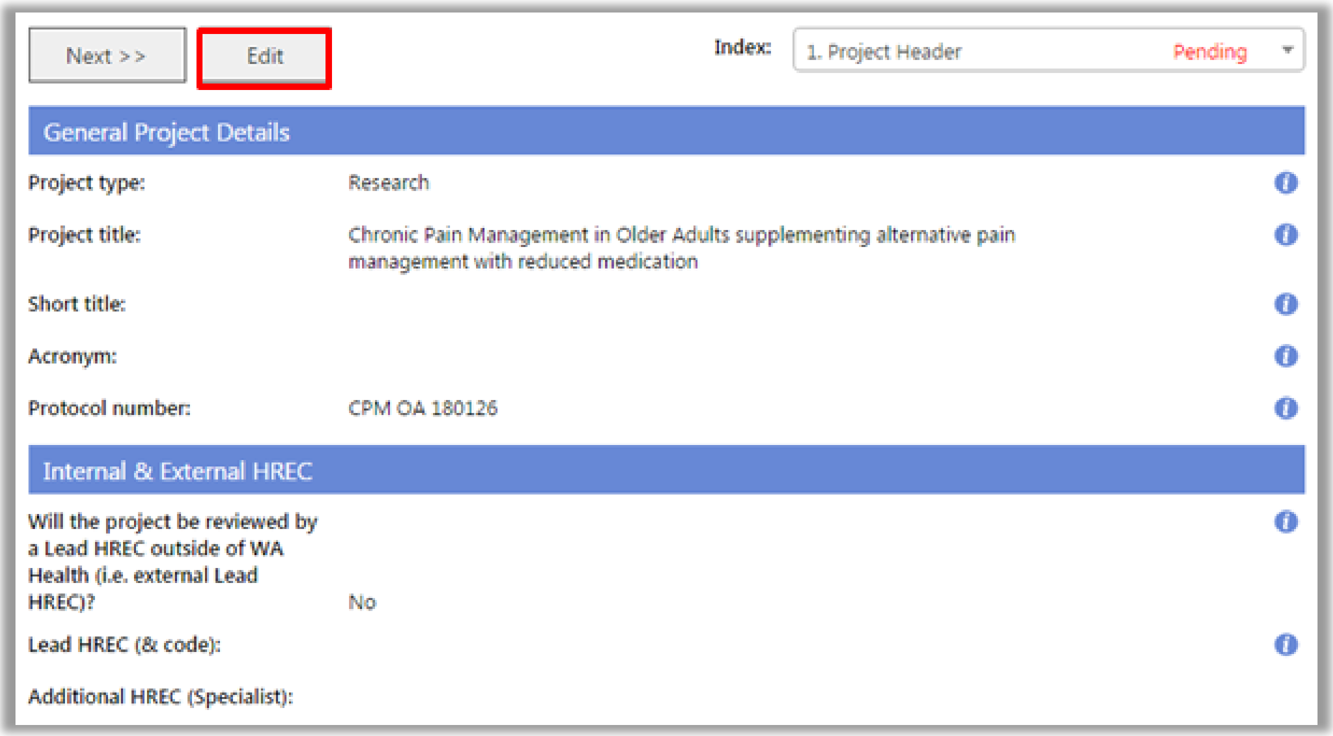


7. If you have the relevant role, click 'Authorise'.

1.2 Complete the Project Header Information

1. In the project's workspace, click on the 'Project Details' tab.

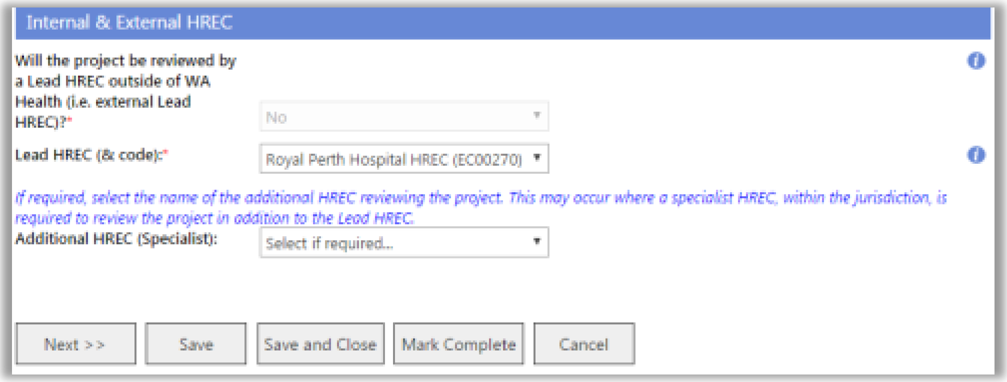
2. Select 'Project Header' in the index, and click 'Edit'.



You are only allowed to edit the section when its status is **'Pending'**.

- If the status is already **'Completed',** the form must be unlocked first by clicking on 'Unlock'. This can be done by any Project Member.
- If the status is already **'Authorised'**, the project's CPI, CPI Delegate, PI or PI Delegate must unauthorise the form first by clicking on 'Unauthorise'.

3. Update the relevant fields. All mandatory fields have a red asterisk (*) next to them. Place your pointer over the tooltips to read more information about the section or field to be completed.



Note that the Additional HREC (Specialist) is only selected if your project is to be submitted to the Department of Health HREC in addition to the Lead HREC.

4. Click 'Save' to save changes, 'Save & Close' to save changes and exit 'Edit' mode, or 'Cancel' to discard any changes made.

5. When the project header is complete, click 'Mark Complete'. If you are the CPI, CPI Delegate, PI or PI Delegate, click 'Authorise'.

Once authorised by the CPI, CPI Delegate, PI or PI Delegate, the project header, found on all standard pages within the project's workspace, will be updated to show the updated information.

1.3 Complete Project Header for National Mutual Acceptance (NMA)

1.3.1 WA Health is the Lead HREC (With a WA Health Specialist HREC)

1. For NMA, if a WA Heath HREC is the Lead HREC, select 'No' to the question '**Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?'.** Select the Lead HREC and add an Additional HREC (Specialist). Currently the Department of Health (Department) WA HREC is the only WA Health Specialist HREC and should be selected if access to the Department data collections or data linkage is required. Refer to Help Wiki: WA Specific Information.

2. When complete, click 'Mark Complete' and 'Authorise' (refer to Help Wiki: Complete the Project Header information).

1.3.2 WA Health is the Lead HREC (Without a WA Health Specialist HREC)

1. For NMA, if a WA Heath HREC is the Lead HREC, select ‘No’ to the question ‘**Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?’.** Select the Lead HREC. No Additional HREC (Specialist) is selected.

2. When complete, click ‘Mark Complete’ and ‘Authorise’ (refer to Help Wiki: Complete the Project Header information).

1.3.3 External Lead HREC (With a WA Health Specialist HREC)

1. For NMA, if an External HREC (outside of WA Heath) is the Lead HREC, select ‘Yes’ to the question ‘**Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?’.** Select the Lead HREC jurisdiction and the External Lead HREC. The HREC must be participating in the NMA (Refer to NMA HREC, RG Offices and Organisations). Enter the External HREC Reference number if known; this is important for national reporting.

Add an Additional HREC (Specialist). Currently the Department of Health (Department) WA HREC is the only WA Health Specialist HREC and should be selected if access to the Department data collections or data linkage is required. Refer to Help Wiki: WA Specific Information.

2. When complete, click ‘Mark Complete’ and ‘Authorise’ (refer to Help Wiki: Complete the Project Header information).

1.3.4 External Lead HREC Only

1. For NMA, if an External HREC (outside of WA Heath) is the Lead HREC, select ‘Yes’ to the question ‘**Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?’.** Select the Lead HREC jurisdiction and the External Lead HREC. The HREC must be participating in the NMA (Refer to NMA HREC, RG Offices and Organisations). Enter

the External HREC Reference number if known; this is important for national reporting. No Additional HREC (Specialist) is selected.

2. When complete, click 'Mark Complete' and 'Authorise' (refer to Help Wiki: Complete the Project Header information).

1.4 Add the Funder Details in the Governance Information

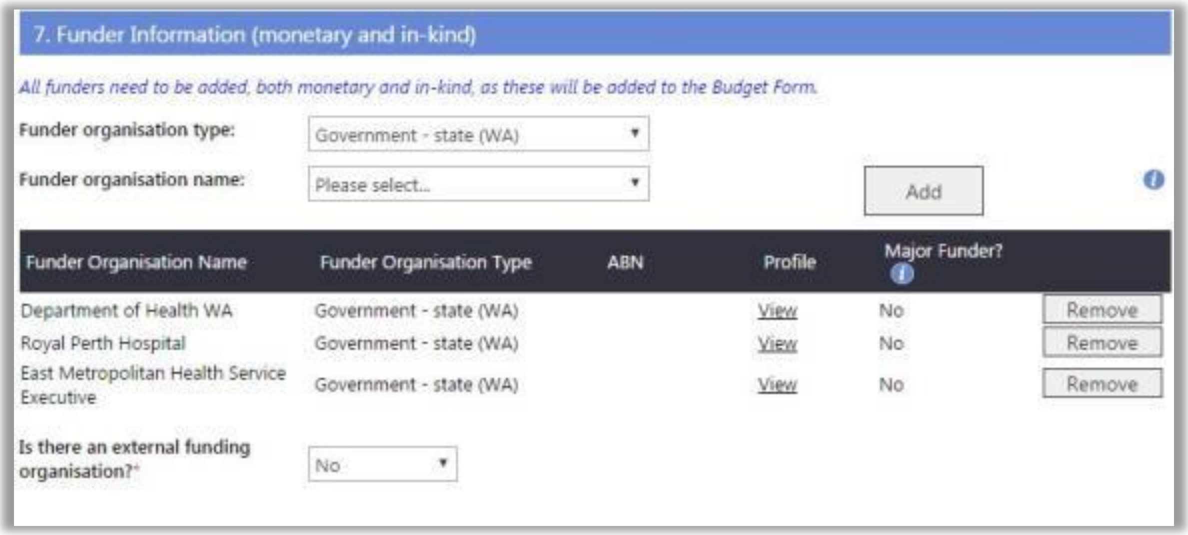
1. All funders (both monetary and in-kind) involved with the project must be added to **question 7** in the Governance Information section of the Project Details tab before the governance forms are commenced, as this information is populated into the Budget Form. If you cannot find a funder, contact the RGS Support.

2. For monetary funding: the funder organisation is where the funding or grant is coming from (e.g. the sponsor or NHMRC), not who the administrating organisation or contract research organisation is. There may be several funders providing monetary funding in a project. The administrating organisation or contract research organisation details can be added to question 7.1 for invoicing.

3. For in-kind funders: the funder organisation is the one that is providing the in-kind support, examples include:

- in-kind support of project member's salaries if they are not covered by monetary funding; their employing organisation must be nominated (e.g. Royal Perth Hospital)
- in-kind support by organisations hosting HRECs and RG Offices for the ethics and governance review fees that are not charged for non-commercial projects (e.g. East Metropolitan Health Service Executive).

Contact the Ethics and RG Offices to find out how much should be recorded in the Budget Form either for monetary fees or in-kind support. If the latter, also ascertain which host organisation name should be added as a Funder.



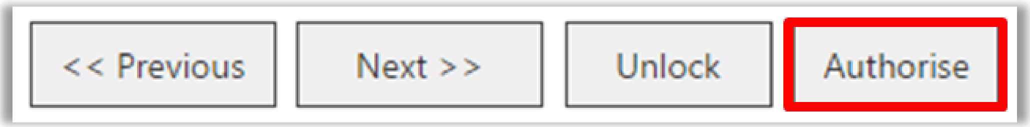
1.5 Authorise or Unauthorise a Section of the Project Details Tab

Authorise

Only the CPI, CPI Delegate, PI or PI Delegate (refer to **'Project Member Role to Authorise / Unauthorise Project Details'**) have the authority to authorise the Project Details sections once it has the 'Completed' status.

1. If you have the authority to authorise (or unauthorise) a project the 'Authorise' button will appear at the bottom of the screen. Click on 'Authorise' to mark the specific section of Project Details as 'Authorised'.

Please note: You can still complete and authorise Project Details, and complete your forms (but not submit them) if not all invited members have accepted their invitation. Any changes to Project Members (e.g. acceptance of invitation) will automatically unauthorise the Project Details - Investigator Contact Information to update the new investigator details. Any active forms (i.e. unsubmitted) marked as complete must be unlocked to update the forms.



2. Once relevant sections are authorised, Project Members can add new forms in the Forms & Documents tab.

Unauthorise

Only the CPI, CPI Delegate, PI or PI Delegate (refer to **'Project Member Role to Authorise / Unauthorise Project Details'**) have the authority to unauthorise a Project Details section once it has an 'Authorised' status.

1. If you wish to make changes to the section but the status of the section is 'Authorised' the section must be unauthorised by clicking 'Unauthorise'.

1.6 Systematic Unauthorisation of the Project Details Tab

Note that changes to other tabs in the project workspace will trigger certain sections of the Project Details tab to be automatically unauthorised, and reverted back to 'Completed' status. This is to show Project Members that updates have been made to the relevant tab:

Project Details Section	Project Workspace Tab
Ethics Information	Unauthorised when there are changes to the project sites (Sites tab)
Investigator Contact Information	Unauthorised when there are changes to the project sites (Sites tab) and/or in the project membership (Members tab)

If the user changes anything in Project Details tab, any Active forms (i.e. unsubmitted) marked as complete must be unlocked, to ensure there are no additional questions that have to be answered or answers that should be amended.

2. Add, Fill Out and Authorise an Ethics Form

All Project Members (including Sponsors) can add, edit and unlock the ethics forms. However, only certain project roles are allowed to force check-in, remove, mark complete, sign, authorise, unauthorise and submit an ethics form, this is to ensure the information is correct on submission.

Project Member Role for Ethics Forms:

Action	Project Member Role
1. Add, Edit, Unlock	All Project Members
2. Mark Complete	All Project Members, except Sponsor
3. Remove, Force-Check-In, Unauthorise, Submit	CPI or CPI Delegate
4. Sign	CPI and PI
5. Authorise	CPI

2.1 RGS Ethics Forms

After Project Members have completed the Sites, Members and Project Details tabs, the ethics forms and supporting documents should be completed and uploaded.

Find information on which ethics and governance application forms to complete in the WA Health Research Authorisation Monitoring Form Guidelines.

The following ethics forms are available in the RGS for completion and submission to the relevant WA Health HREC(s):

- Western Australian Specific Module (WASM)
- WA Health Ethics Application Form (WAHEAF)

Currently the NHMRC's Human Research Ethics Application (HREA) is not available in the RGS. To facilitate its submission to WA Health HRECs, the HREA must be completed externally and uploaded to the RGS as a supporting document.

2.2 NMA Ethics Forms

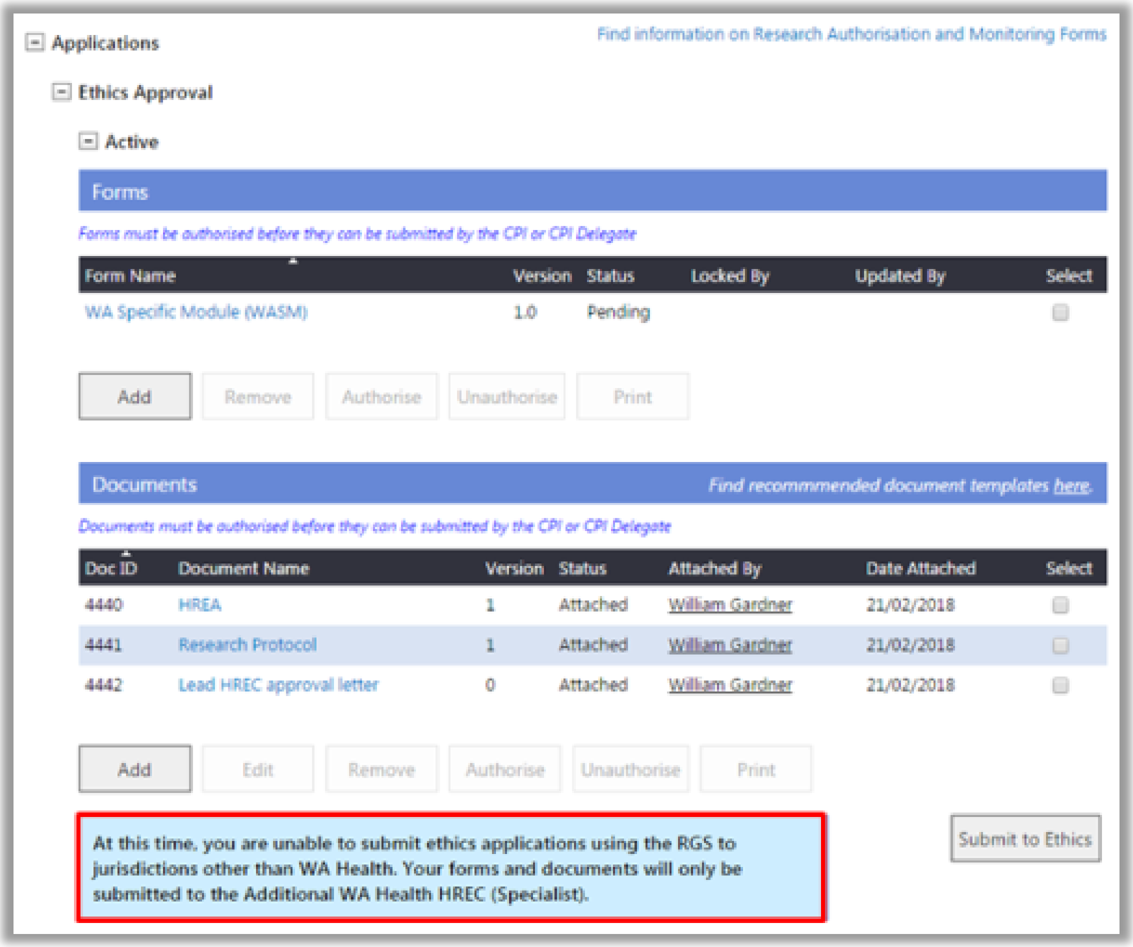
For NMA, the WASM must be completed in the RGS and the HREA uploaded as a supporting document. You cannot use the WAHEAF for NMA.

2.2.1 WA Health Lead HREC (With or Without Specialist HREC)

1. For NMA, if a WA Heath HREC is the Lead HREC, with or without an Additional WA Health HREC (Specialist), then you should complete the WASM, upload the HREA and supporting documents and submit them via the RGS.

2.2.2 External Lead HREC (With a WA Health Specialist HREC)

1. For NMA, if an External HREC (outside of WA Heath) is the Lead HREC and you are still submitting the ethics application to an Additional WA Health HREC (Specialist), then you should complete the WASM and upload the HREA and supporting documents and submit them via the RGS to the Specialist HREC. At this time, you are unable to submit ethics applications using the RGS to jurisdictions other than WA Health. You must print the WASM and submit it along with your ethics application to the external HREC outside of RGS (refer to WA Health NMA Guidelines).



2.2.3 External Lead HREC Only

1. For NMA, if an External HREC (outside of WA Heath) is the Lead HREC at this time, you are unable to submit ethics applications using the RGS to jurisdictions other than WA Health. You must complete and print the WASM and submit it along with your ethics application to the external HREC outside of RGS (refer to WA Health NMA Guidelines).

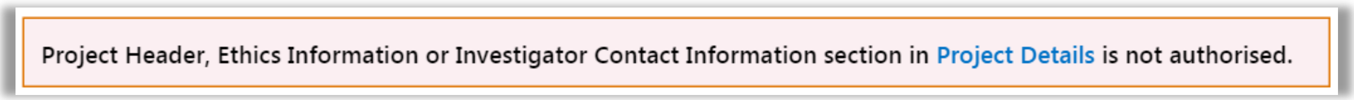
2. When the External Lead HREC has approved the ethics application, the CPI or CPI Delegate, must upload to the Ethics Approval Active section, the approved HREA and supporting documents (including the ethics approval letter) and submit them with the approved WASM to the RG Office. Refer to Help Wiki: Ethics Submission, Validation and Review Assessment.

2.3 Add an Ethics Form

1. In the project workspace, click on the ‘Forms and Documents’ tab.

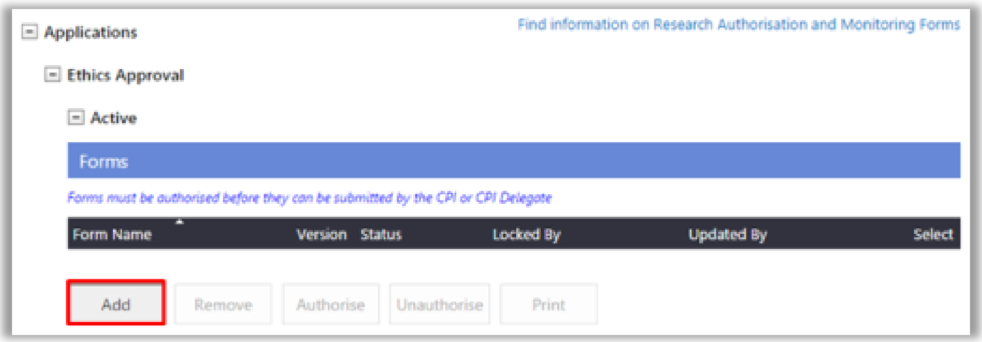
2. Click on the ‘+’ sign next to the desired phase (e.g. Applications) and category (e.g. Ethics Approval, Site Authorisation) grouping to expand that section. To add an ethics form, you must click on the 'Applications', 'Ethics Approval' and 'Active' groupings to see the 'Forms' grid and the corresponding buttons.

A form may be added only after the required sections of the Project Details tab have been completed and authorised. Otherwise, you will be prompted with an error message in the Ethics Approval section of the Forms & Documents tab. Click on the link to the Project Details tab and complete and authorise the required sections (refer to Help Wiki: Fill out and authorise Project Details).

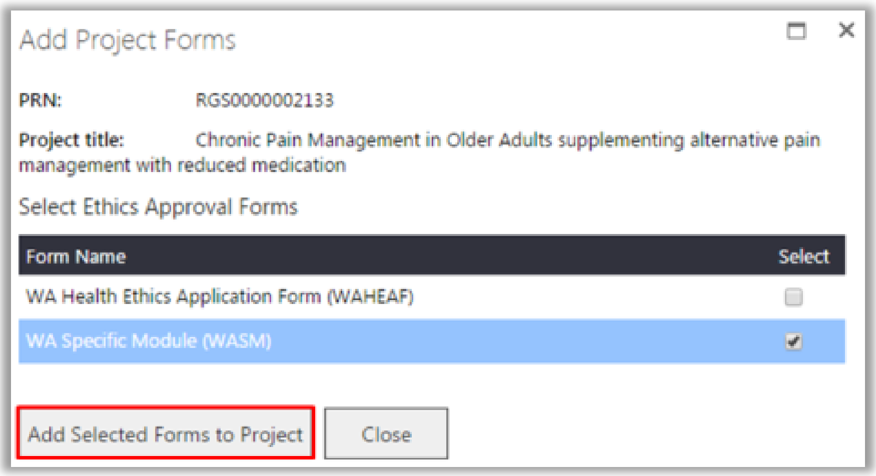


If the user changes anything in Project Details tab, any Active forms (i.e. unsubmitted) marked as complete must be unlocked, to ensure the updated information is populated into the forms and there are no additional questions that have to be answered or answers that should be amended.

3. Click 'Add' under the 'Forms' grid. The ‘Add Selected Forms’ screen will automatically launch.

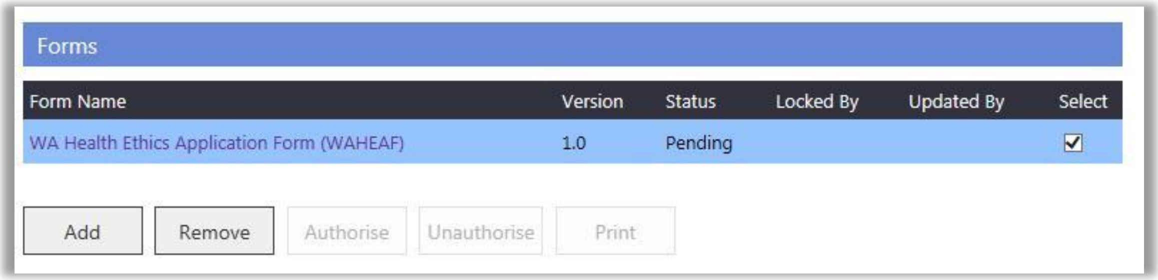


4. ‘Select’ either the WA Health Ethics Application (WAHEAF) OR WA Specific Module (WASM) and then click ‘Add Selected Forms to Project’. The WASM should be selected if you are intending to use the HREA as your ethics application form. The HREA must be completed externally and uploaded to the RGS as a supporting document.

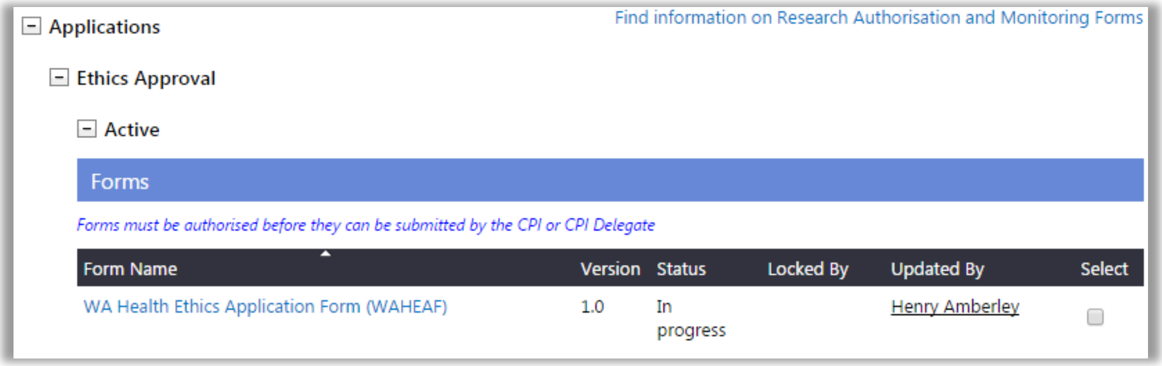


The RGS will only allow you to add either the WAHEAF or WASM. These form options will disappear from this screen once an ethics form has been added to the project.

5. When the form is successfully added, you will be directed back to the Forms & Documents tab. Version 1.0 of the selected ethics form now appears under the 'Ethics Approval', 'Active' section of the Forms & Documents tab. For ethics approval, a project can have only one 'Active' form at a time. If you added the incorrect form, you must remove the existing form by selecting it and clicking 'Remove' before adding the correct one.



6. All Project Members can click on the embedded link in the form name to open it, allowing for viewing or editing.



Following submission, if the Ethics Executive Officer (EEO) requires revisions to a form and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid**; **a new version of the form will automatically be created under the 'Active' grid.** You must implement the required changes to this version, which will then be submitted to the EEO for their review. Refer to Help Wiki: Ethics Submission, Validation and Review Assessment.

2.4 Fill Out an Ethics Form

1. The form created is automatically populated with information previously entered in the Sites tab, Members tab and Project Details tab. Refer to Help Wiki: Fill out and authorise Project Details for the steps to complete and authorise the Project Details tab. To edit the other form fields that were not populated from the Project Details tab, click 'Edit'. Click 'Close' to close the form and return to the Forms & Documents tab.

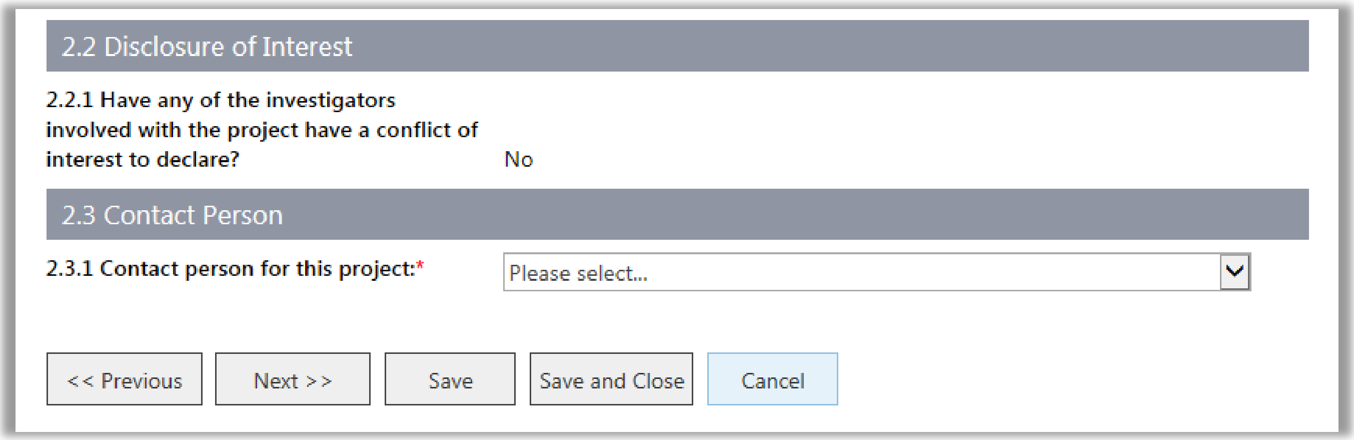
You are only allowed to edit the section when its status is **'Pending'**. If you wish to edit the form and it has a different status, the following will apply:

- **If the status is 'In Use':** you may need to contact the Project Member who is editing the form. The other Project Member must click 'Cancel' or 'Save & Close' to release the lock on the form. If the Project Member is away for an extended period the CPI or CPI Delegate can 'Force Check-in the form. Alternatively, you may contact the RGS Administrator to 'Force Check-in' the form.

- **If the status is already 'Completed':** the form must be unlocked first by clicking 'Unlock'. This can be done by any Project Member.
- **If the status is already 'Authorised':** the section must be unauthorised first by clicking 'Unauthorise'. Only the CPI, CPI Delegate can unauthorise the ethics forms.

2. Update the relevant fields. All mandatory fields have a red asterisk (*) next to them. Placing your pointer over the information icon on the right-hand side of the screen will provide you with tool tips and information about the section or field to be completed. This is only viewable on edit mode.

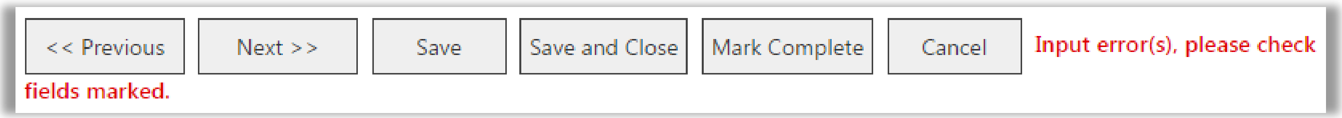
3. Click 'Save' to save changes, 'Save & Close' to save changes and exit 'Edit' mode, or 'Cancel' to discard any changes made.



User tip: Click 'Save' every 5-10 minutes to ensure entered data is saved. You can click 'Save and Close' at any time and log out of the RGS and then return to the form later.

Mandatory Fields

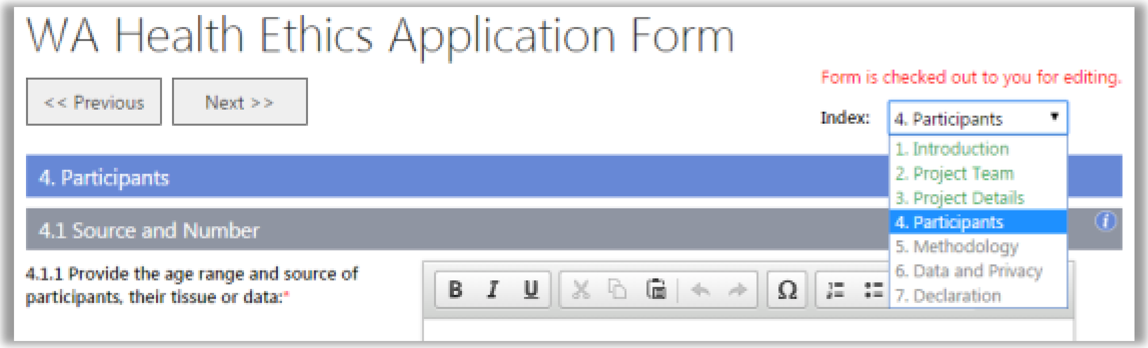
If a mandatory field is left blank when you 'Mark Complete' or click 'Next', you will receive a notification error and the RGS will automatically highlight fields that require mandatory information entered.



Use the Form Index

You may navigate through different sections of a form by clicking on a section title in the 'Form Index' found on the upper right-hand corner of the form. For example, there are seven sections within the WAHEAF that require completion. The index will show

- Green is the sections have been completed
- Black is the last section edited or currently being edited
- Grey is any section after the section last edited or being edited as answers given in a section will determine the questions asked in the following sections.



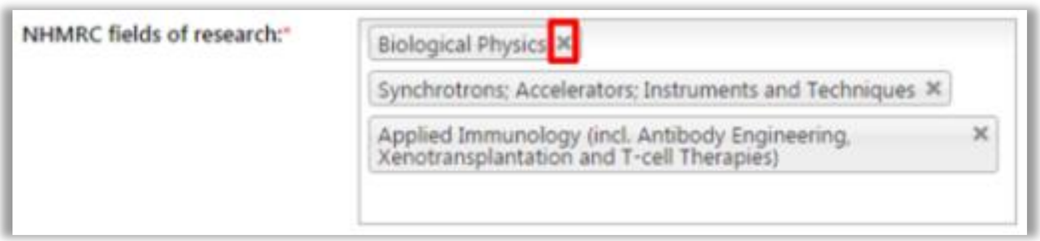
Whilst in edit mode, you can only use the index to navigate through the completed section (green) up to the black section of the form. When you click 'Edit' you will be taken to the last edited section of the form.

Pasting in data from other sources

You have the ability to paste data into the form from word documents by right clicking on the text field and a 'paste' symbol appears. **However note, that if you are pasting text with links to 'Endnotes' or 'Footnotes' for citations; the text should first be pasted into a word document to break the link/code with the 'Endnotes' or 'Footnotes' and then pasted into RGS.** The Endnotes can then be added to the RGS field separately. The Hyperlink in any text should also be removed prior to pasting into a text field.

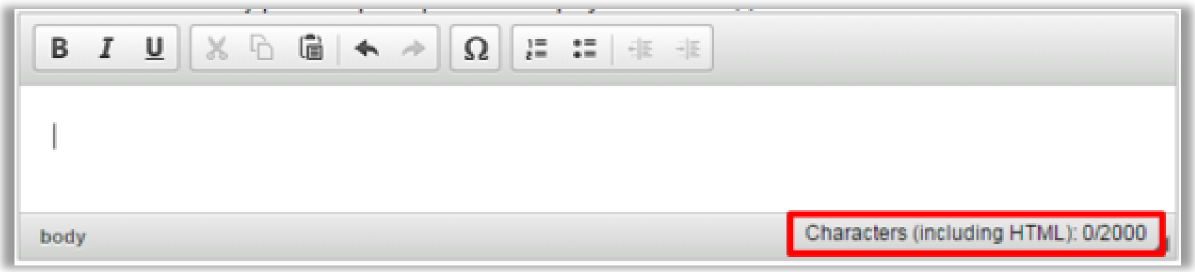
Enter Data in Multi-select Fields

If a field allows multiple selections, click on the desired option to add it into the list. If you have selected an option in error and wish to remove it, click on the X beside the option.

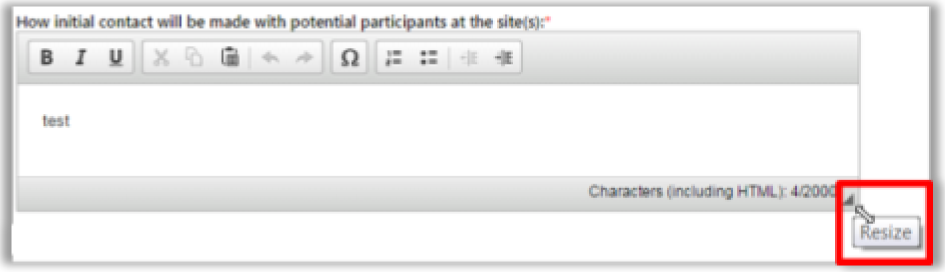


Enter Data in Rich Text Fields

Rich text fields for entering free text show a character or word count on the bottom left-hand corner of the box. Use this as guide to ensure you do not go beyond the limit; otherwise, you will be prompted with an error.



You may also drag the border of the box to extend its length.



Click on Your Web Browser's Refresh button to fetch the Latest Information

If changes were made to the Sites tab, Members tab or Project Details tab, click the web browser's 'Refresh' button (typically F5 in your keyboard) to fetch the latest information and to refresh the current form. Below is an example, if Google Chrome is used:

4. If a Project Member has completed all of the form's fields and the form is ready for signing and authorisation, click 'Mark Complete'. The form's status is now 'Completed (pending signatures)', this is to inform all Project Members that the form has been finalised and is ready for authorisation.

2.5 Sign, Authorise and Unauthorise an Ethics Form

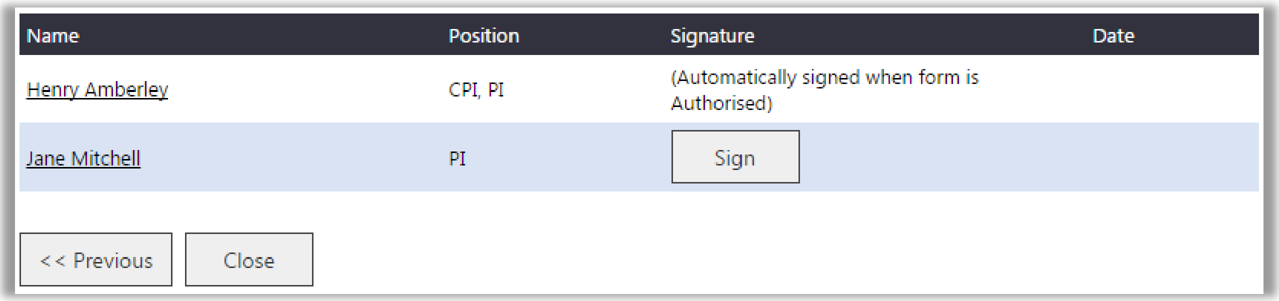
Once marked complete, if you have the authority to sign or authorise a form, a 'Sign' or 'Authorise' button will appear.

Sign and Authorise

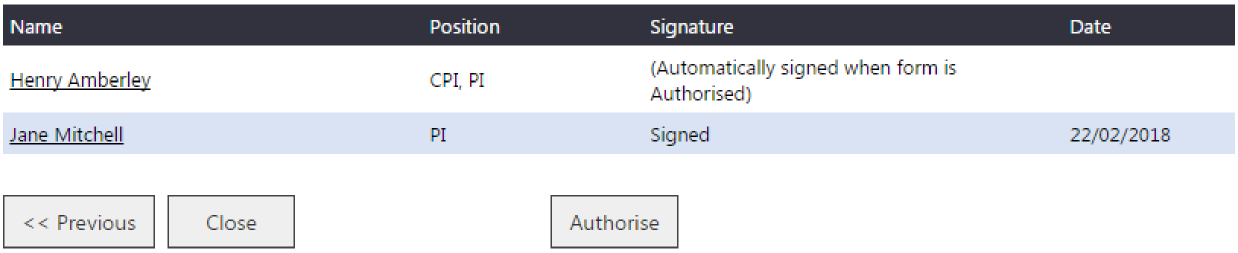
The WAHEAF requires the PIs and then the CPI to sign the form in the Declarations section prior to authorisation. The CPI will automatically sign and authorise the WAHEAF, when they click 'Authorise' within the form. The WASM has no required signatures and requires authorisation only by the CPI. **Only the CPI can authorise an ethics form**.

1. To sign and/or authorise a WASM or WAHEAF, click on the embedded link in the form located in the project workspace's Forms & Documents tab, under 'Applications', 'Ethics Approval', 'Active' groupings.

2. For the WAHEAF, navigate to the 'Declaration' page. If you are the PI, click 'Sign' next to your name. The CPI will receive an email to notify them that you have signed the form.

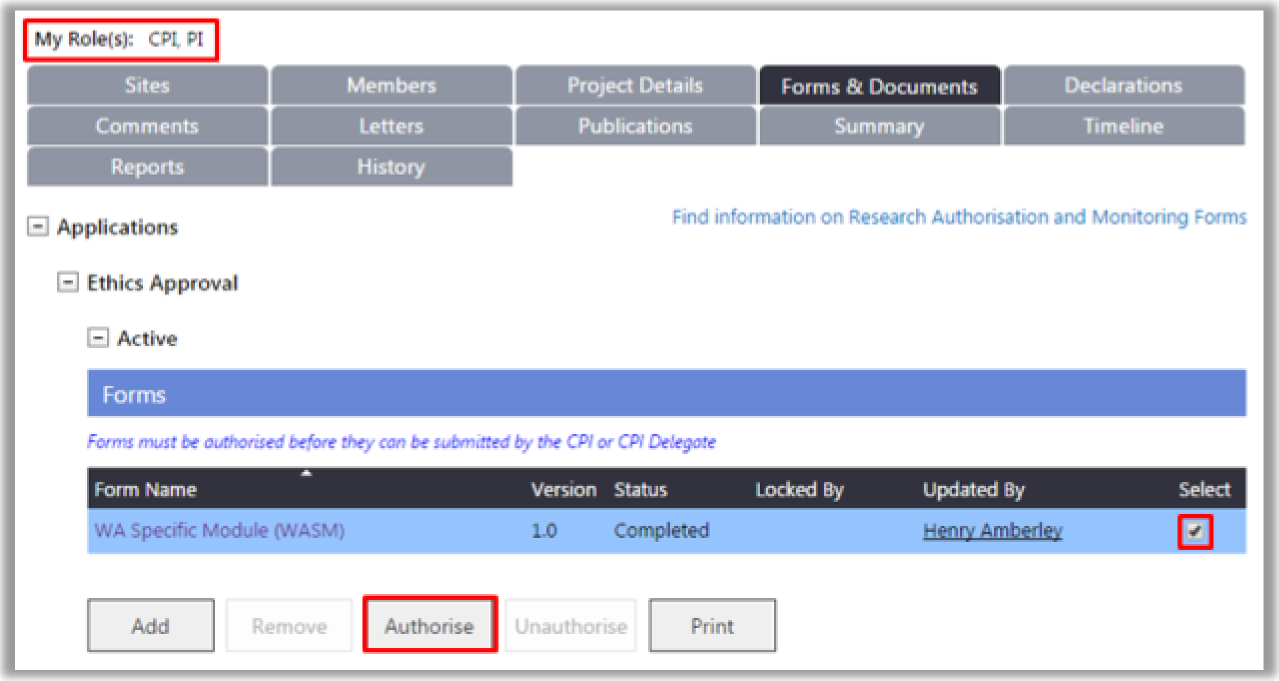


3. If you are the CPI, the Authorise button will not appear until all the PIs have signed the WAHEAF. Once this is done, click ‘Authorise’.



After authorising a form, the ‘Unauthorise’ button should appear. To exit the form, click on the Forms & Documents tab at the top of the form.

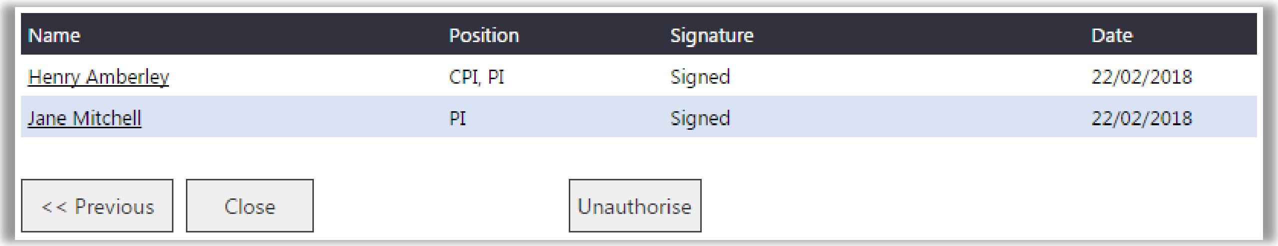
Alternatively, a CPI can authorise and a CPI or CPI Delegate can unauthorise a form in the project workspace's Forms & Documents tab after selecting a form or document.



4. Once a form is authorised, the CPI and CPI Delegate will now be allowed to submit them to a HREC. Refer to Help Wiki: Ethics Submission, Validation and Review Assessment.

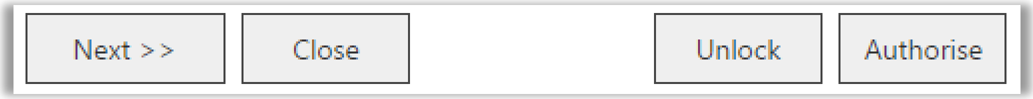
Unauthorise

Only the CPI and CPI Delegate can unauthorise an ethics form.
1. You can unauthorise a form in the project workspace's Forms & Documents tab after selecting a form or document and clicking ‘Unauthorise’. Alternatively in the form, click ‘Unauthorise’.



Note that when you unlock the WAHEAF, you will have to re-invite the PIs to re-sign the form, prior to the CPI re-signing and authorising the form.

2. Click ‘Unlock’, and then ‘Edit’ make your changes and then click ‘Mark Complete’.



3. The form will then have to be signed (by the PI) and authorised by the CPI.

2.6 Systematic Unauthorisation of the Ethics Forms

Note that changes to the project will trigger certain forms to be automatically unauthorised:

Location of changes made	**WAHEAF**	**WA Specific Module**	**Site Specific Assessment Form**	**Access Request Form**
Sites tab	Unauthorise	Unauthorise	Unauthorise only the form that includes a site that has been removed	Unauthorise only the form that includes a site that has been removed
Members tab	Unauthorise	Keep as 'Authorised'	Unauthorise only the form(s) with changes	Unauthorise only when the CPI is changed
Project Details tab - Project Header	Unauthorise	Unauthorise	Unauthorise	Unauthorise
Project Details tab - Ethics Information	Unauthorise	Unauthorise	Unauthorise	Unauthorise
Project Details tab - Governance Information	Keep as 'Authorised'	Keep as 'Authorised'	Unauthorise	Keep as 'Authorised'
Project Details tab - Investigator Contact Information	Unauthorise	Keep as 'Authorised'	Unauthorise	Keep as 'Authorised'

3. Add, Fill Out and Authorise a Governance Form

All **Project Members (including Sponsors) associated with the site** can add, edit, mark complete and unlock the governance forms. However, only certain project roles are allowed to force check-in, remove, sign, authorise, unauthorise and submit a governance form, this is to ensure the information is correct on submission.

Project Members, including the site PI can be added to a site through the Members tab. Refer to Help Wiki: Manage Project Members for the detailed steps.

Although the Access Request (AR) Form is typically completed and authorised by the CPI, **the CPI must also nominate them self as the PI associated with all the sites nominated in the form** to enable it to be submitted to a RG Office.

Project Member Role for Governance Forms:

Action	Project Member Role AR Form	Project Member Role SSA Form	Project Member Role Budget Form
1. **Add**	All site Project Members	All site Project Members	All site Project Members
2. **Edit, Mark Complete Unlock**	All site Project Members	All site Project Members	PI, PI Delegate, HA. (mark complete & unlock N/A)
3. **Remove, Unauthorise**	CPI, PI or PI Delegate	PI or PI Delegate	PI or PI Delegate
4. **Force-Check-In**	CPI, CPI Delegate, PI or PI Delegate	PI or PI Delegate	PI or PI Delegate
5. **Sign**	CPI or PI and HA	PI and HA	PI and HA
6. **Authorise**	CPI or PI	PI or PI Delegate	PI or PI Delegate
7. **Submit**	PI or PI Delegate	PI or PI Delegate	PI or PI Delegate

3.1 RGS Governance Forms

After Project Members have completed the Sites, Members and Project Details tabs, the governance application forms and supporting documents should be completed and uploaded.

Find information on which ethics and governance application forms to complete in the WA Health Research Authorisation Monitoring Form Guidelines. For a multi-centre research project several governance forms may be required.

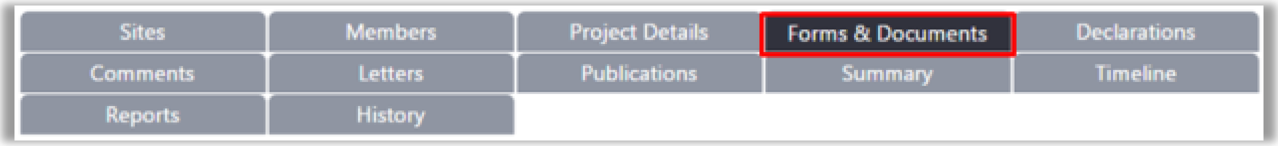
The following governance forms are available in the RGS for completion and submission to the relevant WA Health Research Governance (RG) Office(s):

- WA Health Site Specific Assessment Form and Budget Form
- WA Health Access Request Form
- WA Health Declaration of Confidentiality
- WA Health Research Conflict of Interest Form.

3.2 Add a Governance Form

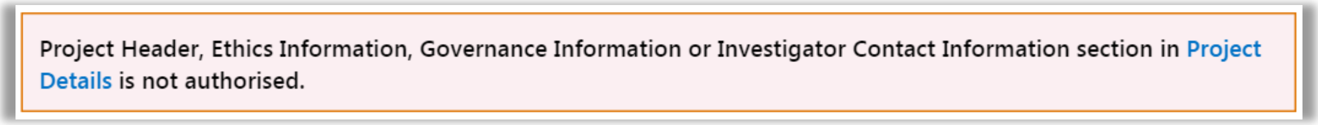
1. Only the CPI, CPI Delegate and Project Members (e.g. PI, PI Delegate, AI, RGM, Sponsor) associated with a site can add governance forms for that site.

If you have the required authority in the project workspace, click on the ‘Forms and Documents’ tab.



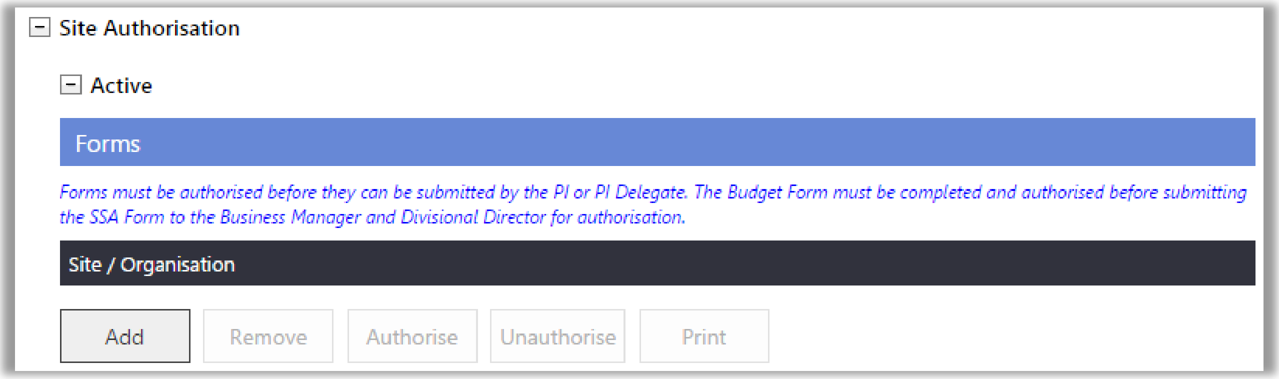
2. Click on the ‘+’ sign next to the desired phase (e.g. Applications) and category (e.g. Site Authorisation) grouping to expand that section. To add a governance form, click on the 'Active' to see the 'Forms' grid and the corresponding buttons.

A form may be added only after the required sections of the Project Details tab have been completed and authorised. Otherwise, you will be prompted with an error message in the Site Authorisation section of the Forms & Documents tab. Click on the link to the Project Details tab and complete and authorise the required sections (refer to Help Wiki: Fill out and authorise Project Details).



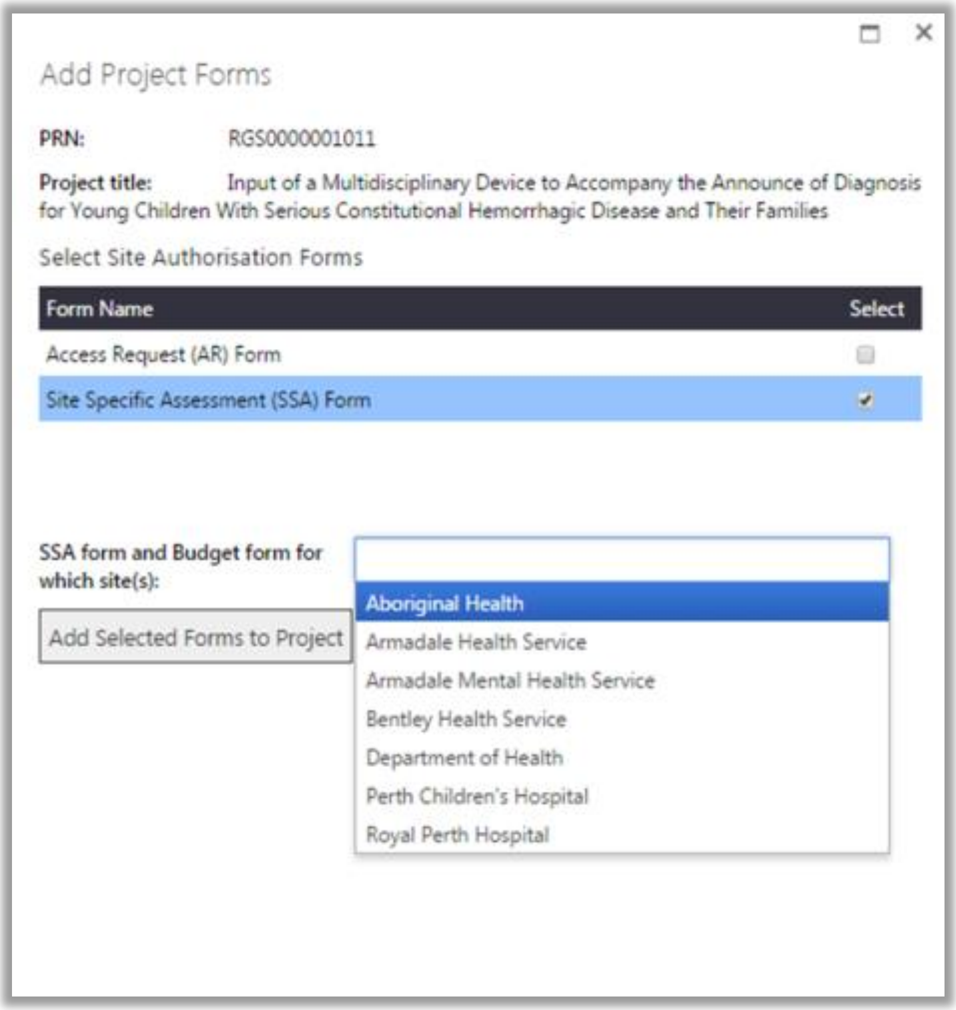
If the user changes anything in Project Details tab, any Active forms marked as complete must be unlocked, to ensure the updated information is populated into the forms and there are no additional questions that have to be answered or answers that should be amended.

3. Click 'Add' under the 'Forms' grid. The ‘Add Selected Forms’ screen will automatically launch.



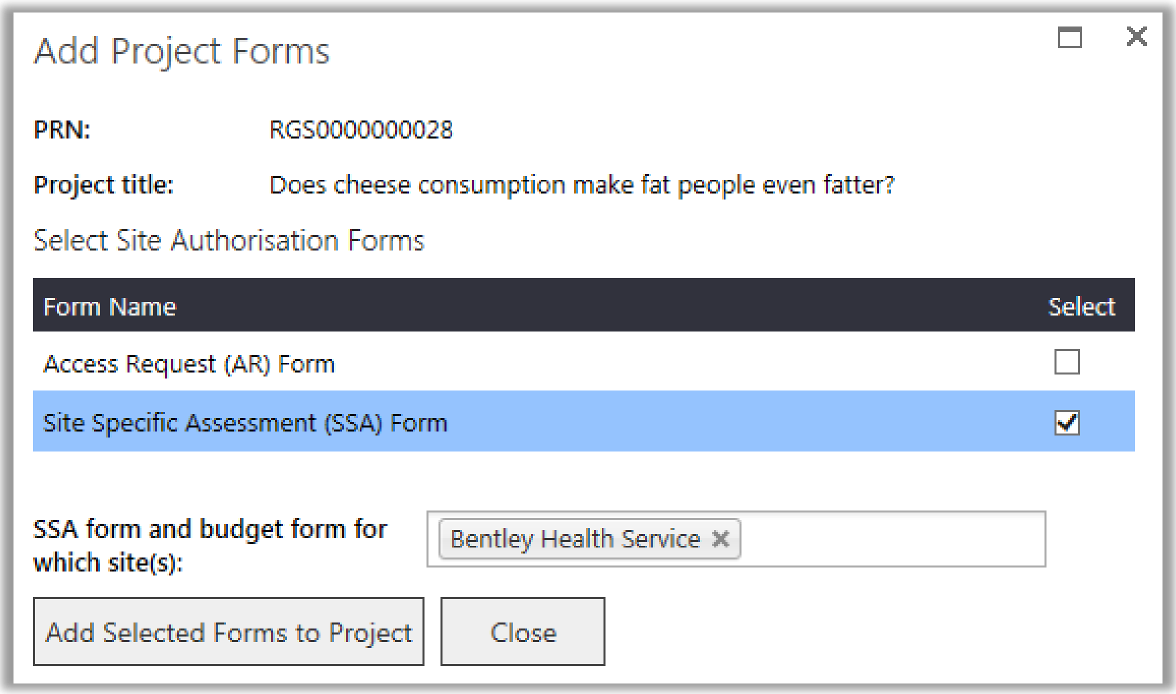
4. ‘Select’ either the Site Specific Assessment (SSA) Form OR Access Request (AR) Form. Nominate one or multiple sites to be associated with the form. Users that do not have membership of that site in the Members tab will not be able to see the site name.

If the form is to cover multiple sites within the jurisdiction of one RG Office, please contact the RG Office to confirm that these sites can be grouped on one form (refer to the WA Health Research Authorisation Monitoring Form Guidelines for guidance on adding multiple sites to a governance form). You will find the RG Offices listed in the Contacts page.

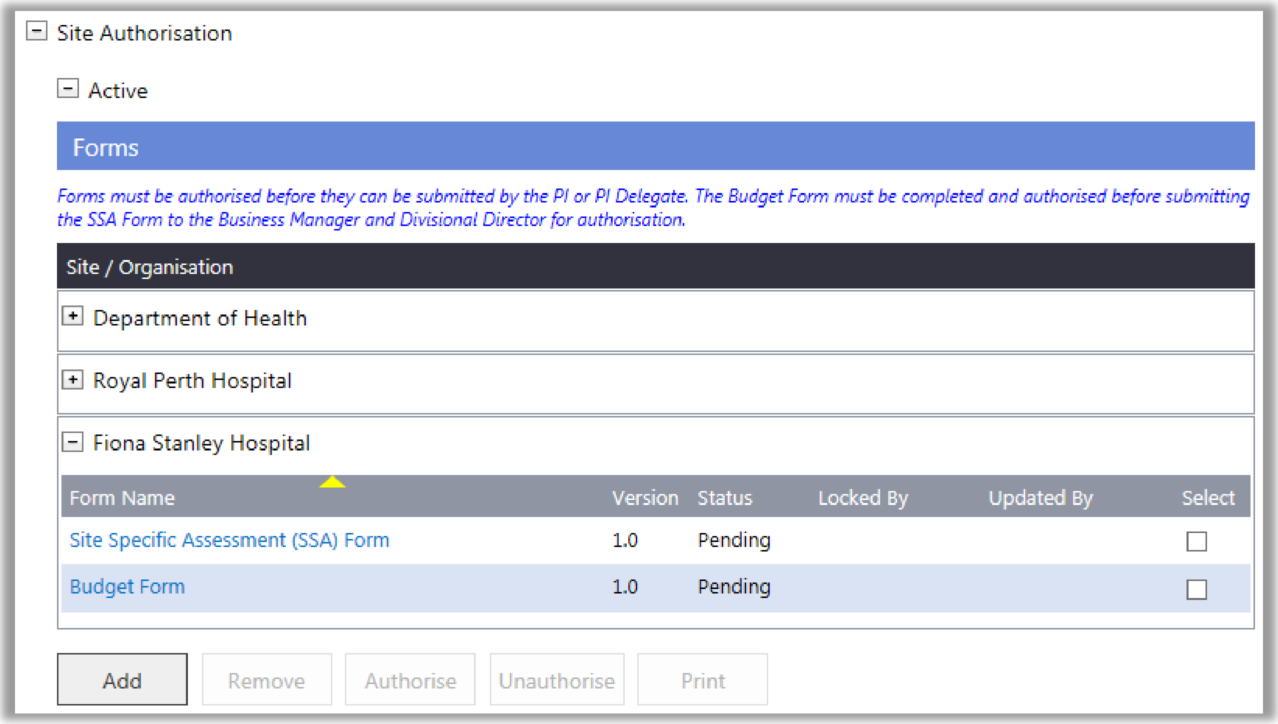


5. Click 'Add Selected Forms to Project'. When a SSA Form is added to a project an associated Budget Form will be automatically created. The Budget Form is not viewable by a Sponsor.

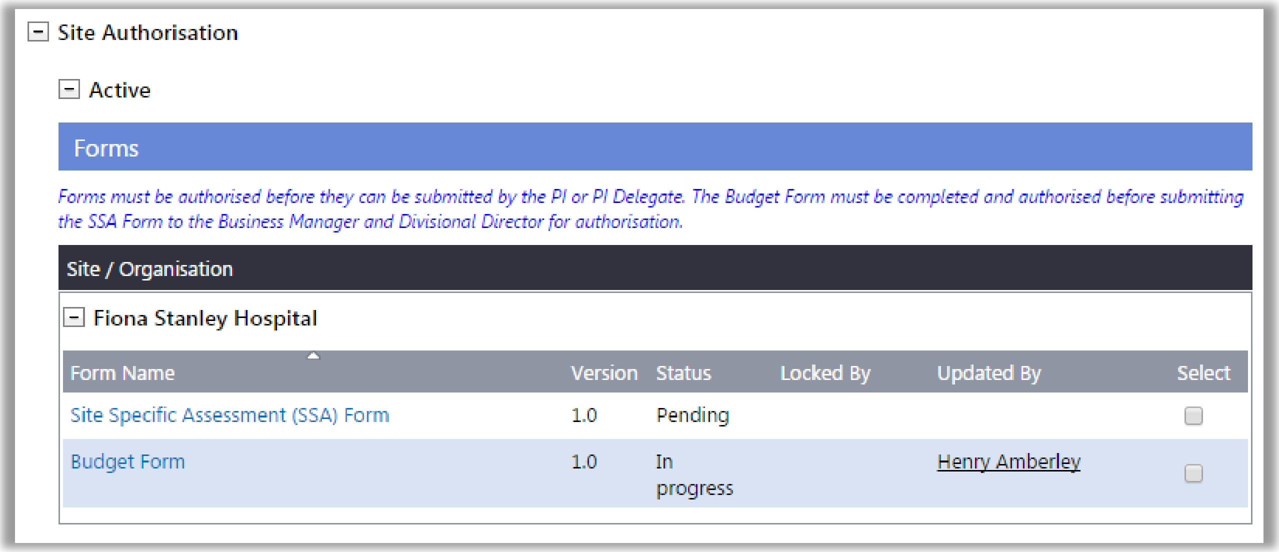
The RGS will only allow you to add either the SSA or AR forms for a site. The site name will disappear from this screen once a governance form has been added for the site.



6. When the form is successfully added, you will be directed back to the Forms & Documents tab. Version 1.0 of the selected governance form now appears under the 'Site Authorisation, Active section of the Forms & Documents tab. If you added the incorrect form, you must remove the existing form by selecting it and clicking 'Remove' before adding the correct one.



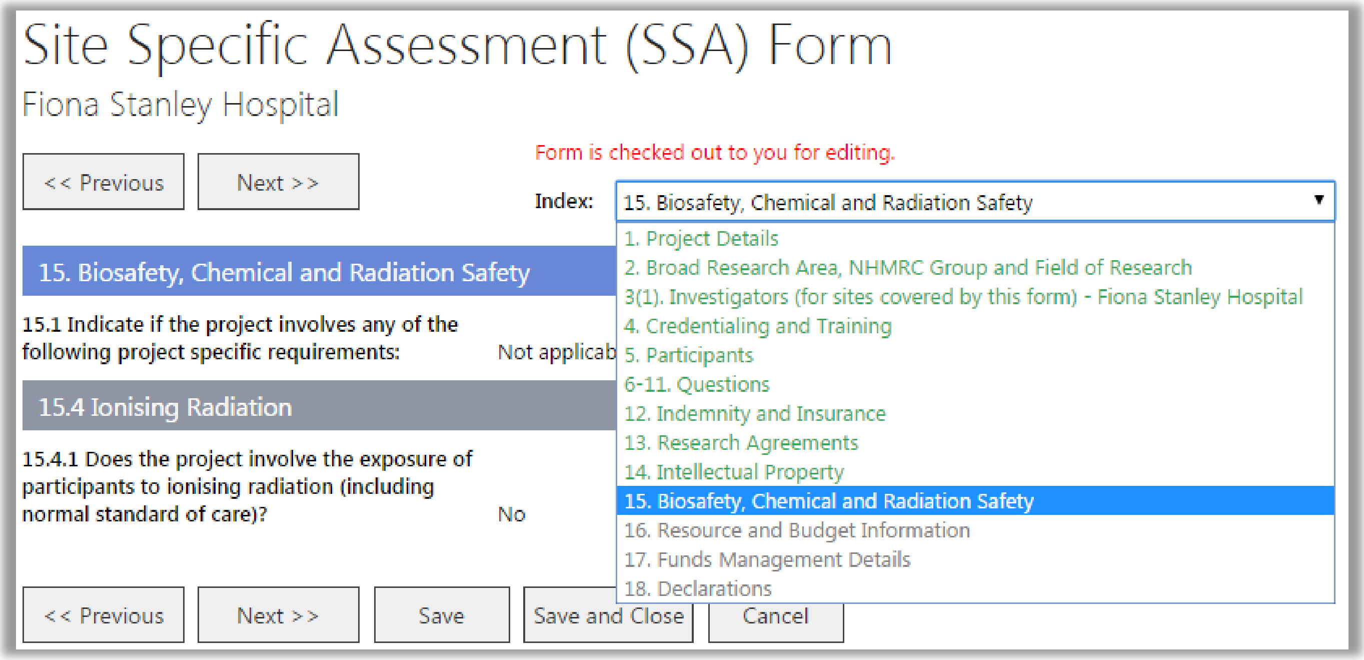
7. All Project Members affiliated with the site can click on the embedded link in the form name to open it, allowing for viewing or editing.



Following submission, if the Research Governance Officer (RGO) requires revisions to a form and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid; a new version of the form will automatically be created under the 'Active' grid.** You must implement the required changes to this version, which will then be submitted to the RGO for their review. Refer to Help Wiki: Governance Submission, Validation and Review Assessment.

3.3 Fill Out a Governance Form

1. The form created is automatically populated with information previously entered in the Sites tab, Members tab and Project Details tab. Refer to Help Wiki: Fill out and authorise Project Details for the steps to complete and authorise the Project Details tab. To edit the other form fields that were not populated from the Project Details tab, click 'Edit'. Refer to Help Wiki: Fill out an ethics form for directions on completing forms.



Whilst in edit mode, you can only use the index to navigate through the completed section (green) up to the black section of the form. When you click 'Edit' you will be taken to the last edited section of the form.

2. If a Project Member has completed all of the form's fields and the form is ready for signing and authorisation, click 'Mark Complete'. The form's status is now 'Completed', this is to inform all Project Members that the form has been finalised and is ready for authorisation.

3.4 Sign, Authorise and Unauthorise a Governance Form

Once **marked complete**, the form will be ready for signing by the PI and the Hospital Administrators.

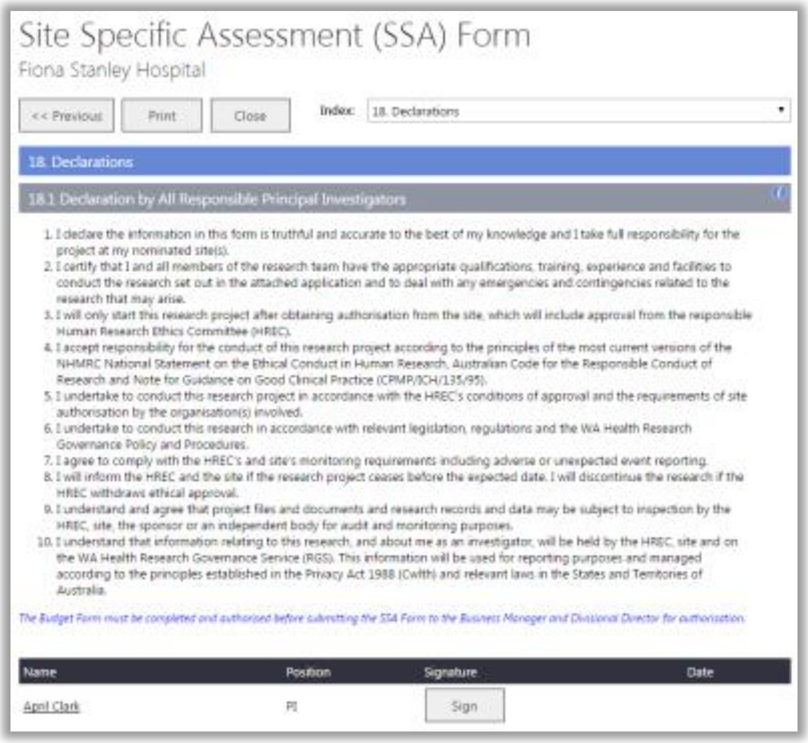
3.4.1 Sign and Authorise a Site Specific Assessment Form

The SSA Form requires the site PI to sign the Declarations section prior to inviting the Hospital Administrators (e.g. Business Manager, Divisional Director and Regional Director) to sign prior to the site PI or PI Delegate authorising the SSA Form.

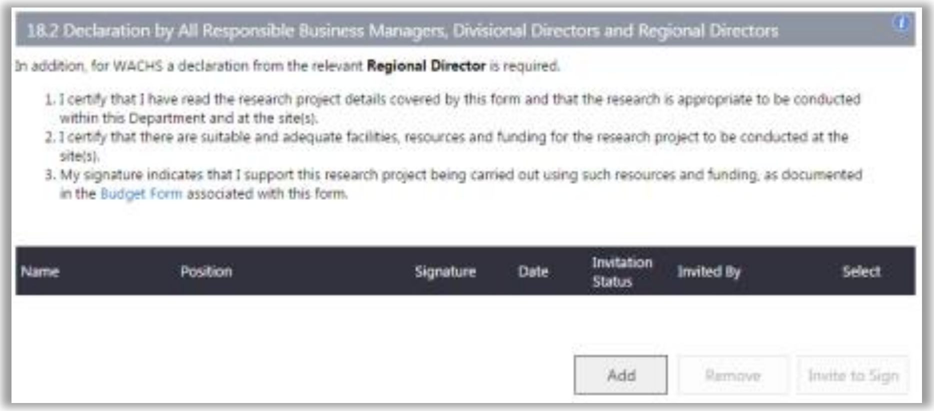
1. To sign a SSA Form, click on the embedded link in the form located in the project workspace's Forms & Documents tab, under 'Applications', 'Site Authorisation, 'Active' groupings, the form will have the status of Competed (Pending Signatures). You can navigate to the 'Declaration' page using the index.

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Completed (Pending Signatures)		Henry Amberley	

2. If you are the PI, click 'Sign' next to your name **(do not click 'Unlock' on the form, if you do need to edit the form you will have to click 'Mark Complete' again before signing)**. A confirmation message will appear stating that "You are signing for both the SSA Form and Budget Form for all sites", and that signing cannot be undone. Click 'OK' to proceed.

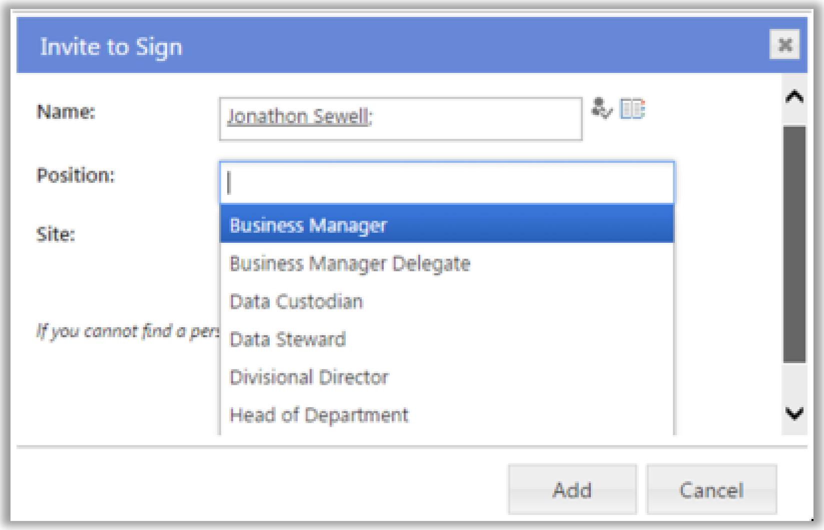


3. If you are the PI or PI Delegate, click 'Add' to invite the Hospital Administrator (e.g. Business Manager, Divisional Director or Regional Director) to sign. You can invite as many Hospital Administrators as required to sign the SSA Form, though at a minimum it should be signed by a Business Manager and Divisional Director. If your Divisional Director has already signed the Budget Form (instead of a Head of Department) a second signature on the SSA Form may not be required, check with your RG Office.



Note: You should not invite the Hospital Administrators to sign the SSA Form before the Budget Form has been 'Authorised' by the PI or PI Delegate.

4. The Invite to Sign screen will launch, add the Hospital Administrator's name, click the person icon to display the link. Select the Postion and Site, and click 'Add', or 'Cancel' to discard the changes.



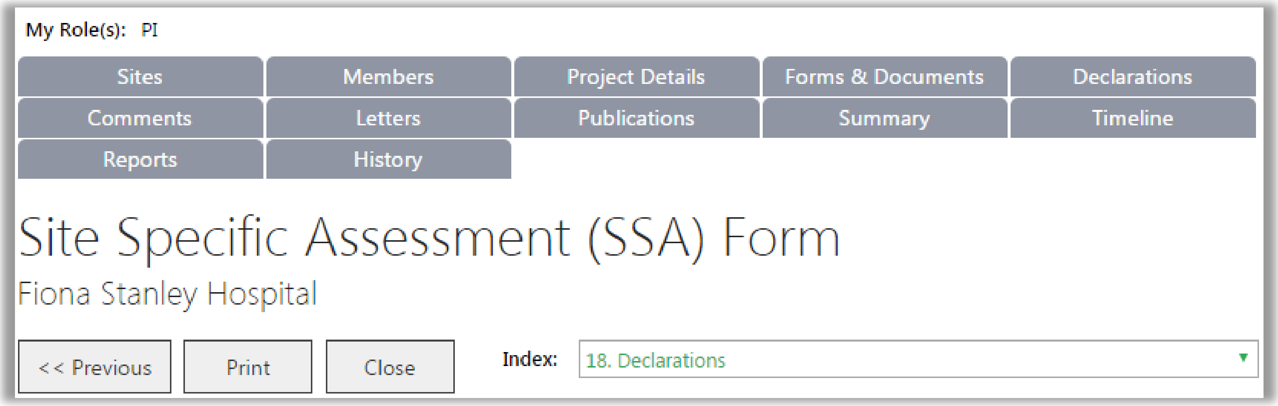
5. Select the Hospital Administrator and click 'Invite to Sign' or 'Remove' if you wish to remove them. The Hospital Administrator User will be sent an email and Task, to review and sign the form. Refer to Help Wiki: Sign the declaration on a SSA Form (for Hospital Administrators). If you remove a Hospital Administrator once you have invited them, they will receive a notification email that you have withdrawn your request to sign the declaration and the task will be removed from their My Tasks. The form status will be Completed (Pending Signatures).**You can remove Hospital Administrators if their status is 'pending' or 'invited' without unlocking the form.**

Note: If you unlock the form, you will remove any signatures.

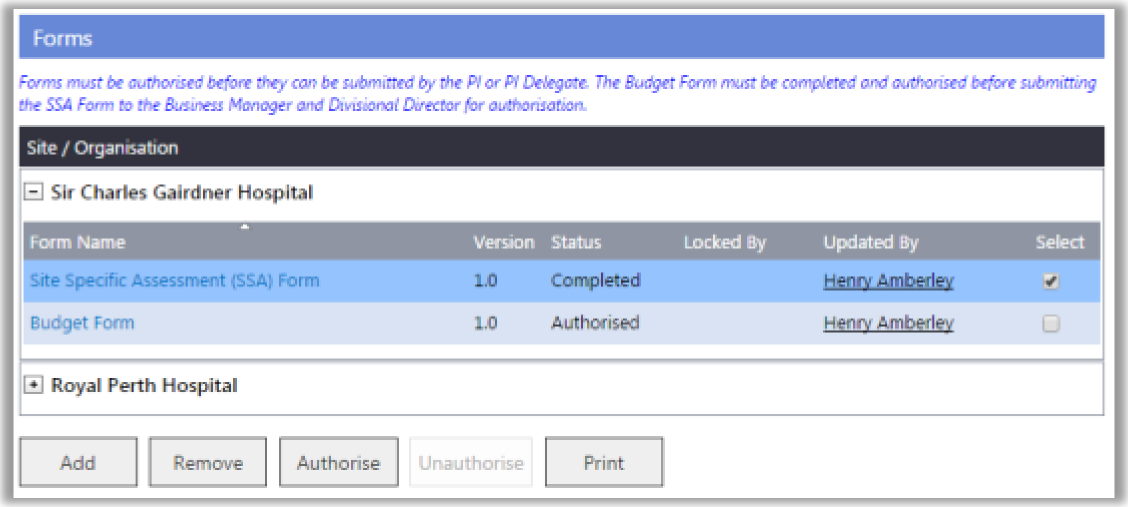
6. Once the Hospital Administrators have signed the form the PI and PI Delegate will receive an email and their signature will display 'Signed' and. The PI can now authorise the SSA Form so that it can be submitted. Open the form and **Click 'Authorise', which appears at the bottom of each page of the SSA Form (there is no requirement to click edit or unlock).** Click 'Unlock' to edit the form before authorisation if you wish to change something before authorisation.

Note: If you unlock the form, you will remove any signatures.

7. After authorising a form, the 'Unauthorise' button should appear. To exit the form, click the Close button at the top or bottom of the form this will take you to the Forms & Documents tab.



Alternatively, a PI can authorise and a PI or PI Delegate can unauthorise a form in the project workspace's Forms & Documents tab after selecting a form or document. **Note the Budget Form must be authorised within the form and not in the Forms & Documents tab.**



8. Once the SSA Form and Budget Form are authorised, the PI and PI Delegate will be allowed to submit them to a RG Office. Refer to Help Wiki: Governance Submission, Validation and Review Assessment. **The SSA Form and Budget Form must be submitted together.**

3.4.2 Sign and Authorise an Access Request Form

The CPI with additional Site PI role (CPI/PI) should sign and authorise the AR Form after it has been signed by the relevant Hospital Administrators in the Site Declaration of Support.

1. Refer to Sign and Authorise a SSA Form for steps in inviting a Hospital Administrator to sign the form, and for the CPI/PI to sign and authorise the AR form.

2. Once the Hospital Administrator has signed the form, CPI/PI has to sign/authorise the form. When the CPI/PI open the form the following message appears, when you click ‘OK’ the form will be checked out to you for editing.

3. Click ‘Mark Complete’ and this will take you to the Declarations section and the sign button will be enabled next to your name, click ‘Sign’. The ‘Authorise’ button should then appear. Click ‘Authorise’. To exit the form, click ‘Close’.

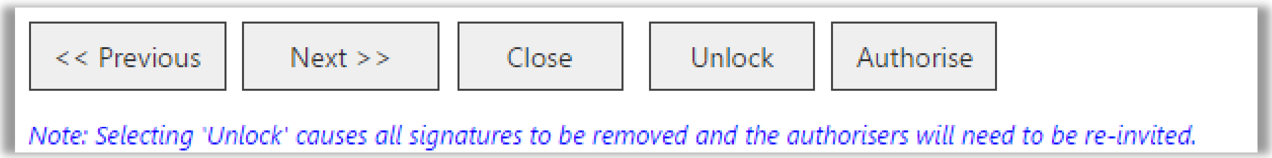
4. Once the AR Form is authorised, the PI and PI Delegate will be allowed to submit it to a RG Office. The CPI must add them self as the PI for the relevant site(s) to enable submission of the AR Form. Refer to [Help Wiki: Governance Submission, Validation and Review Assessment.].

3.4.3 Unauthorise a Site Specific Assessment Form

Only the site PI and PI Delegate can unauthorise a SSA Form. *Note that when you unauthorise the SSA Form, all signatures will be removed, the PI will have to re-sign the form and then the PI or PI Delegate will have to reinvite the Hospital Administrators to re-sign the form, prior to the PI/PI Delegate authorising the form*

1. You can unauthorise a form in the project workspace's Forms & Documents tab after selecting a form or document. If you only need to obtain an additional signature on the form then you do not have to unlock or edit the form to do this only unauthorise it. The form can be authorised again when the signature/s have been obtained.

2. Alternatively in the form, click ‘Unauthorise’. You only need to unlock the form if you need to edit sections 1 to 17. To do this you will need to go to one of the previous section of the form and click ‘Unlock , you will receive a warning message.



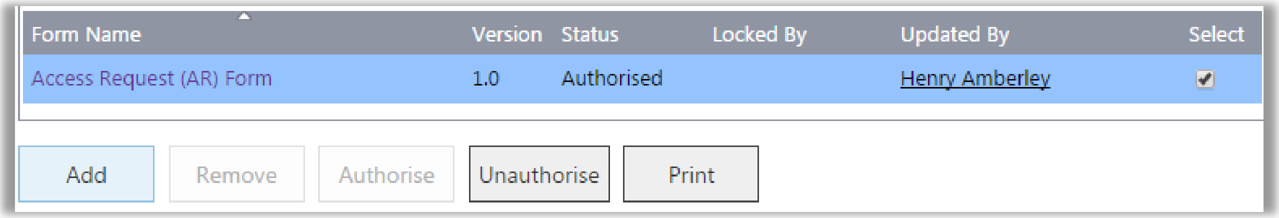
Click ‘OK’ on the message to proceed or ‘Cancel’ for the form to remain locked. If you click ‘OK’ it will remove all signatures from the form. If you click ‘OK’ you can then click ‘Edit’ to make any changes to the form. You will then have to go through the process of obtain any signatures needed.

3.4.4 Unauthorise an Access Request Form

Only the CPI with additional site PI role (CPI/PI) and PI Delegate can unauthorise an AR Form.

Note that when you unauthorise the AR Form, you do not have to reinvite the Hospital Administrators to re-sign the form, prior to the CPI/PI re-signing and authorising the form.

1. You can unauthorise a form in the project workspace's Forms & Documents tab after selecting a form or document.



2. Alternatively in the form, click ‘Unauthorise’. Click ‘Edit’, make your changes and then click ‘Mark Complete’.

3. If you are the CPI/PI click ‘Authorise’. To exit the form, click on the Forms & Documents tab at the top of the form.

3.5 Systematic Unauthorisation of the Governance Forms

Note that changes to the project will trigger certain forms to be automatically unauthorised.

Location of changes made	**WAHEAF**	**WA Specific Module**	**Site Specific Assessment Form**	**Access Request Form**
Sites tab	Unauthorise	Unauthorise	Unauthorise only the form that includes a site that has been removed	Unauthorise only the form that includes a site that has been removed
Members tab	Unauthorise	Keep as 'Authorised'	Unauthorise only the form that includes investigator changes	Unauthorise only when the CPI is changed
Project Details tab - Project Header	Unauthorise	Unauthorise	Unauthorise	Unauthorise
Project Details tab - Ethics Information	Unauthorise	Unauthorise	Unauthorise	Unauthorise
Project Details tab - Governance Information	Keep as 'Authorised'	Keep as 'Authorised'	Unauthorise	Keep as 'Authorised'
Project Details tab - Investigator Contact Information	Unauthorise	Keep as 'Authorised'	Unauthorise	Keep as 'Authorised'

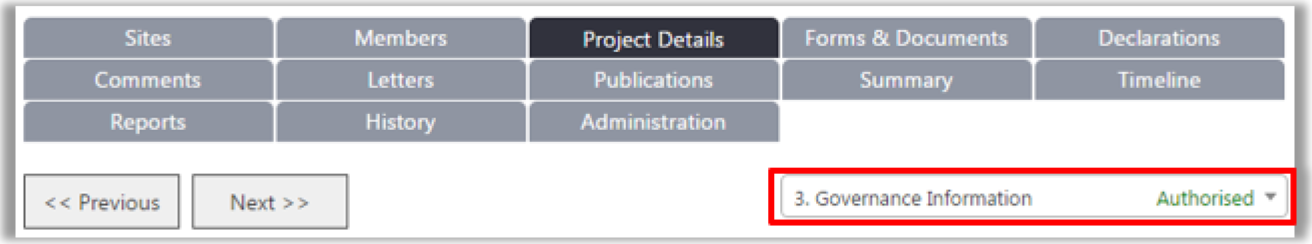
4. Add, Fill Out and Authorise a Budget Form

Guidance documents for completing the budget can be found under RGS Education.
A Research Budget Template is also available on the Research Governance tab to help calculate costs related to the Protocol. Additional information in compiling clinical trial budgets is available from the Independent Hospital Pricing Authority (IHPA) Determination of Standard Costs Associated with Clinical Trials in Australia June 2015.

4.1 Add Information to Project Details Tab for a Budget Form

Before you start completing a Budget Form, you should ensure that the necessary pre-requisites to proceed with completing the Budget Form have been met:

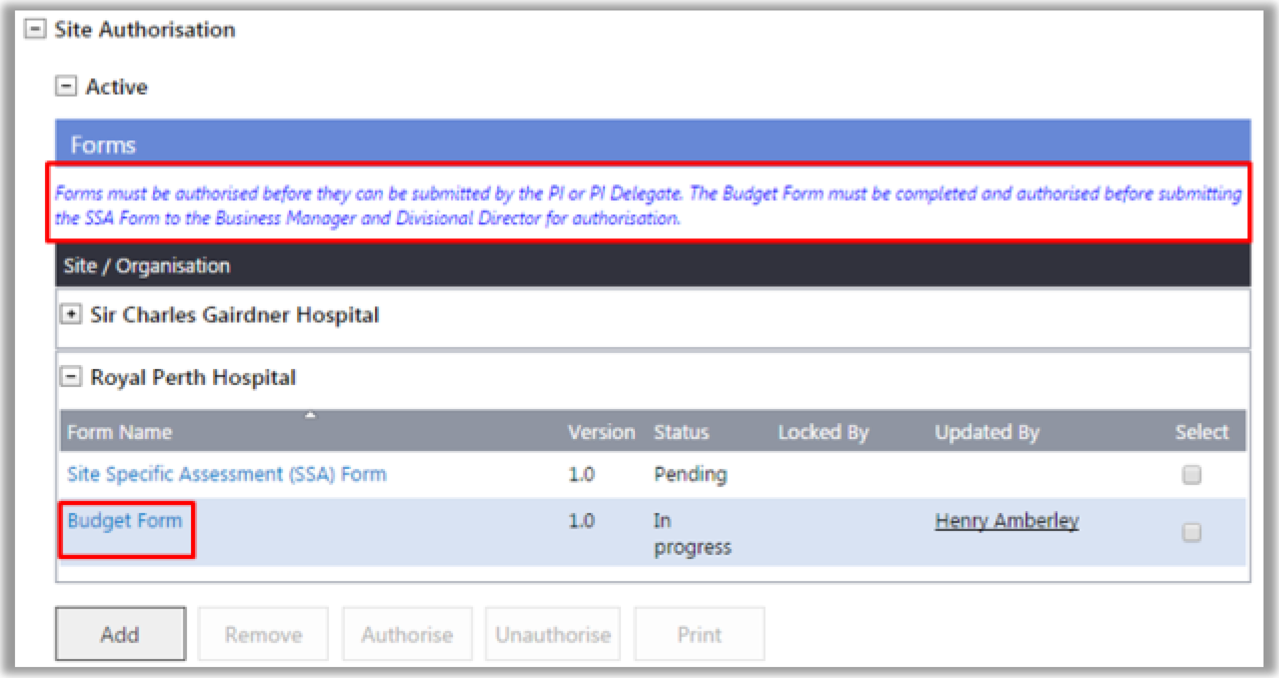
The 'Governance Information' section of the Project Details tab, particularly the 'Funder Contact Information' (section 7), has been completed and authorised. Refer to the Add the funder details in the Governance Information section of the Help Wiki: Add, fill out and authorise a governance form. If you cannot find a funder, contact the RGS Support.



A SSA Form with a corresponding Budget Form has been added in the Forms & Documents tab.

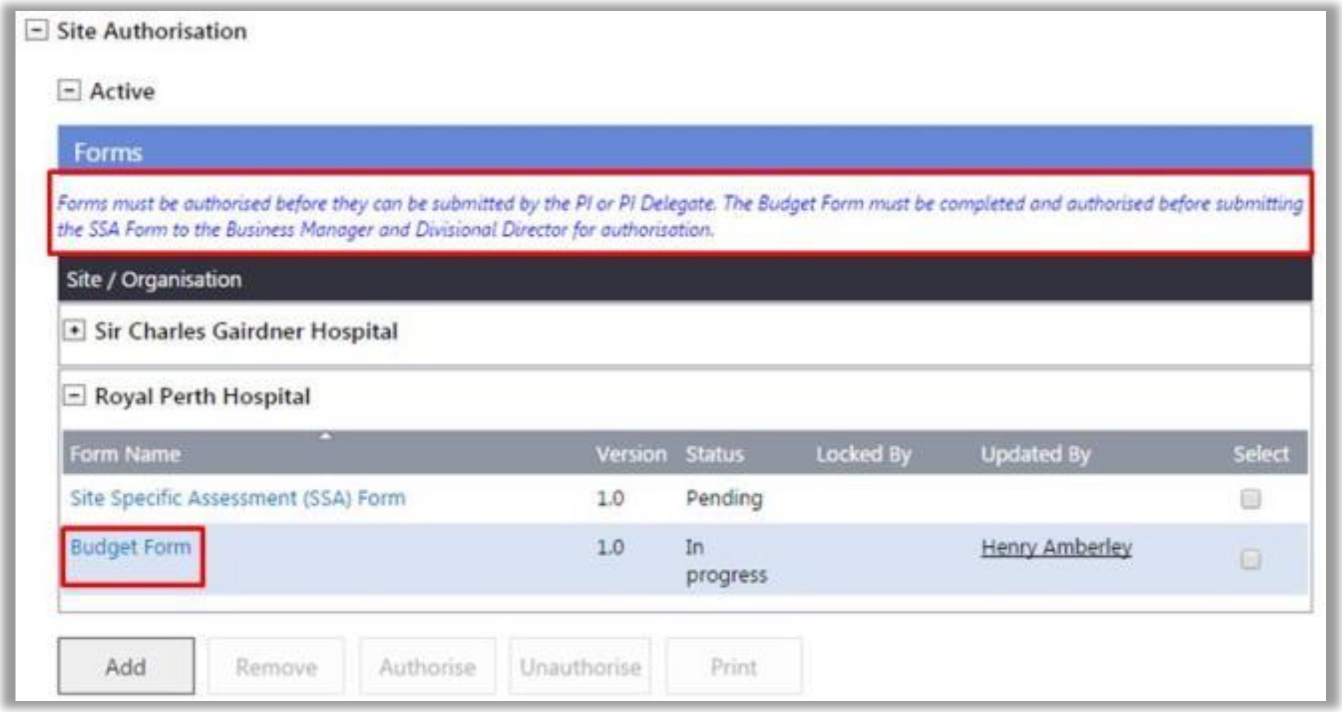
4.2 Add a Budget Form

When a SSA Form is added to a project, a corresponding Budget Form is automatically created as well. A budget must be completed for each site listed on the SSA Form, **it should be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.** Any Project Member can view the Budget Form, with the exception of the Sponsor. Refer to Help Wiki: Add, fill out and authorise a governance form.

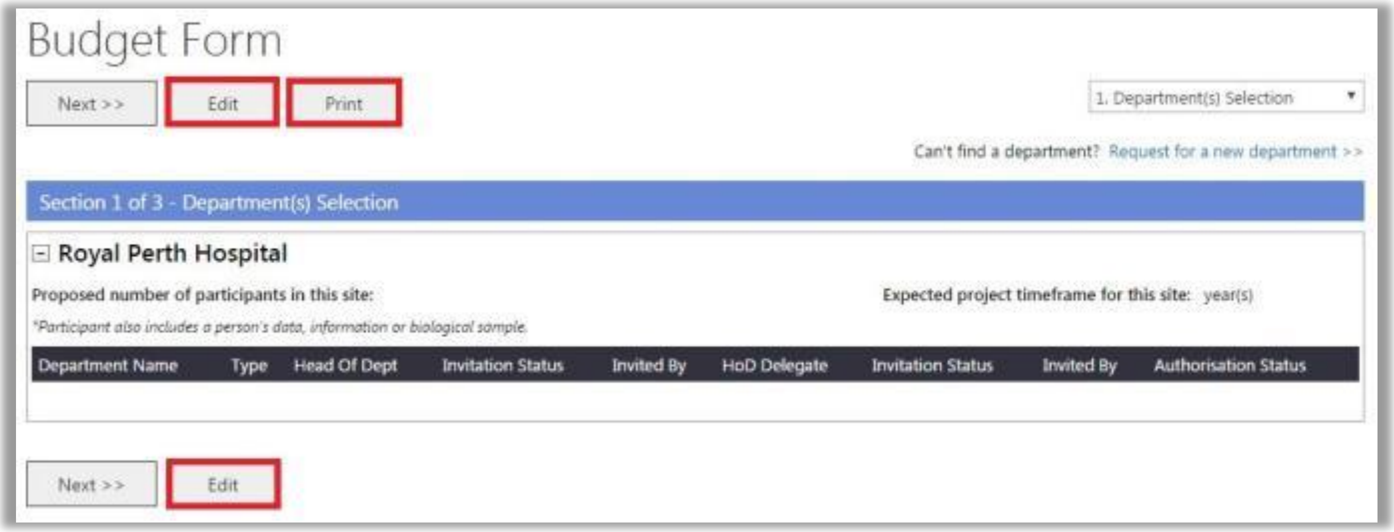


4.3 Fill Out and Authorise a Budget Form

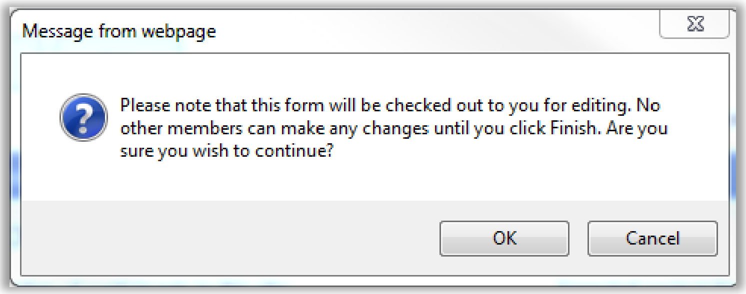
Completing the Budget Form is the responsibility of the PI and the PI Delegate at each site. The site PI, PI Delegate and invited Hospital Administrators can edit the Budget Form, click on the embedded link in the Budget Form name to open it. As required you will need to provide the costs and funding for the project. Note the Budget Form will automatically open in a separate window (Internet Explorer) or tab (Chrome).



1. In the Budget Form, click ‘Edit’.Note: Click ‘Print’ to print the Budget Form at any time.



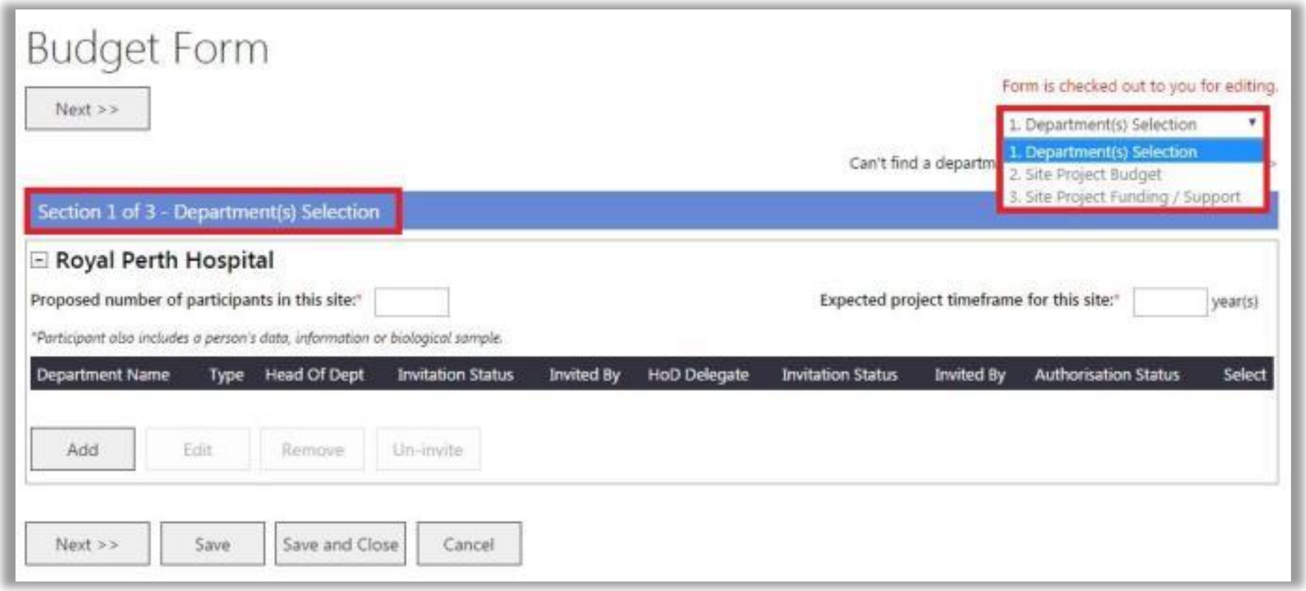
2. A confirmation message will appear. Click ‘OK’ to proceed.



Take note that you are now on ‘Edit’ mode, and the form will be checked out to you until you click ‘Save & Close’.

3. At any time you can click on the ‘Forms & Documents' tab to review the project's protocol or other documents in order to determine what services are required, this can be done by right clicking the Forms & Documents tab and opening it in a new tab or window or you can go to the window/tab the you used to open the Budget Form.

There are three sections of the Budget Form that require completion. These are Department(s) Selection, Site Project Budget and Site Project Funding / Support. Click on either the ‘Index’ or ‘Next’ to navigate between the different sections.



4.3.1 SECTION 1: DEPARTMENT(S) SELECTION

4.3.1.1 Add a Department

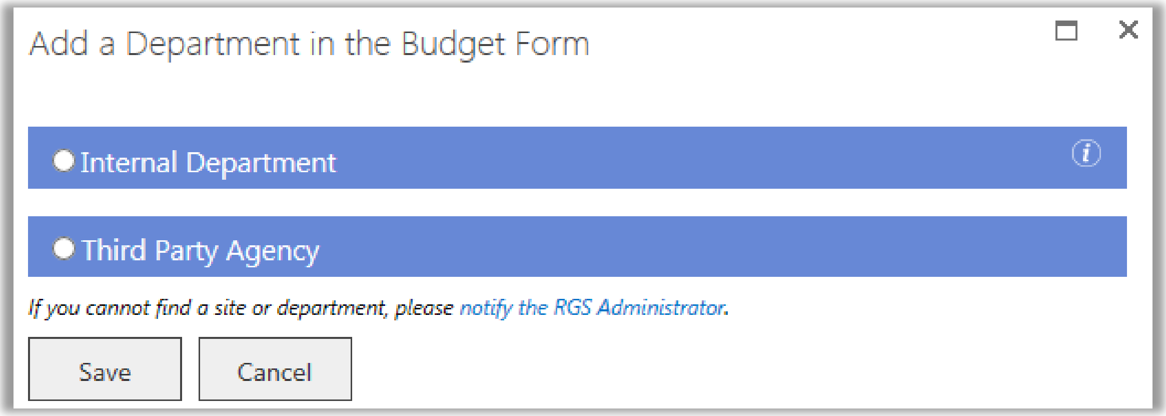
1. In the 'Department(s) Selection' section, enter the 'Proposed number of participants for this site' and the 'Expected project timeframe for this site' at the top of the form. Note that participant also includes a person's data or biological sample.

2. Select/nominate the departments that will be involved in the project at the site e.g. research department, supporting department (s) and any third party agency. **Add them to the Budget Form in the following order:**

- Research Department (i.e. where the research is being conducted, there should always be one research department nominated)
- Supporting Department(s) (e.g. Pharmacy, Pathology, Radiology, Nuclear Medicine, Medical Records, Theatre)
- Third Party Agency (i.e. agency outside WA Health providing support services e.g. a private Radiology site).

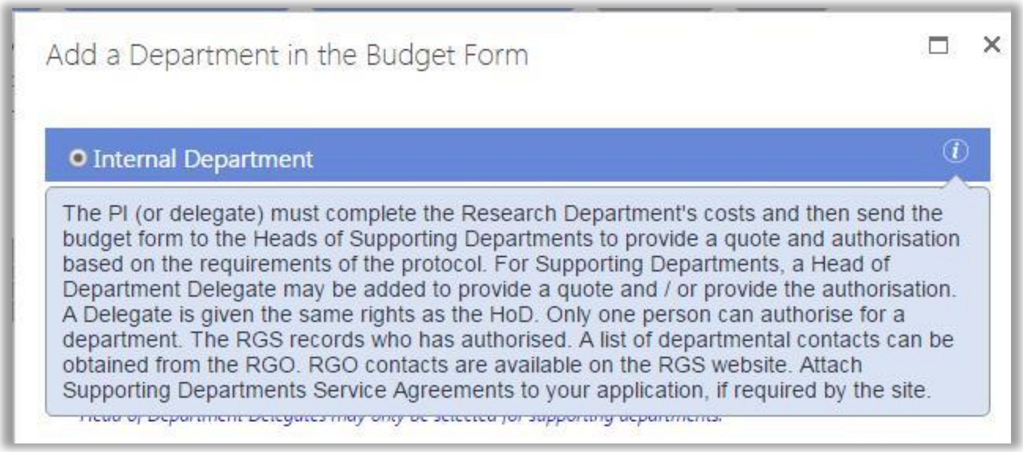
Add a research or supporting department or a third party agency by clicking 'Add' while in the 'Department(s) Selection' section.

3. The 'Add a Department in the Budget Form' screen will launch. If you wish to add a research or supporting department at the site, select 'Internal Department'. Select 'Third Party Agency' if the supporting department will be external to the site.



4.3.1.2 Add an Internal Department

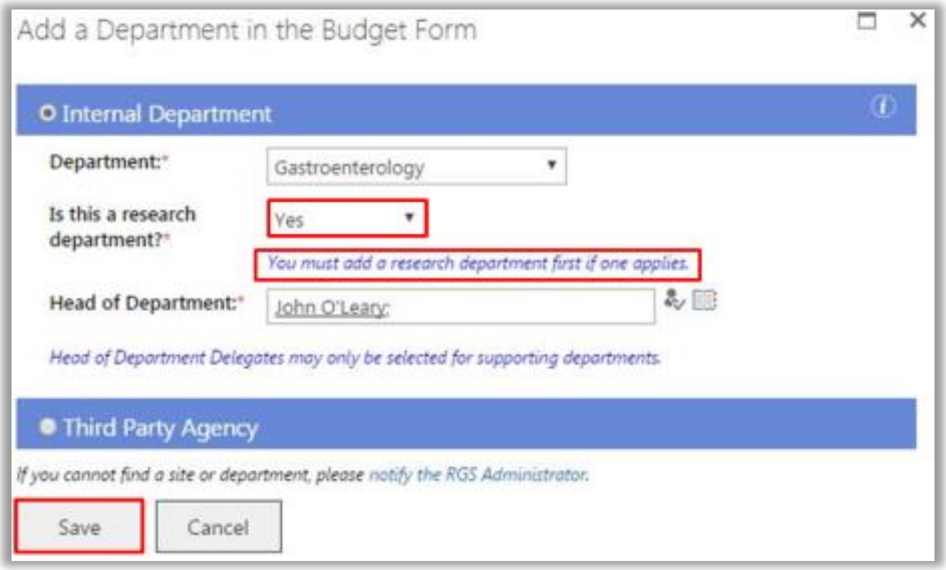
1. The 'Add a Department in the Budget Form' screen appears when you click on 'Internal Department', with the following tool tip if you hover your pointer over it. For a supporting department both a Head of Department and delegate can be added to provide quotes and/or authorise their costs, both users will have access to the Budget Form once invited.



2. Select the 'Department' to be added. **Add a research department first if one applies** (the research department is the department that is initiating the research (i.e. where the PI is located). If you cannot find a site or department please notify the RGS Support.

Select 'Yes' or 'No' to the question 'Is this a research department?', depending on your selection the following will apply:

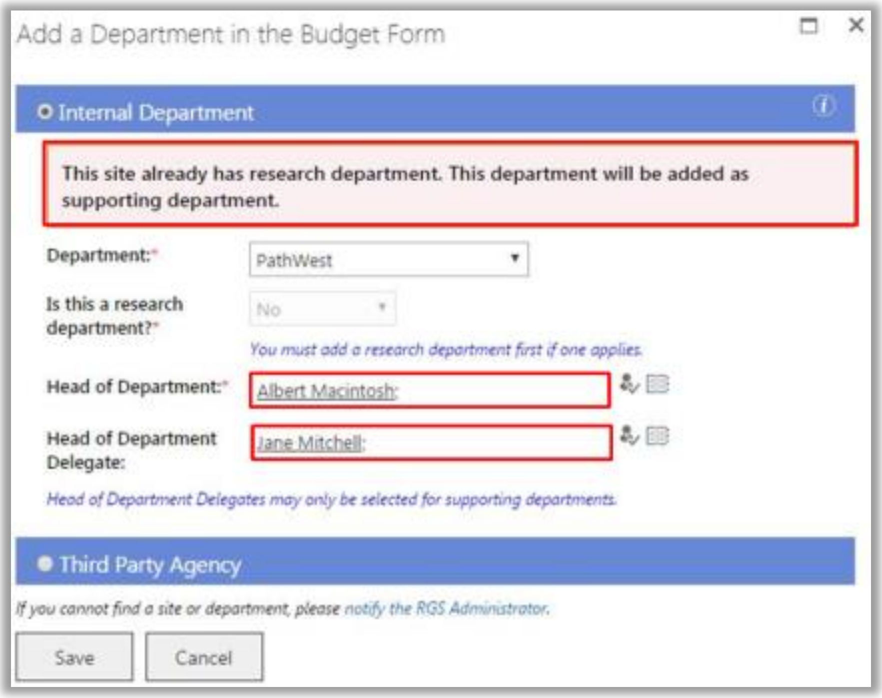
- Research Department: enter the name of the Head of Department (HoD).
- Supporting Department: enter the name of the Head of Supporting Department (HoSD). In addition, you can enter the name of a HoSD Delegate. Both users can be invited to either provide a quote and/or authorise their department's costs. If you are only inviting the HoSD Delegate they are added to the HoD field (do not also add them to the HoD Delegate field).



Click 'Save'.

Project Members cannot be added as a HoD or HoSD to authorise either the SSA Form or the Budget Form, select the next line manager above the Project Member (e.g. Divisional Director).

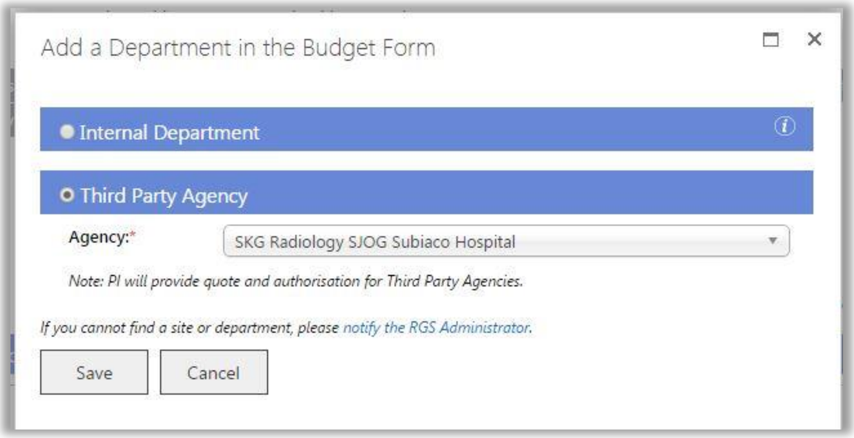
3. A site may nominate only one research department, once added, the 'Add a Department in the Budget Form' screen shows a message that a research department has been assigned.



4.3.1.3 Add a Third Party Agency

There will be occasions where an external service provider may be required to provide some sort of goods or services to the project which cannot be provided by the site (e.g. transport of specimens or imaging). A quotation request can be generated to the external service provider and uploaded as an additional document.

1. This external provider should be added as a third party agency and the PI/PI Delegate for the site is automatically assigned to provide a quote and authorisation as the third party agency does not have access to RGS. If you wish to add a third party agency, select 'Third Party Agency'. Select the third party agency you wish to add. If you cannot find an agency please notify the RGS Support.



2. Once the Agency is added, click ‘Save’.

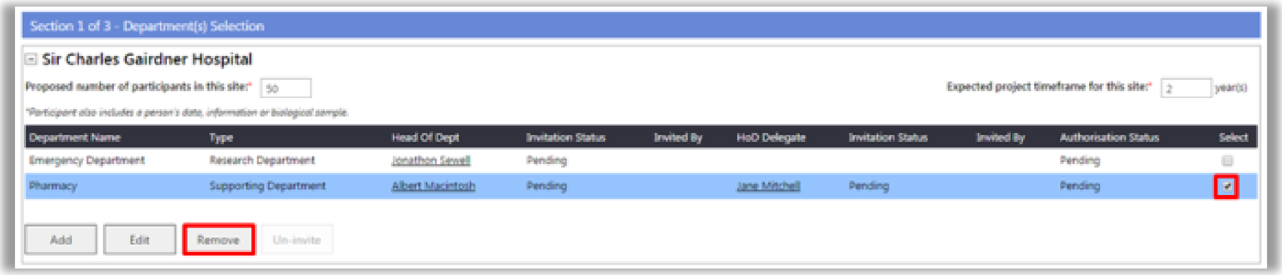
4.3.1.4 Edit and Remove a Department or Head of Department

If a department has been added or assigned as the research department or supporting department by mistake, it can be edited or removed.

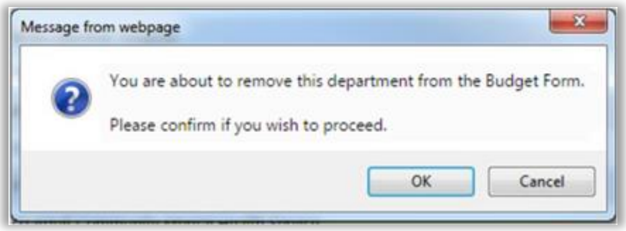
Note: if you remove the department all data (costs and funding) related to that department will be deleted.

The Department and the HoD, HoSD or HoSD Delegate can be edited as long as the HoD, HoSD or HoSD Delegate has an Invitation Status of 'Pending'. If the Invitation Status is ‘Invited’, the HoD, HoSD or HoSD Delegate must be un-invited before the department/person can be changed (refer to Un-invite User).

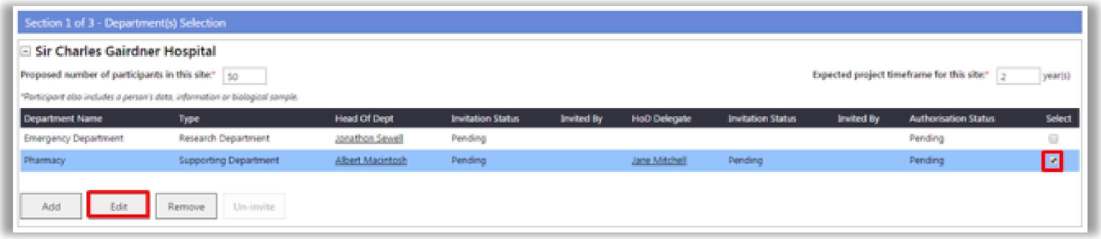
1. To remove a department, select it and click ‘Remove’.



2. A confirmation message will appear. Click ‘OK’. You can now add a new department.



3. To edit an existing department, select the department and click 'Edit'.



4. In the 'Edit a Department in the Budget Form', you can change the Department or the HoD, HoSD or HoSD Delegate. The HoD, HoSD or HoSD Delegate must have a 'Pending' invitation status. If the Invitation Status is 'Invited', the HoD, HoSD or HoSD Delegate must be un-invited before the department/person can be changed (refer to Un-invite User).

To change a supporting department to a research department, you must first change the research department to a supporting department. Select 'No' to the question 'Is this a research department?. Click 'Save'.

5. Then edit the supporting department that you wish to make the research department and change the question 'Is this a research department?' to 'Yes'. Click 'Save'.

4.3.1.5 Next Steps

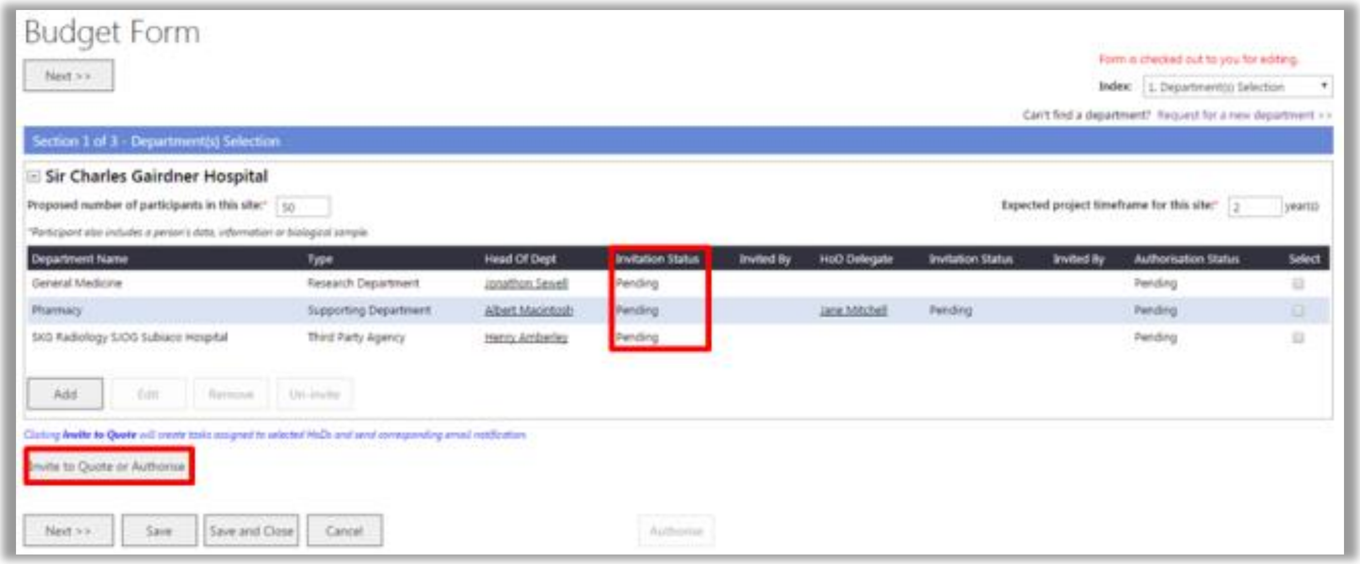
To reduce time to complete the Budget Form, it is recommended that the PI/PI Delegate:

1. Complete the Research Department costs (refer to SECTION 2: SITE PROJECT BUDGET). In section 1, click 'Next' to go to 'Site Project Budget'.
2. Invite the Heads of Supporting Departments to give their cost quotes and authorisation in parallel (refer to Help Wiki: Invite a HoD to authorise or HoSD to quote and authorise).

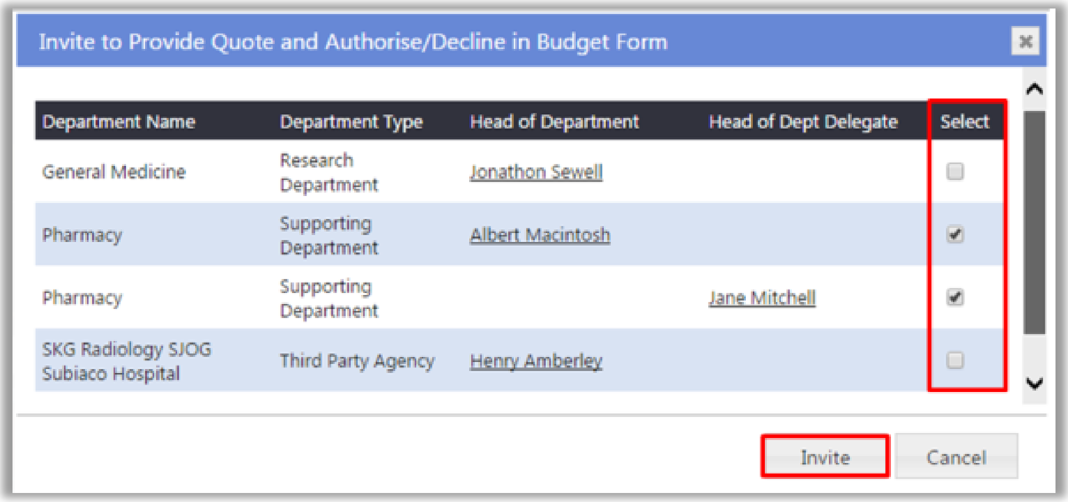
4.3.2 SECTION 1: INVITE A HOD TO AUTHORISE OR HOSD TO QUOTE AND AUTHORISE

1. In the Department(s) Selection page, click the 'Invite to Quote' button to invite the HoSD and/or their delegate to provide a quote and authorise their supporting department's costs or Research Department HoD to authorise the Research Department section. This button appears only when there are HoD, HoSD or HoSD Delegate selected but have not been invited yet.

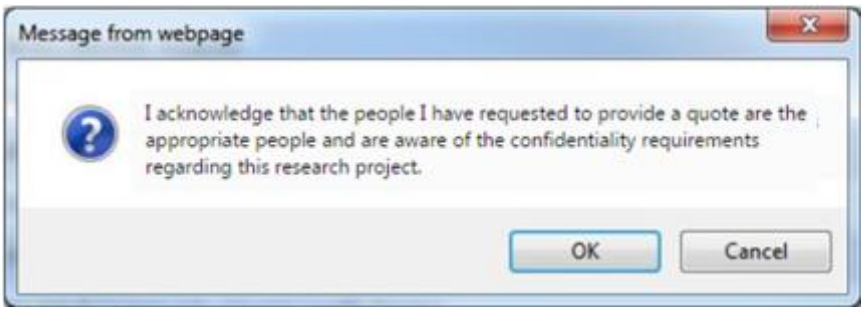
You should wait until the whole Budget Form is complete before inviting the Head of the Research Department to authorise, so that they can review the impact of the whole project's budget on the Research Department.



2. The 'Invite to Quote' screen will launch. Select the HoD, HoSD or HoSD Delegate that you wish to invite. Selecting multiple persons in this section is allowed. Click 'Invite'.

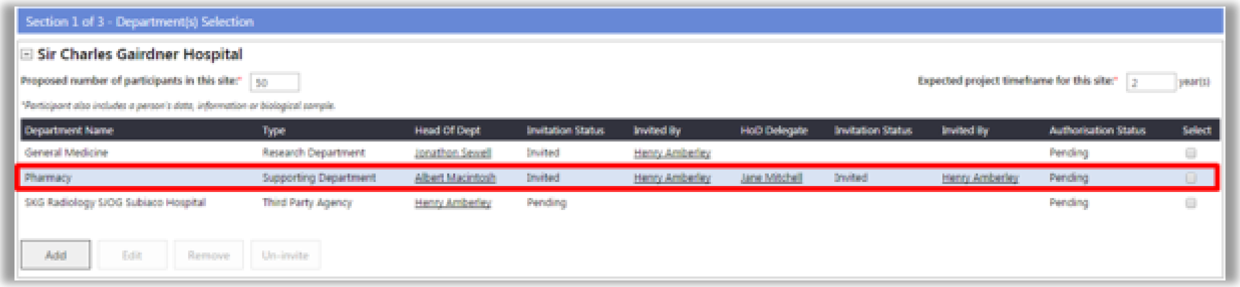


3. A message will appear. Once you have clicked OK' you will return to the 'Department(s) Selection' page.

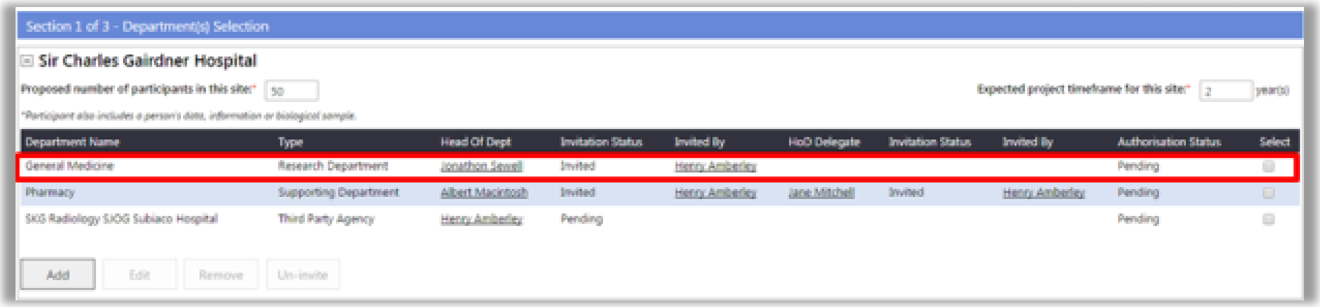


The status of the HoD, HoSD or HoSD Delegate will become 'Invited', and they will receive the Task and email notification from RGS. The PI and PI Delegate will receive and email when the HoD or the HoSD (or their Delegate) authorises or declines their department's costs.

To provide a quote and authorise the Budget Form the HoSD or HoSD Delegate should refer to [Help Wiki: Fill out and authorise a Budget Form (for supporting department HA).]



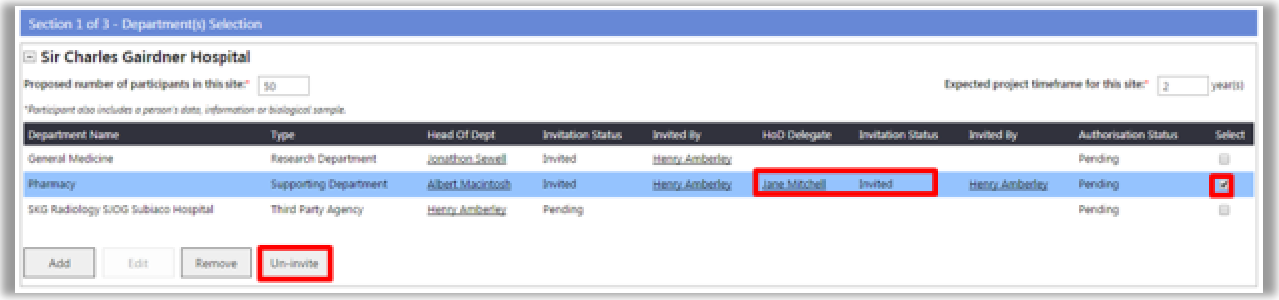
To authorise the Budget Form the HoD should refer to [Help Wiki: Authorise a Budget Form (for Research Department HA)].



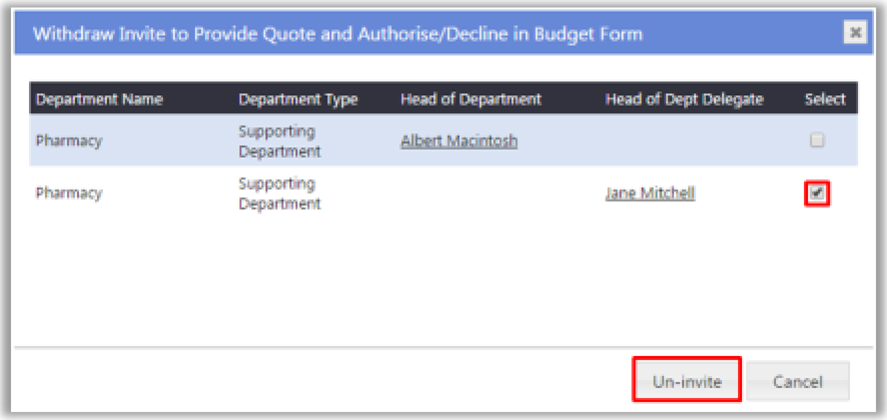
As the HoD and HoSD authorise the Budget Form, they no longer authorise the SSA Form.

4.3.2.1 Un-invite a User

1. To un-invite a HoD, HoSD or HoSD Delegate that has an Invitation Status of 'Invited', select the user and click 'Un-invite'.



2. The Withdraw Invite to Provide Quote and Authorise/Decline in Budget Form screen will launch. Select the user and click 'Un-invite', the person will receive and email that their invitation the budget has been withdrawn.

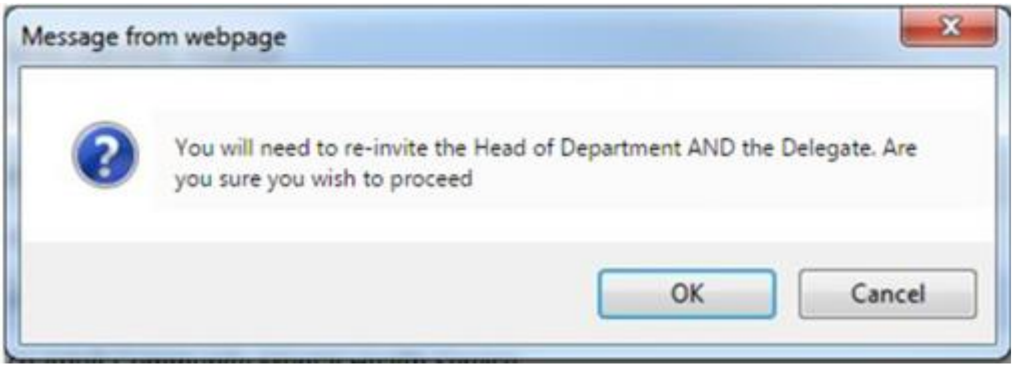


4.3.2.2 Edit an Authorised or Declined Section

1. To be able to edit a section, ensure that the service and support items for the desired department (research, supporting department or third party agency) have not been authorised (or declined) by the department's HoD, HoSD or HoSD Delegate.

If the section has a status of either 'Authorised' or 'Declined', the PI, PI Delegate, HoD, HoSD or HoSD Delegate must click 'Unlock' to be able to edit the section. Doing so will reset the previous authorisation made.

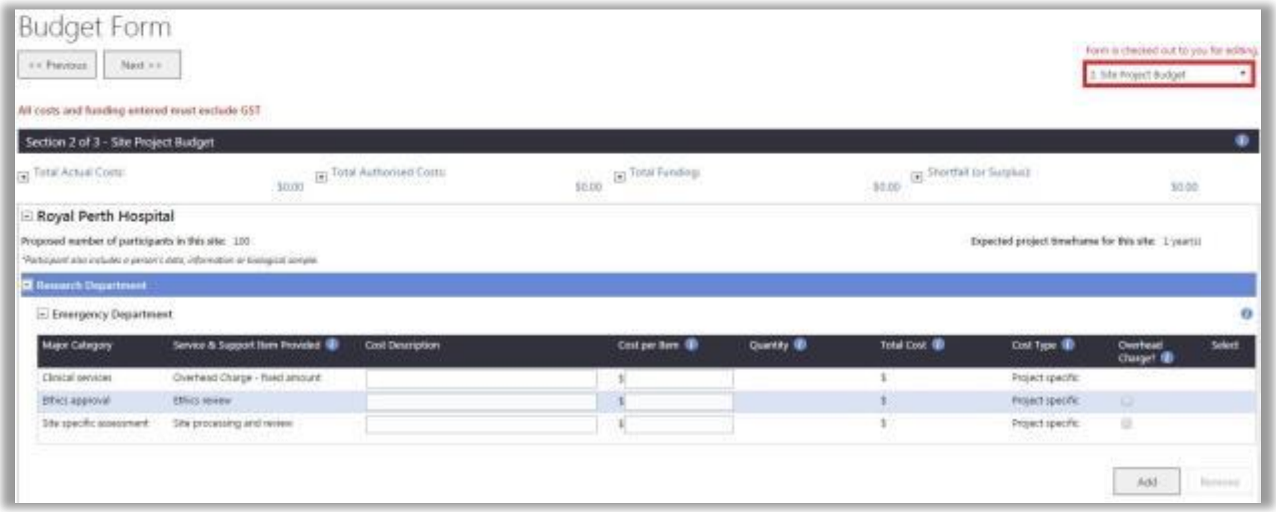
2. If the PI or PI Delegate unlocks the section they will receive a confirmation message that the HoD, HoSD or HoSD Delegate will need to be re-invited to provide authorisation. Click 'OK' to proceed.



4.3.3 SECTION 2: SITE PROJECT BUDGET

In Section 2: 'Site Project Budget', *all costs and resources involved in the* conduct of the research project at the site *(i.e. activities that are secondary to the primary purpose of providing patient care) must be detailed and authorised*. *Projected costs should be based on the research protocol, total time period of the project and proposed number of participants to be recruited.*

Section 3: 'Site Project Funding / Support' can be completed once all costs are accounted for in Section 2 (refer to [Help Wiki: Site Project Funding / Support](#)).

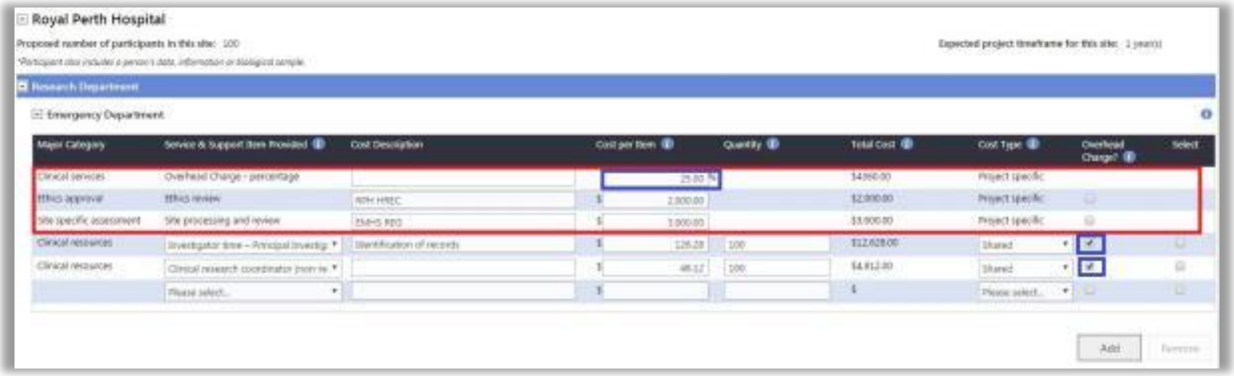


User tip: Refer to the ⓘ at any time.

4.3.3.1 Research Department Default Items

1. The following items are added by default under a Research Department:

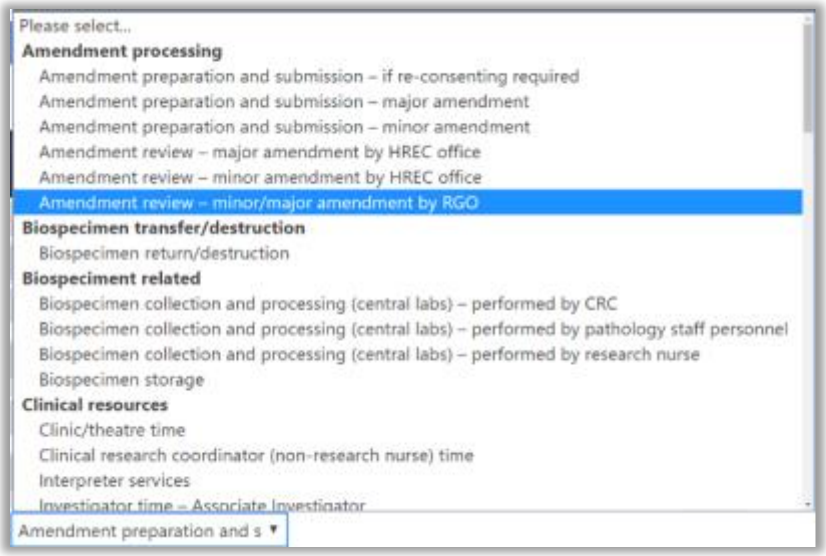
Major Category	Services
1. Clinical services	Overhead Charge – percentage *If 'Overhead charge' tick box is checked for one or more items, a percentage must be nominated* **OR** Overhead Charge – fixed amount *If none of the items' 'Overhead charge' is checked, a fixed amount must be provided*
2. Ethics approval	Ethics review – *refer to the HREC's fees and charges for amounts. The usual fee (i.e. commercial rate) should be added as a cost even if the service is provided by the HREC's sponsoring organisation in-kind (i.e. there is no charge) to the project.*
3. Site specific assessment	RG Office review - *refer to the RG Office's fees and charges for amounts. The usual fee (i.e. commercial rate) should be added as a cost even if the service is provided by the RG Office's sponsoring organisation in-kind (i.e. there is no charge) to the project.*



4.3.3.2 Complete the Research Department and Third Party Agency Costs

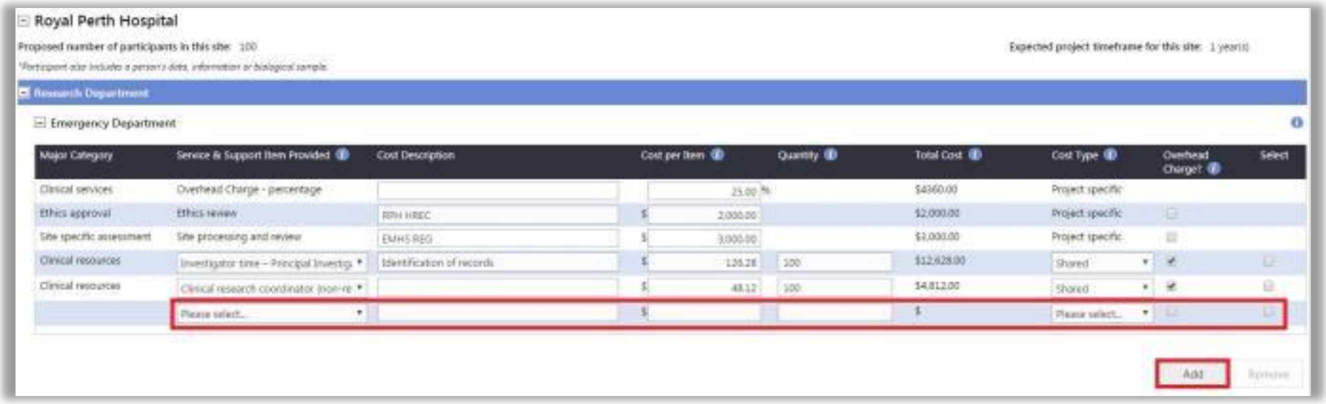
1. Ensure that you have clicked 'Edit'. The PI/PI Delegate can enter the following items as required for the research department and third party agency. They can also add items for the supporting departments (but cannot authorise the supporting department costs):

Major Category Service & Support Item Provided	Select all the support or services for the project that will be provided by the department. Select the service from the drop-down list and the 'Major Category' will automatically be populated.

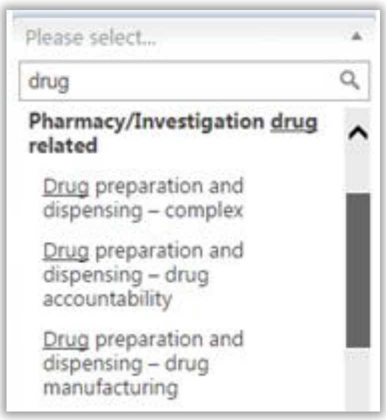


Cost Description	Provide comment or description of the service or support item provided if the Service & Support Item does not give enough detail.
Cost per Item	Provide the individual cost per service or support item e.g. cost per test/procedure or salary per participant.
Quantity	Insert the quantity that the cost per service or support item should be calculated by, to produce the total cost per site (Total Cost column).
Total Cost	This is calculated as the total cost per service or support item for the whole site, for the proposed number of participants.
Cost Type	Indicate if the cost is project-specific (e.g. diagnostics, tests, drugs) or shared (e.g. salaries). All research department salary based items should be marked as shared so that they can be accounted for in shared cost centres.
Overhead Charge?	Overhead charge is the additional corporate costs to the site which the institution provides to support the conduct of the project (i.e. administration, facilities, utilities). The overhead must be applied in accordance with the Financial Management Manual. An overhead % should only be applied to the Research Department salary based time and procedures, not to the total cost of the project. If this is ticked for one or more items, a percentage must be nominated in the 'Overhead charge' item found under the Research Department; otherwise, if none of the items is ticked, a fixed amount must be provided in the field.
Select	Tick this to remove an item. When an item is selected, the 'Remove' button will be enabled. *This does NOT have to be ticked when adding a service or support item, or authorising/declining the department.*

2. To add a service and support item click 'Add'. After clicking 'Add', a blank row will be added at the bottom of the list.



3. Go to the drop down under 'Service & Support Item Provided' you can then search within the list of items. The search is dynamic and will list all items with the word that you have typed. The budget category list is available on the Help Wiki [Help Wiki: Add, fill out and authorise a Budget Form]



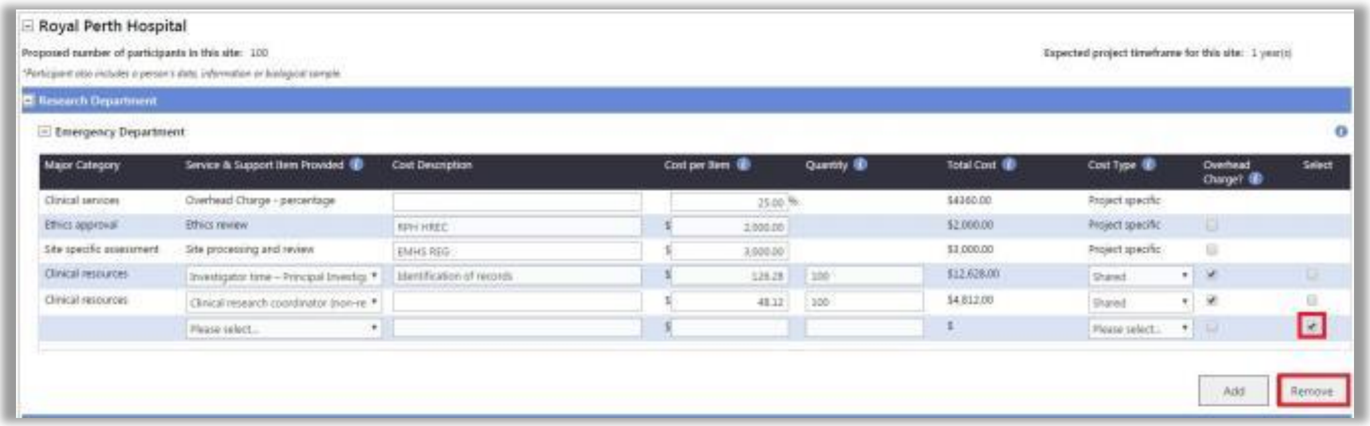
3. Remember to click ‘Save’ or ‘Save and Close’ to keep any changes made. Click ‘Cancel’ to discard any changes.

4. Once saved, the Total Actual Costs (Project Specific and Shared) will display at the top of the screen. The Total Authorised Costs will display once the costs are authorised by a HoD/HoSD.

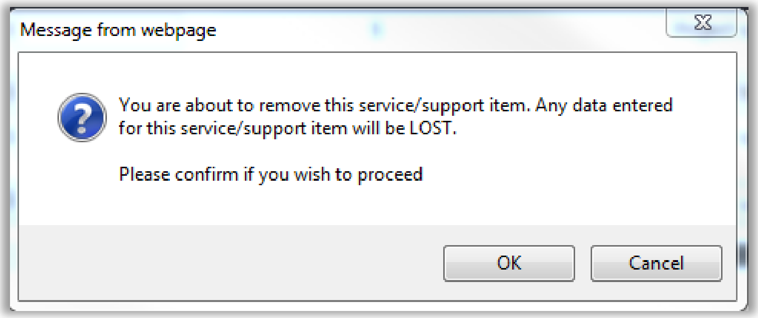
5. When not in edit mode, you can view the cost details of Section 2 and print it at any time. In this example the PI has added the costs for the research department, supporting department and third party agency:

4.3.3.3 Remove a Service or Support Item

1. To remove an item, ‘Select’ the item you wish to delete. When an item is selected, the ‘Remove’ button will be enabled. Note that the default items added under the Research Department cannot be deleted.



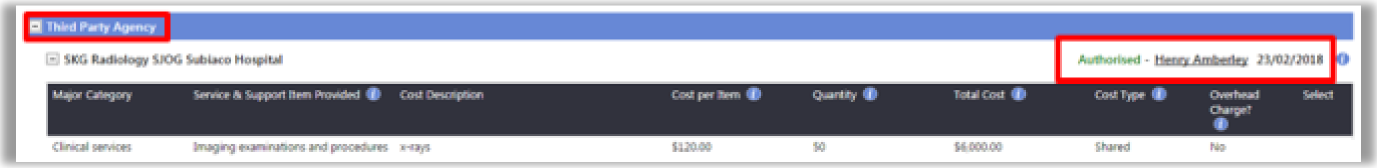
2. A confirmation message will be shown. Click ‘OK’ if you wish to proceed with the deletion; otherwise, click ‘Cancel’.



When you have finished completing this section, the nominated HoD or HoSD will need to provide a quote and/or ‘authorise' or 'decline' their respective departments.

4.3.3.4 Authorise the Third Party Agency Costs

1. The PI or PI Delegate authorise the Third Party Agency costs after they have been entered by the PI or PI Delegate. Click ‘Authorise’ and then ‘Save’.



4.3.4 SECTION 3: SITE PROJECT FUNDING / SUPPORT

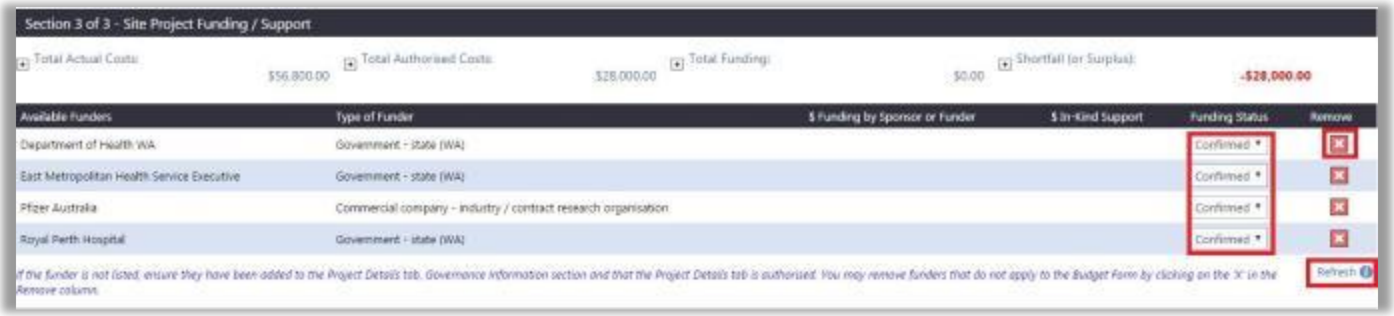
Once Section 2: Site Project Budget has been competed for all departments, the PI or PI Delegate must complete Section 3: Site Project Funding / Support. *all funding or in-kind support must be detailed and align with costs based on the research protocol, total time period of the project and proposed number of participants to be recruited.*

The HoSD or HoSD Delegate can edit their department to indicate that a Service & Support Item may be provided in-kind, but they cannot authorise this section.

4.3.4.1 Complete the Site Project Funding / Support

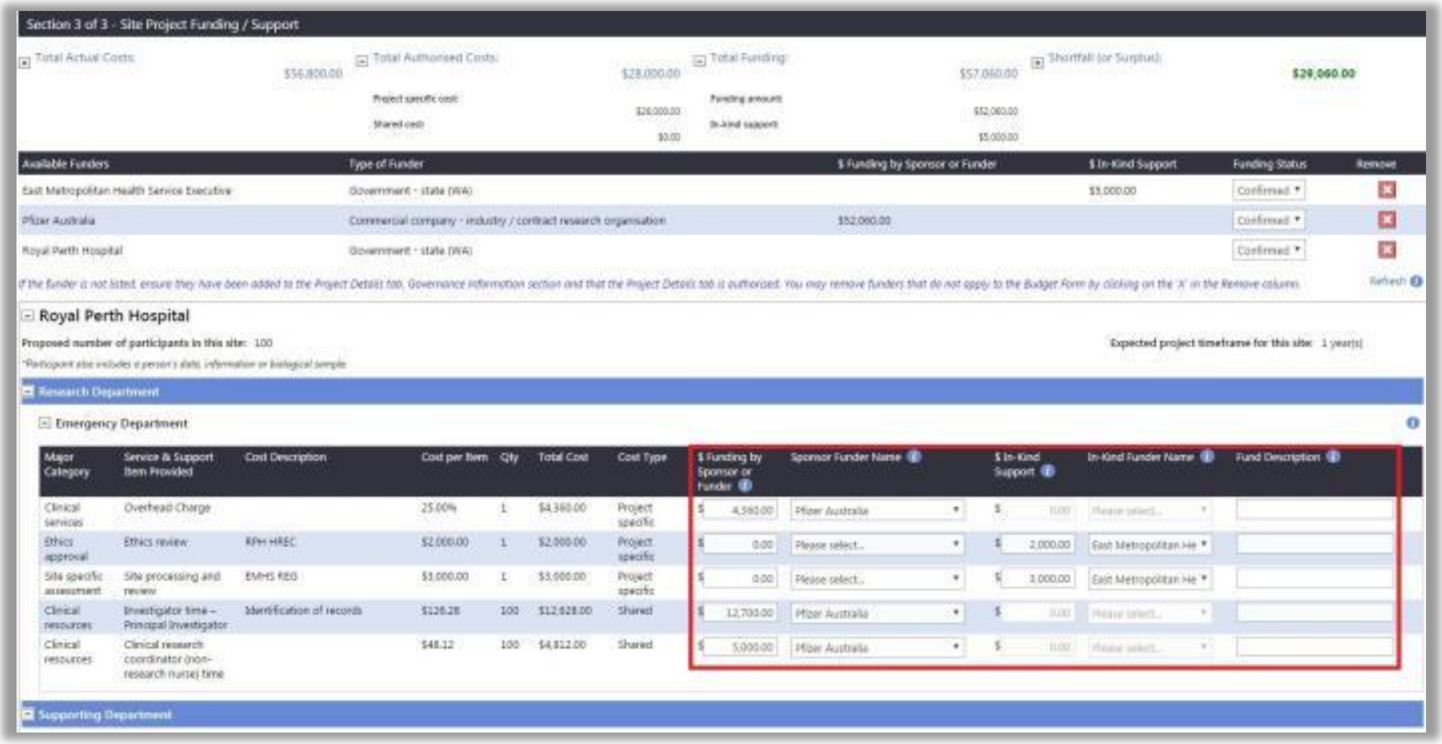
1. Ensure that you have clicked 'Edit'. The PI/PI Delegate should edit the Funders at the top of the form. This is populated from Project Details – Governance Information – question 7, if the funder does not apply to this Budget Form, click ‘Remove’. For the remaining Funders nominate whether the funding has been received, confirmed or is being sought.

If you remove a Funder in error, click ‘Refresh’.



2. The following items should be added as required for the Research Department and Supporting Department(s) to align with the cost displayed (populated from Section 2):

Amount of Funding by Sponsor or Funder	Provide the dollar amount of funding per cost item.
Sponsor Funder Name	Provide the source of funding or in-kind support i.e. sponsor or departmental support. These Funders should have been added in question 7 of Project Details – Governance Information.
Amount of In-Kind Support	Provide a dollar amount for all in-kind support provided per cost item.
In-Kind Funder Name	Provide the source of in-kind support i.e. sponsor or departmental support.
Fund Description	Provide comment or description of the service or support item funded if the funder describes it differently.



4.3.4.2 Calculation of Costs and Funding

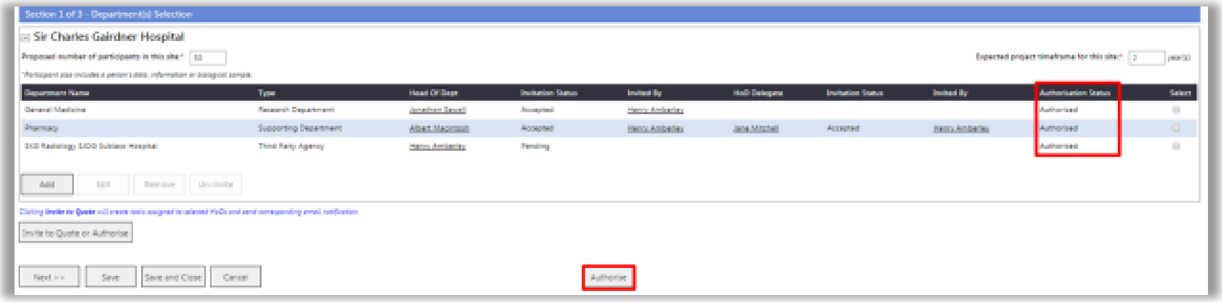
1. The Budget Form will automatically calculate costs and funding:
   - Actual costs – costs prior to authorisation
   - Authorised costs – costs once authorised by HoD, HoSD
   - Total funding – funding once saved
   - Shortfall (or Surplus) – funding minus authorised costs.

4.3.4.3 General Comments (mandatory in cases of shortfall)

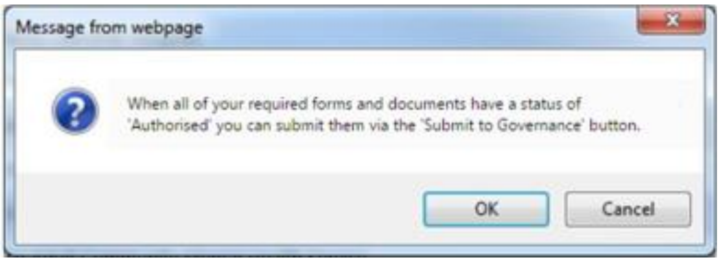
If there is a ‘Shortfall’, (i.e. the ‘Total Funding’ is less than the Total Authorised Costs) the PI must provide an explanation in the ‘General Comments’ section. This shortfall must be approved by the HoD, Business Manager and Divisional Director when they authorise the Budget Form and/or SSA Form. **The shortfall/surplus will not be calculated until all costs are authorised.**

4.3.5 SECTION 3: PI AUTHORISATION WHEN BUDGET FORM COMPLETE

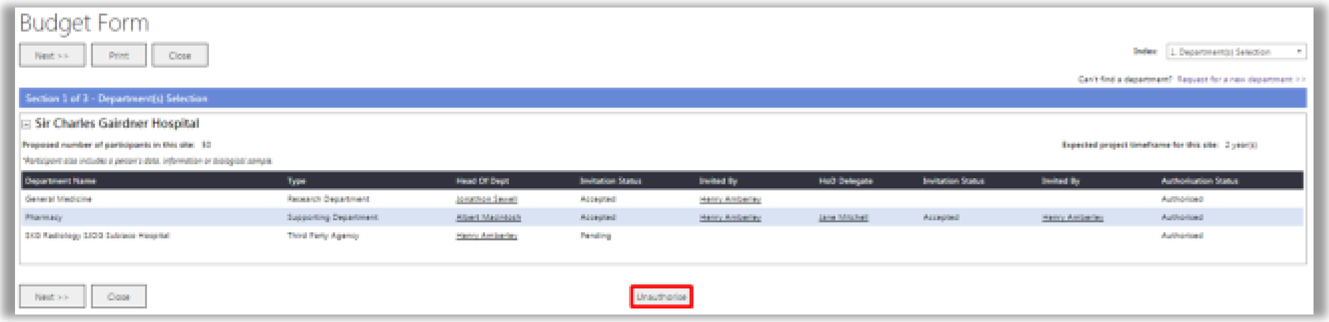
1. When the Budget Form is completed, including the HoD/HoSD authorisation(s), the PI/PI Delegate can click 'Authorise' in the Budget Form.



2. Click 'Edit', the Authorise button will be at the bottom of all three sections of the budget form, click ‘Authorise’. A pop up message will appear, click ‘OK’.



3. A PI or PI Delegate can unauthorise the Budget Form in the project workspace's Forms & Documents tab after selecting the form (but cannot authorise it this way, it must be authorised within the form). The Budget Form can also be unauthorised within the form.



5. Upload Supporting Documents

5.1 RGS Supporting Document Templates

Ethics Supporting Document Templates

The following ethics supporting documents are available from the RGS as document templates. These can be completed externally and uploaded to the RGS as supporting documents:

- Research Protocol Templates
- Participant Information & Consent Forms.

Governance Supporting Document Templates

The following governance supporting documents are available from the RGS as document templates. These can be completed externally and uploaded to the RGS as supporting documents:

- Student Research and Confidentiality Declaration
- Confidentiality Agreement
- Clinical Trial and Clinical Investigation Research Agreements
- Research Agreements
- Indemnity Forms.

5.2 Upload a Supporting Document

Ethics Supporting Documents

In addition to forms, you can add ethics supporting documents relevant to your project (e.g. participant information and consent forms, recruitment letters, survey tools, information brochures). As a minimum all research projects should have a protocol added as a document.

Currently the NHMRC's Human Research Ethics Application (HREA) is not available in the RGS. To facilitate its submission to WA Health HRECs, the HREA must be completed externally and uploaded to the RGS as a supporting document. The HREA must accompany the WA Specific Module.

Governance Supporting Documents

In addition to forms, you can add governance supporting documents relevant to your project (e.g. sponsor contracts, site participant information and consent forms, insurance certificates and indemnity forms).

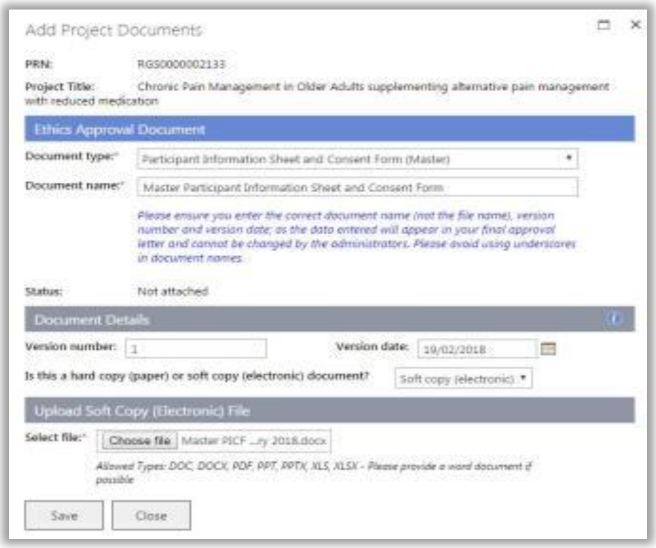
Process for Ethics and Governance

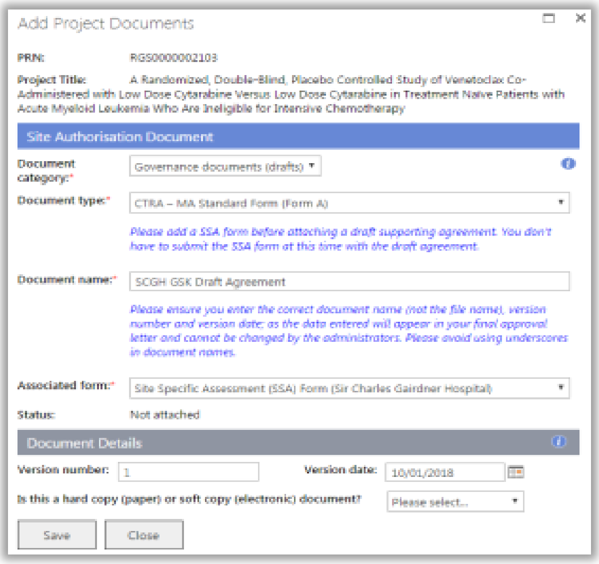
1. In the project's workspace, click on the 'Forms & Documents' tab.

2. Under the desired phase (i.e., Application or Monitoring) and category (i.e. Ethics Approval, Site Authorisation, Ethics or Governance Monitoring), click 'Add' under the 'Active' header and 'Documents' grid.

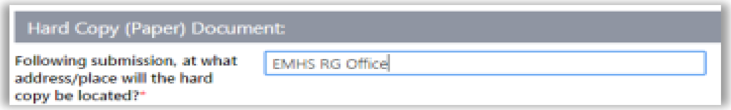
3. The screen will automatically launch the screen ‘Add Project Documents’. Select the 'Document Type' from the list provided. For governance documents you have the option of selecting draft and final documents. Drafts are normally unsigned documents that may require review and approval to ensure they are correct before the final submission.

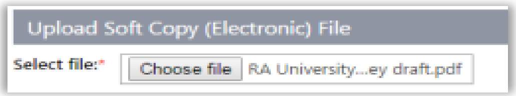
4. Enter a 'Document Name'. For governance documents you must choose an ‘Associated form’, except for the ‘Confidentiality Agreement’ under ‘Document category’ draft or final. Fields under the 'Document Details' section are optional at this point, but you may wish to provide the 'Version number', ‘Version date', and whether the document is a hard copy (paper) or soft copy (electronic). **Please ensure you enter the correct document name (not the file name), version number and version date; as the data entered will appear in your final approval letter and cannot be changed by the administrators. Please avoid using underscores in document names.** Click ‘Save’ and then ‘Close’ to return to the ‘Forms & Documents’ tab.





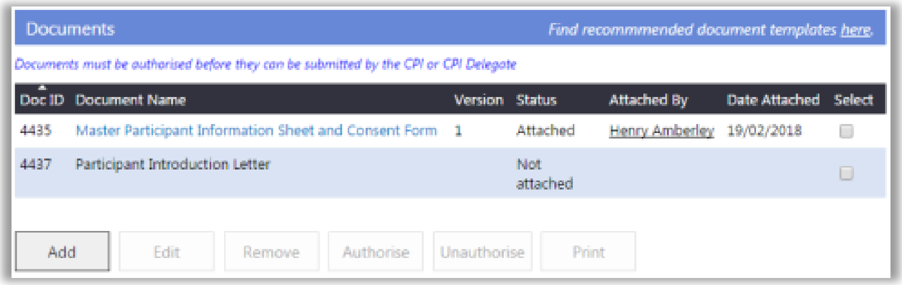
5. Based on your selection in 'Is this a hard copy (paper) or soft copy (electronic) document?', these fields are mandatory:





6. Click 'Save' to save changes or 'Cancel' to discard any changes made.

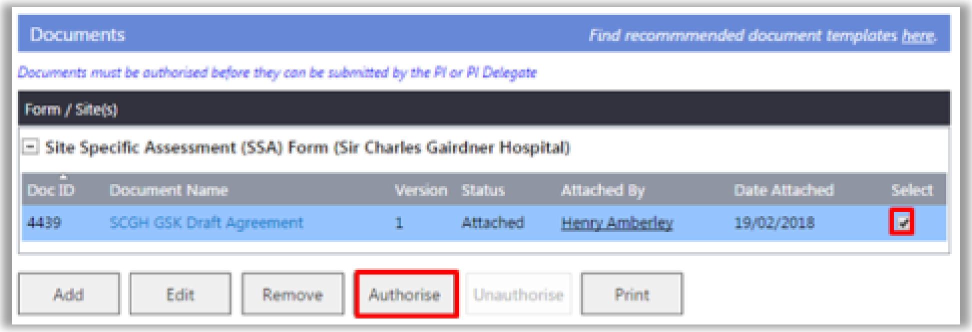
7. If a hard/soft copy has been provided, the document's status will be set to 'Attached'. Otherwise, the document's status is 'Not Attached'. Only 'Attached' documents are ready for authorisation.



*If the EEO or RGO requires revisions to a document and has marked it as **'Additional Information Required' (AIR),** a placeholder for the new version of the document will automatically be created under the 'Active' grid. You must upload the revised document version to this placeholder that addresses the EEO or RGO review comments, which will then be submitted to the EEO or RGO for their review.*

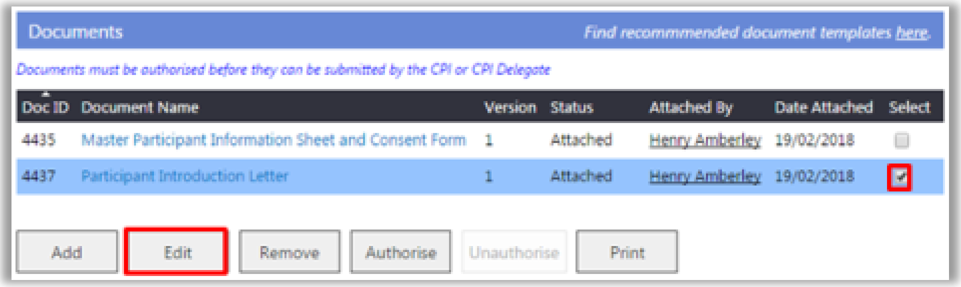
5.3 Authorise a Supporting Document

Prior to submission the documents need to be authorised. The CPI, CPI Delegate can authorise ethics documents and the PI and PI Delegate can authorise governance documents. The documents need to be individually 'selected' and 'authorised'. Note the governance documents are associated to a form and site as per this example:

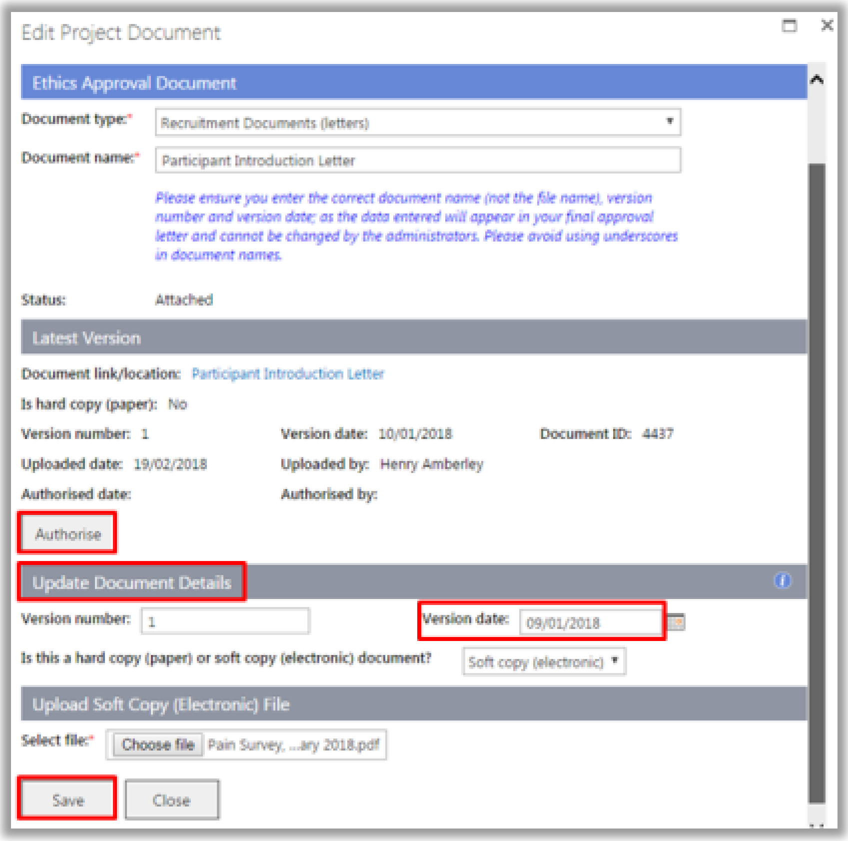


5.4 Edit a Supporting Document

1. Prior to submission, you can edit a supporting document. Select the document and click 'Edit'.



2. The Edit Project Document screen will launch. Click 'Authorise' to authorise the document in this screen (you don't need to click 'Save'). Alternatively you can update document details, click 'Save' to retain your changes or 'Cancel' to discard them.

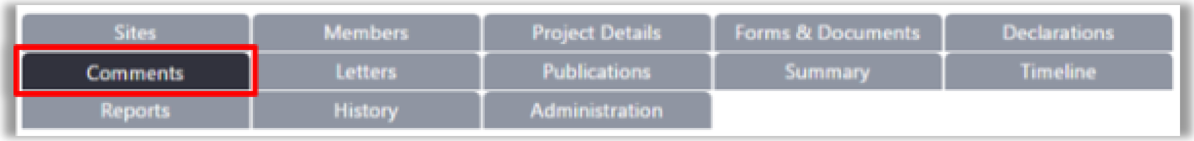


5.5 Sort Documents

Both Forms and Documents can be sorted by clicking on column name that you want them sorted by, clicking the name again will reverse the order.

6. Add a Comment

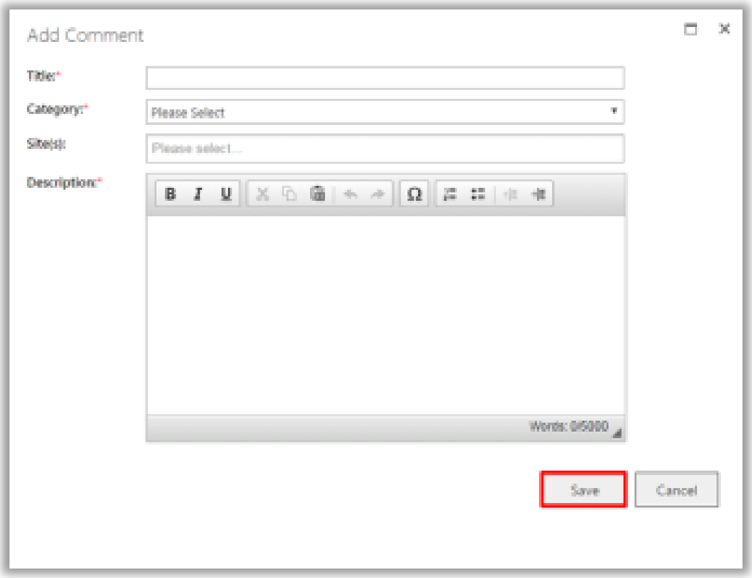
RGS is intended to be a collaborative workspace that allows easy interaction between the Project Members with the ability to post comments.



1. To add a new comment or to respond to an existing one, click on the 'Comments' tab.

2. Click 'Add Comment'.

3. The 'Add Comment' screen will be shown. All mandatory fields have a red asterisk (*) next to them. Click 'Save' to add the comment, or 'Cancel' to discard the comment.

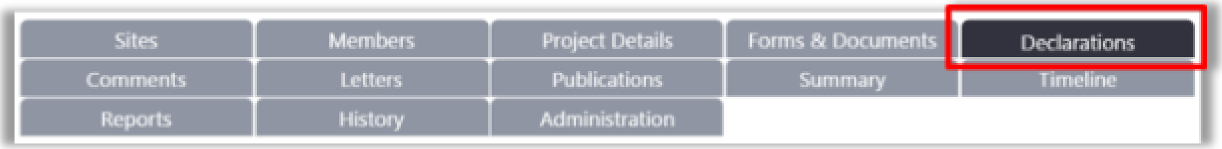


4. If the comment was successfully posted, it should appear under the category and the site(s) selected after clicking 'Save'. The Comments tab will notify anyone going to the project workspace that there is a new comment there for the next 7 days. The number of days is shown in the red circle.

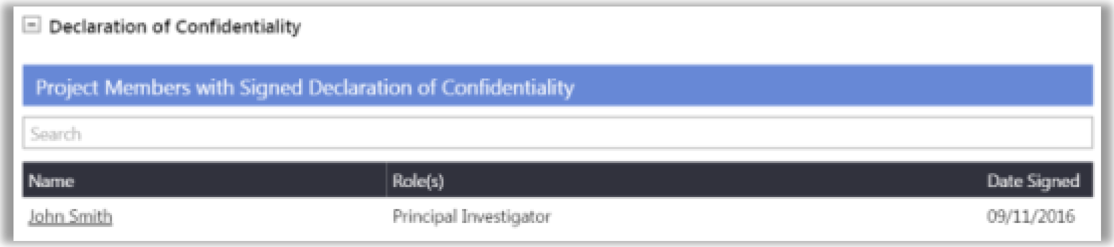
7. View or Add a Declaration

View a Declaration

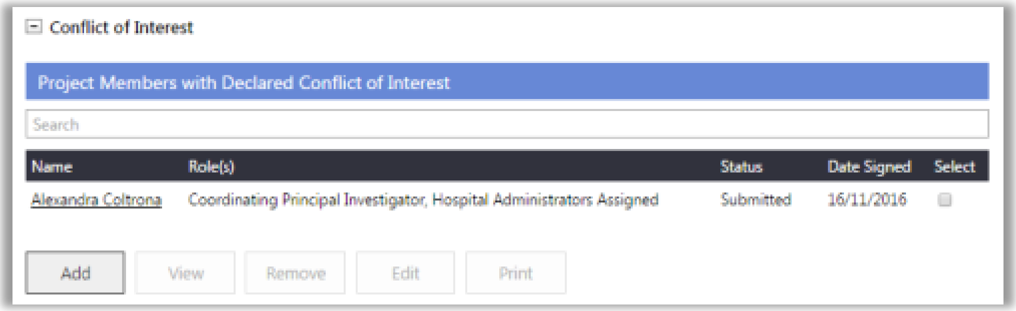
1. To view all Project Members who have signed the Declaration of Confidentiality (DOC) or Conflict of Interest (CoI) Form, click on the 'Declarations' tab in the project's workspace.



2. The Declaration of Confidentiality section will show the list of Project Members who have signed the DOC.



3. The Conflict of Interest section will show the list of Project Members who have submitted a CoI Form. Select the form and click ‘View’.



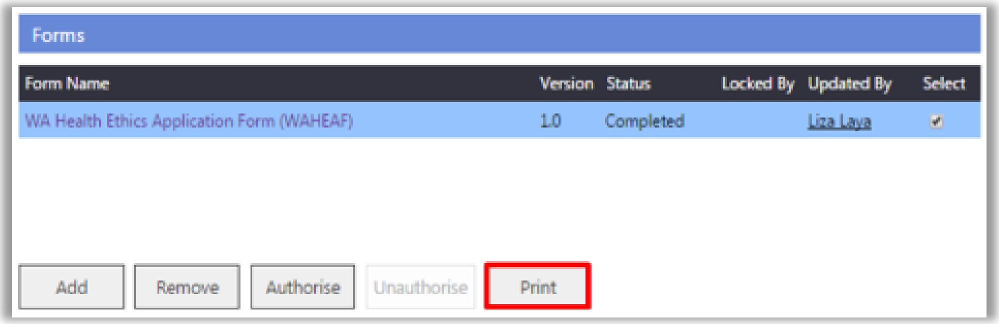
Add a Declaration

1. The CPI, PI or AI can add a CoI Form (i.e. to declare a potential, perceived or actual CoI) in the Declarations tab in the project's workspace, for the RG Office to review. Click ‘Add’ this will add the form is with a pending status. Click the Select box and click ‘Edit’form will launch. Complete and sign the form. Ensure that this CoI Form is recorded in the relevant governance form.

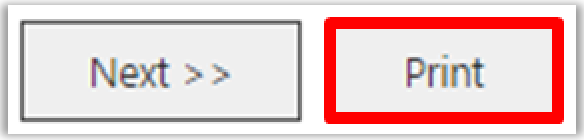
8. Print and PDF an Application Form

8.1 Print a Form

1. You may click 'Print' within the project workspace's Forms & Documents tab after selecting a form or document:



Or within the form itself:



2. A print preview of the form or document will be shown on a separate tab within your web browser.

The Budget Form will show a scroll bar on print preview but when it is printed this will disappear and it will be printed in landscape.

Follow the appropriate instructions for your browser's 'Print' feature to print the webpage. If you cannot find the instructions for your specific version or browser, search your browser's Help menu for "print a page".

8.2 PDF a Form

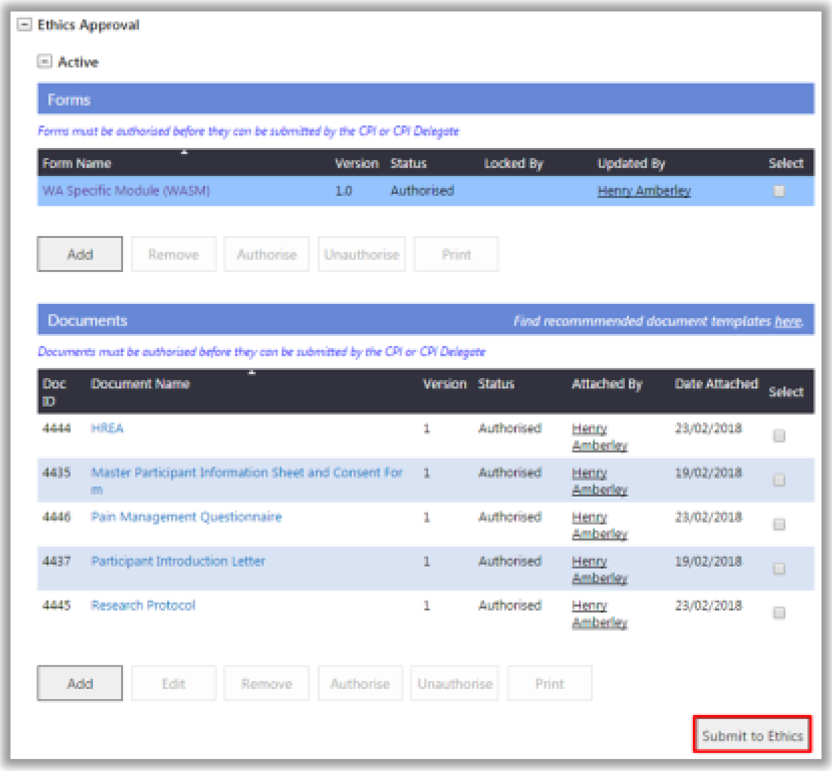
1. In the Forms & Documents tab select the form or document you want to pdf. Click 'Print'

2. A print preview of the form or document will be shown on a separate tab within your web browser. Follow the appropriate instructions for your browser's 'Print' feature to print the webpage as a PDF. If you cannot find the instructions for your specific version or browser, search your browser's Help menu for "print as a PDF".

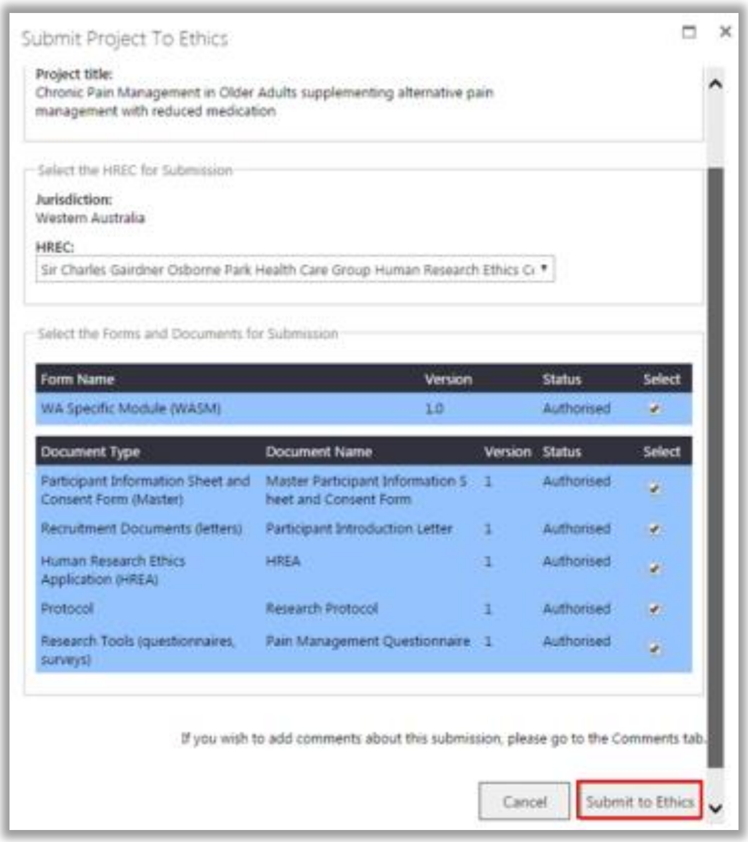
9. Ethics Submission, Validation and Review Assessment

9.1 Submission

1. When all forms and documents for the ethics application are authorised, the CPI or CPI Delegate can select ‘Submit to Ethics’ button in the Form & Documents tab (do not select the forms and documents at this stage).



2. The ‘Submit Project to Ethics’ screen will launch and will display all authorised forms and documents. Select the HREC, and forms and documents for submission. Click ‘Submit Project’.



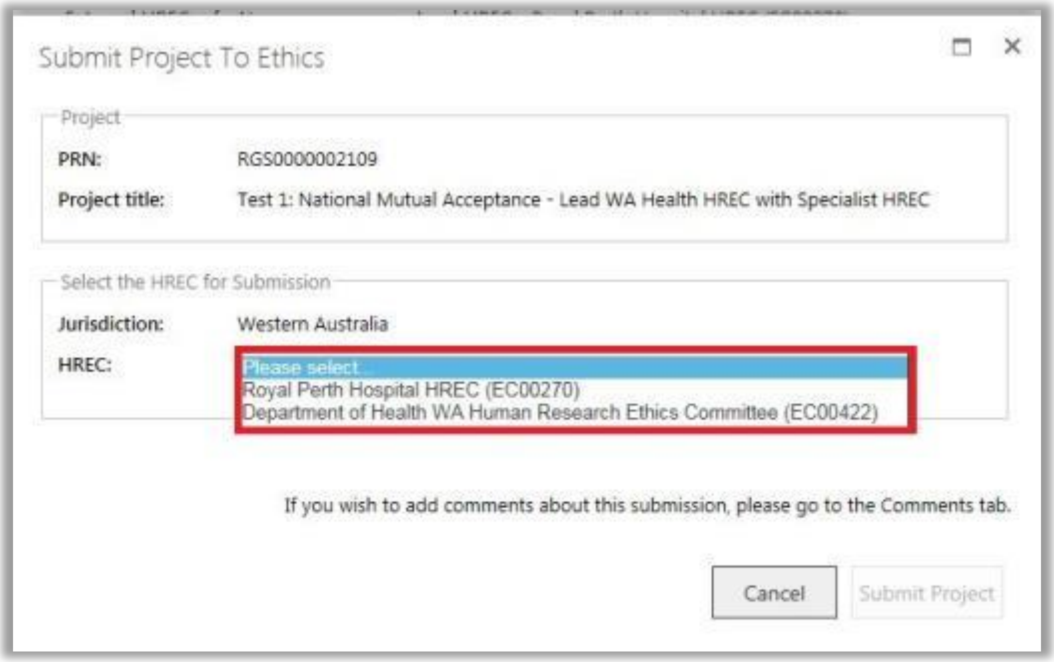
An ethics application requires the form and documents to be submitted as a package. If the ethics form is not ‘Completed’ and ‘Authorised’ you will receive an error message and you will not be able to progress your application to ethics for review. An ethics application requires either a WAHEAF; or a WASM form and a HREA document uploaded to proceed with the submission.

3. You will receive a screen message advising the successful submission of your ethics application. The CPI and CPI Delegate will also receive an email to inform them the ethics submission was successful. The forms and documents will move to ‘Submitted’ in the Forms & Documents tab.

Note that you cannot submit another form or document until the validation of any previous submission has been completed.

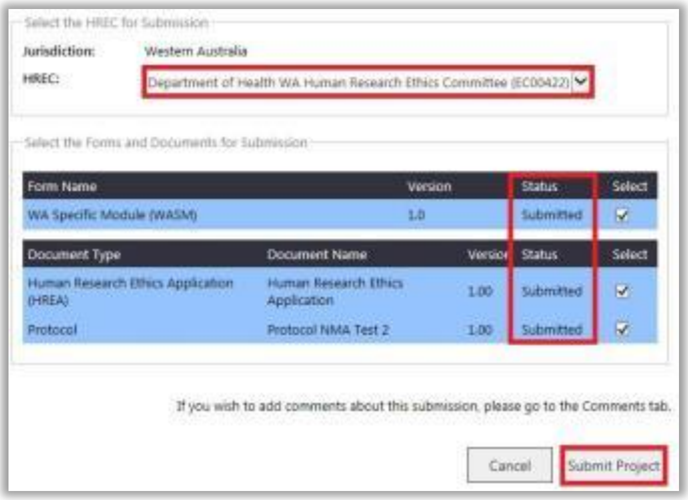
9.1.1 WA Health Lead HREC (With a WA Health Specialist HREC)

1. If you are submitting to a WA Health Lead HREC and an Additional WA Health HREC (Specialist), you be able to submit the same forms and documents to both HRECs. Select the Lead HREC and submit the forms and documents as per steps above.



2. The forms and documents will move to the ‘Submitted’ section of the Forms & Documents tab. Because you have nominated the specialist HREC the Submit to Ethics button is still enabled. Click ‘Submit to Ethics’.

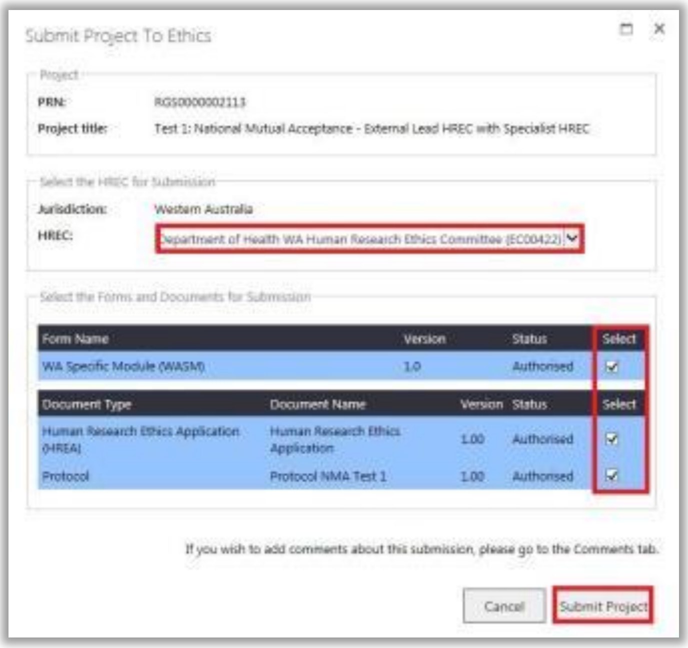
3. The ‘Submit Project to Ethics’ screen will launch. Select the Specialist HREC, the forms and documents will now be displayed as submitted. Select them and then click ‘Submit to Project’. The CPI and CPI Delegate will receive an email to inform them the ethics submission was successful.



4. The forms and documents will appear under the ‘Submitted’ section in the Forms & Documents tab, one set for each HREC.

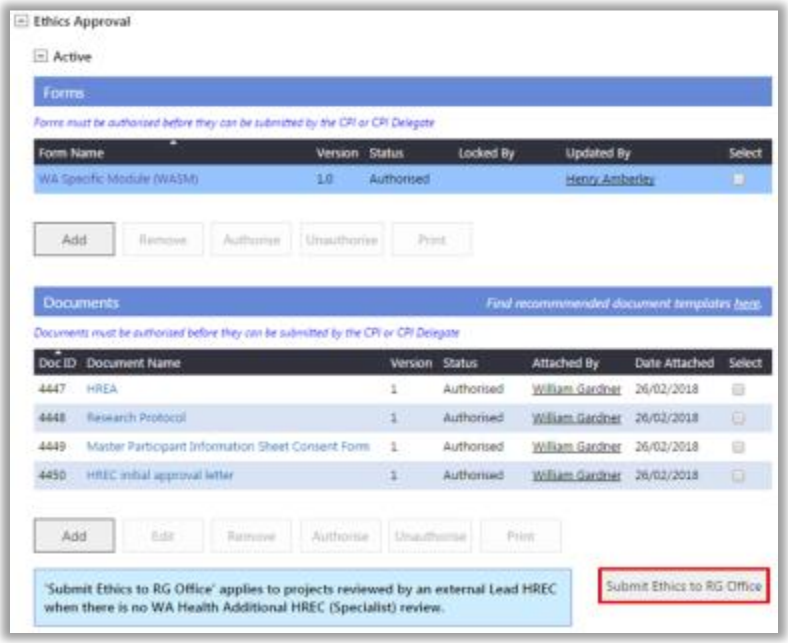
9.1.2 External Lead HREC (With a WA Health Specialist HREC)

1. For NMA, if an External HREC (outside of WA Heath) is the Lead HREC and you are still submitting the ethics application to an Additional WA Health HREC (Specialist)., then you will only be able to select the Specialist HREC as **currently RGS only allows submission of an ethics application to a WA Health HREC.**



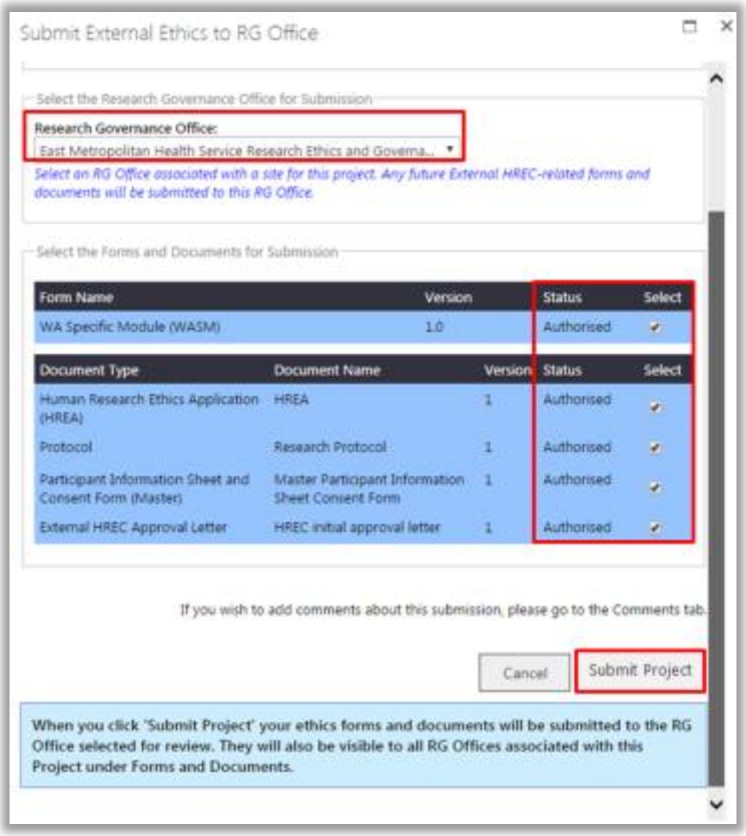
9.1.3 External Lead HREC Only

1. When the External Lead HREC has approved the ethics application, the CPI or CPI Delegate, must upload to the Ethics Approval Active section, the approved HREA and supporting documents (including the ethics approval letter) and submit them with the approved WASM to the RG Office.



2. Prior to submission, the WASM and the Documents must be authorised by the CPI or CPI Delegate. The CPI, CPI, PI or PI Delegate must click “Submit to RG Office’ to submit the approved ethics form and documents to the RG Office for their information.

3. The Submit External Ethics to RG Office screen will launch. Select the RG Office, WASM and documents for submission. Click ‘Submit Project’.



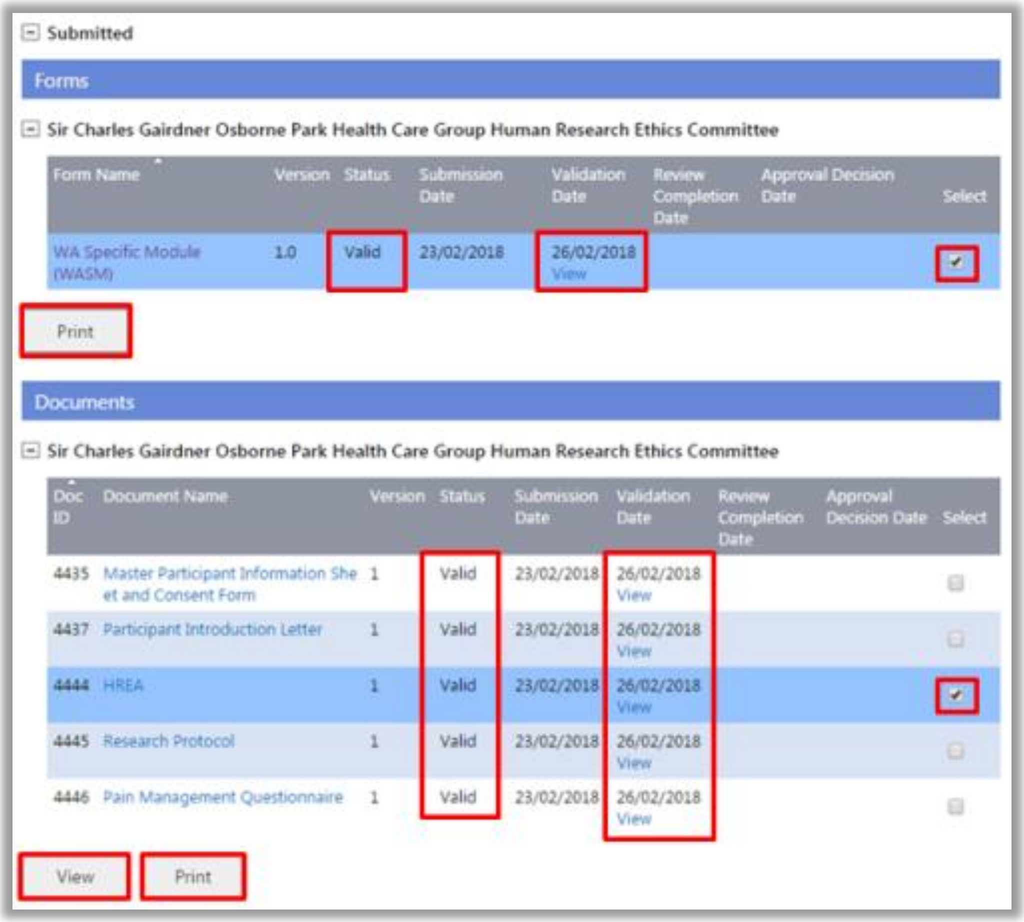
4. The submitted WASM and documents will be displayed under ‘Submitted’ against the RG Office name and a successful submission notification will display. The CPI and CPI Delegate will receive an email to inform them the ethics submission was successful.

9.2 Validation

1. Following the successful submission of the ethics forms and documents, the EEO will validate the submission. Once completed, the CPI and CPI Delegate will receive an email informing them that the submission has been through the validation process and will show the outcome of the validation on the forms and document submitted.

The outcome of the validation process is also viewable in the Forms & Documents tab in the Submitted section. Click on the link in the ‘Validation Date’ to open the ‘View Validation Assessment’ screen.

At any time you can print or view a Form or Document(s). For forms click on the name link to view or select the form and click ‘Print’. For documents either click on the name link to view or select the document and click ‘View’. To print, select the document and click ‘Print’.



Submitted

Forms

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Approval Decision Date	Select
WA Specific Module (WASM)	1.0	Valid	23/02/2018	26/02/2018 View			☑

Print

Documents

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee

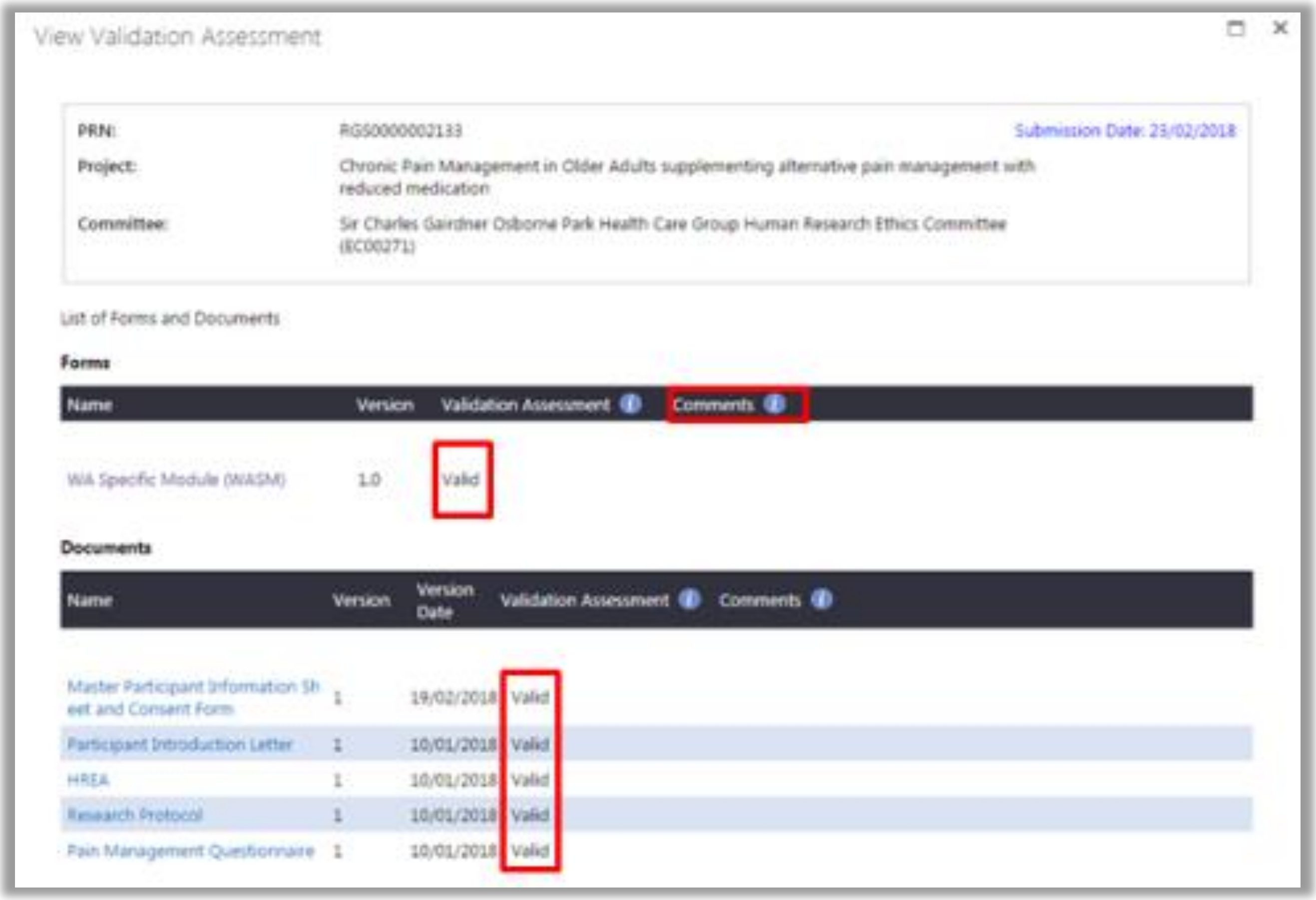
Doc ID	Document Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Approval Decision Date	Select
4435	Master Participant Information Sheet and Consent Form	1	Valid	23/02/2018	26/02/2018 View			☐
4437	Participant Introduction Letter	1	Valid	23/02/2018	26/02/2018 View			☐
4444	HREA	1	Valid	23/02/2018	26/02/2018 View			☑
4445	Research Protocol	1	Valid	23/02/2018	26/02/2018 View			☐
4446	Pain Management Questionnaire	1	Valid	23/02/2018	26/02/2018 View			☐

View Print

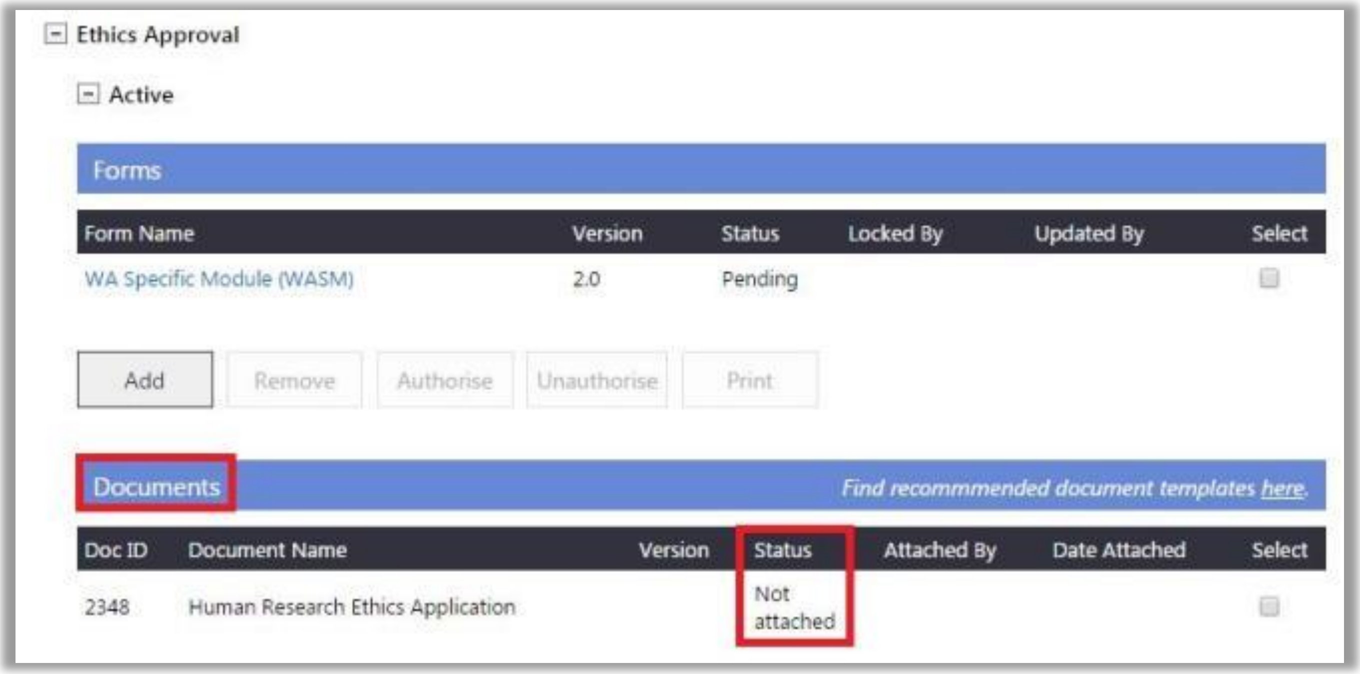
2.The View Validation Assessment screen will launch for you to review the validation status and comments.

The EEO may decide that **addition information is required (AIR)** from the CPI/CPI Delegate if a form or document contains insufficient or incorrect information. The EEO will assign the form or document an 'AIR' status (or Not Valid) and provide information in the ‘Comments’ box. The CPI/CPI Delegate can read the comment and address this when resubmitting the updated or the correct form/document.

3. **<u>If a form is given the validation status of 'AIR'</u> in the 'Submitted' grid, a new version of the form is created in the 'Active' section of the 'Ethics Approval'** (if WAHEAF or WASM). The CPI will need to provide the information requested and submit the new version of the form for validation and review.



4. **<u>If a document is given the validation status of 'AIR'</u> in the 'Submitted' grid, then a placeholder is created in the 'Active' section of the 'Ethics Approval' for the document.** The CPI can then provide the additional information and submit a new version of document.



5. **If the review assessment is 'Not Valid'**, then no place holder is created, so another version of the form or document cannot be resubmitted.

Documents

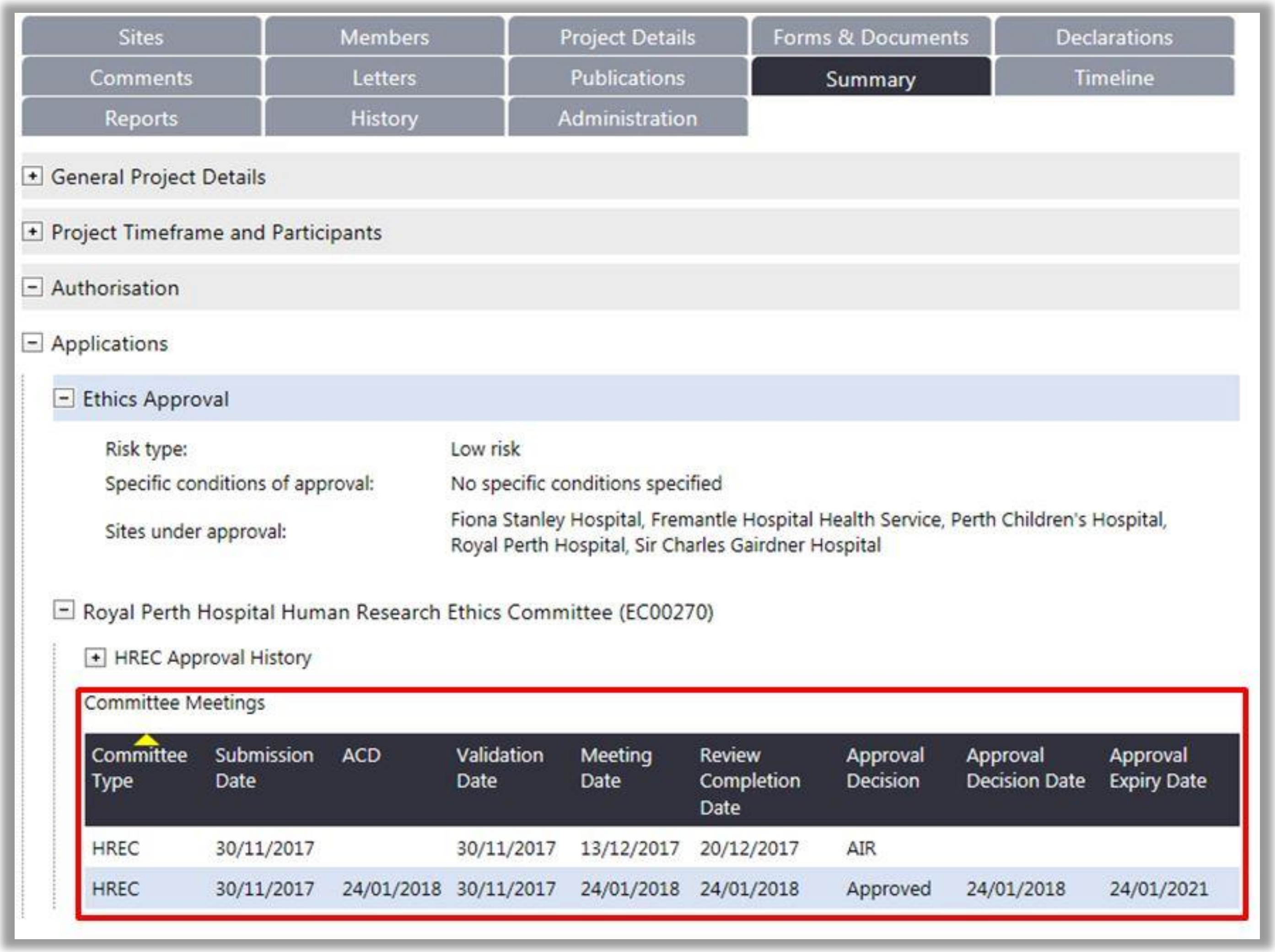
Royal Perth Hospital HREC

Department of Health WA Human Research Ethics Committee

Doc ID	Document Name	Version	Status	Submission Date	Validation Date	Review Decision Date	Approval Decision Date	Select
2348	Human Research Ethics Application	1.00	AIR	16/06/2017	19/06/2017			☐
2349	Protocol NMA Test 2	1.00	Not valid	16/06/2017	19/06/2017			☐

9.3 Review Assessment

1. If all the forms and documents are valid, they will be added to an ethics committee meeting (Alternative Review, Subcommittee and/or HREC meeting).You can track your project's ethics committee review in the Summary tab:



Committee Type	Submission Date	ACD	Validation Date	Meeting Date	Review Completion Date	Approval Decision	Approval Decision Date	Approval Expiry Date
HREC	30/11/2017		30/11/2017	13/12/2017	20/12/2017	AIR		
HREC	30/11/2017	24/01/2018	30/11/2017	24/01/2018	24/01/2018	Approved	24/01/2018	24/01/2021

2. You can track the approval of your projects forms & documents in the Forms & Documents tab:

- 'Review Decision Date' is when the committee review is completed and the EEO enters the decision of the review (i.e. generates a letter).
- 'Status' reflects either the validation or committee review decision
- 'Approval Decision Date' is the date the forms and documents were approved at the committee meeting. The Approval Decision Date for the WASM or WAHEAF is the same date as the HREC approval date.

Submitted

Forms

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Approval Decision Date	Select
WA Specific Module (WASM)	1.0	Approved	14/08/2017	14/08/2017 View	06/12/2017	30/11/2017	

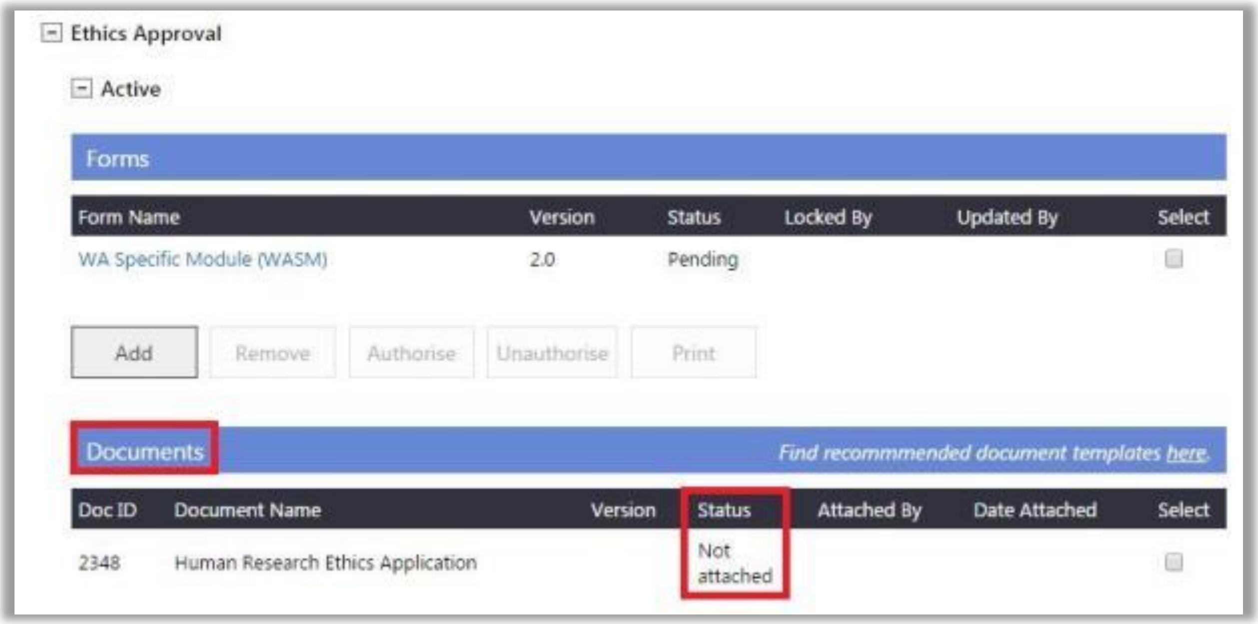
Print

Documents

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee

Doc ID	Document Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Approval Decision Date	Select
3384	HREA	1	Approved	14/08/2017	14/08/2017 View	06/12/2017	30/11/2017	
3386	Study Protocol	1	Approved	14/08/2017	14/08/2017 View	06/12/2017	30/11/2017	
3385	Participant Information Sheet and Consent Form	2	Approved	26/09/2017	26/09/2017 View	06/12/2017	30/11/2017	
3385	Participant Information Sheet and Consent Form	1	AIR	14/08/2017	14/08/2017 View	14/08/2017		

3. Following a review (at an ethics committee meeting), if the EEO requires revisions to a form and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid, a new version of the form will automatically be created under the 'Active' grid.** You must implement the required changes to this version, which will then be submitted to the EEO for review at the next ethics committee meeting.



Ethics Approval

Active

Forms

Form Name	Version	Status	Locked By	Updated By	Select
WA Specific Module (WASM)	2.0	Pending			

Add | Remove | Authorise | Unauthorise | Print

Documents — *Find recommmended document templates here.*

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
2348	Human Research Ethics Application		Not attached			

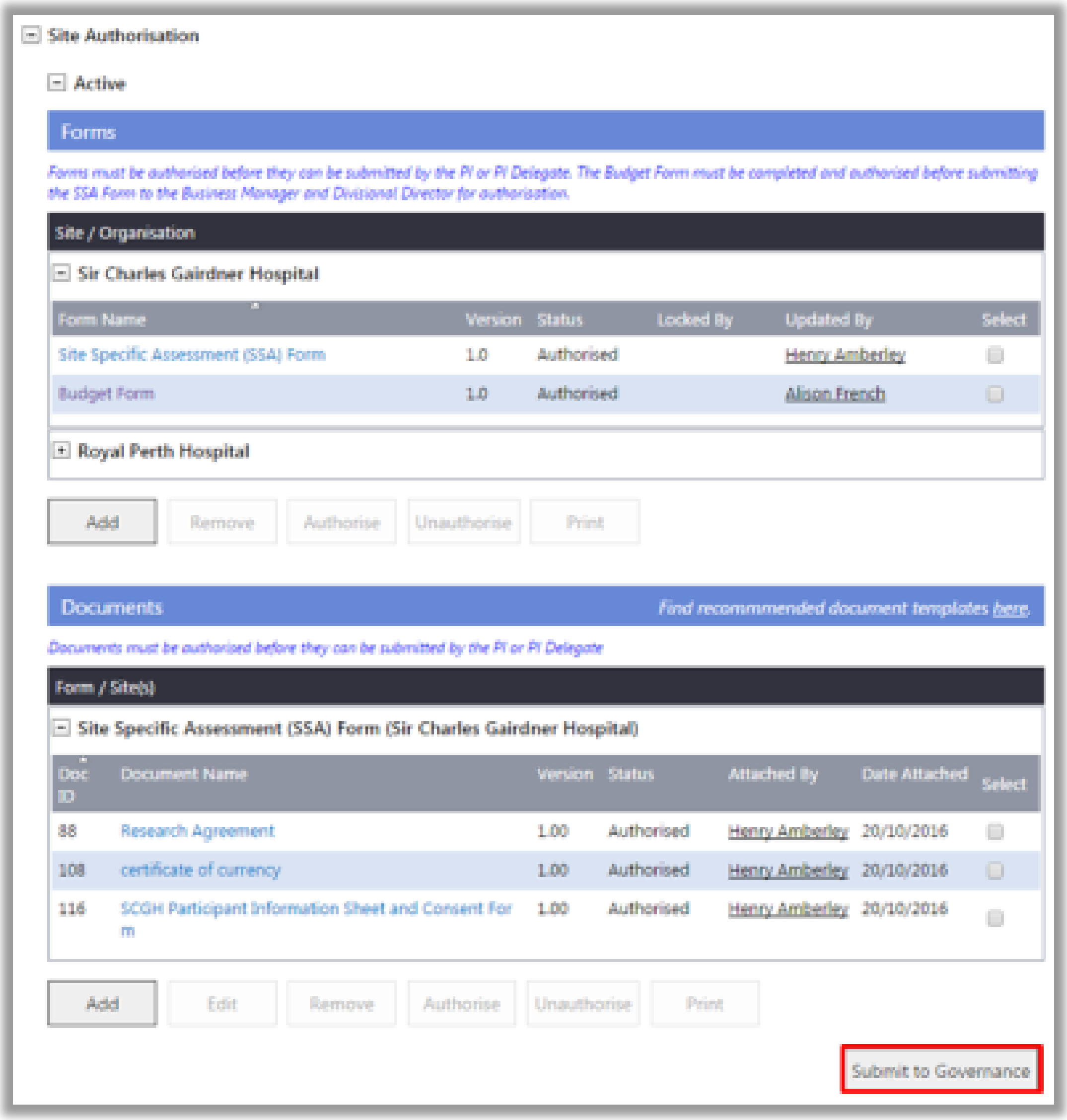
4. Following a review (at an ethics committee meeting) If the EEO requires revisions to a document and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid, a placeholder for the new version of the document will automatically be created under the 'Active' grid.** You must upload the revised document version to this placeholder that addresses the EEO review comments, which should then be submitted to the HREC for review at the next ethics committee meeting.

5. The Project ethics approval status of the Lead HREC is displayed in the Project Header:

10. Governance Submission, Validation and Review Assessment

10.1 Submission

1. When all forms and documents for the governance application are authorised, the PI or PI Delegate can select ‘Submit to Governance’ button in the Form & Documents tab.



2. The ‘Submit Project to Governance’ screen will launch and will display all authorised forms and documents. Select the RG Office associated with the site and forms and documents for submission. Click ‘Submit to Governance’.

A governance application does not require the forms and documents to be submitted as a package but all documents submitted must be associated with a form, except the ‘Confidentiality Agreement’.

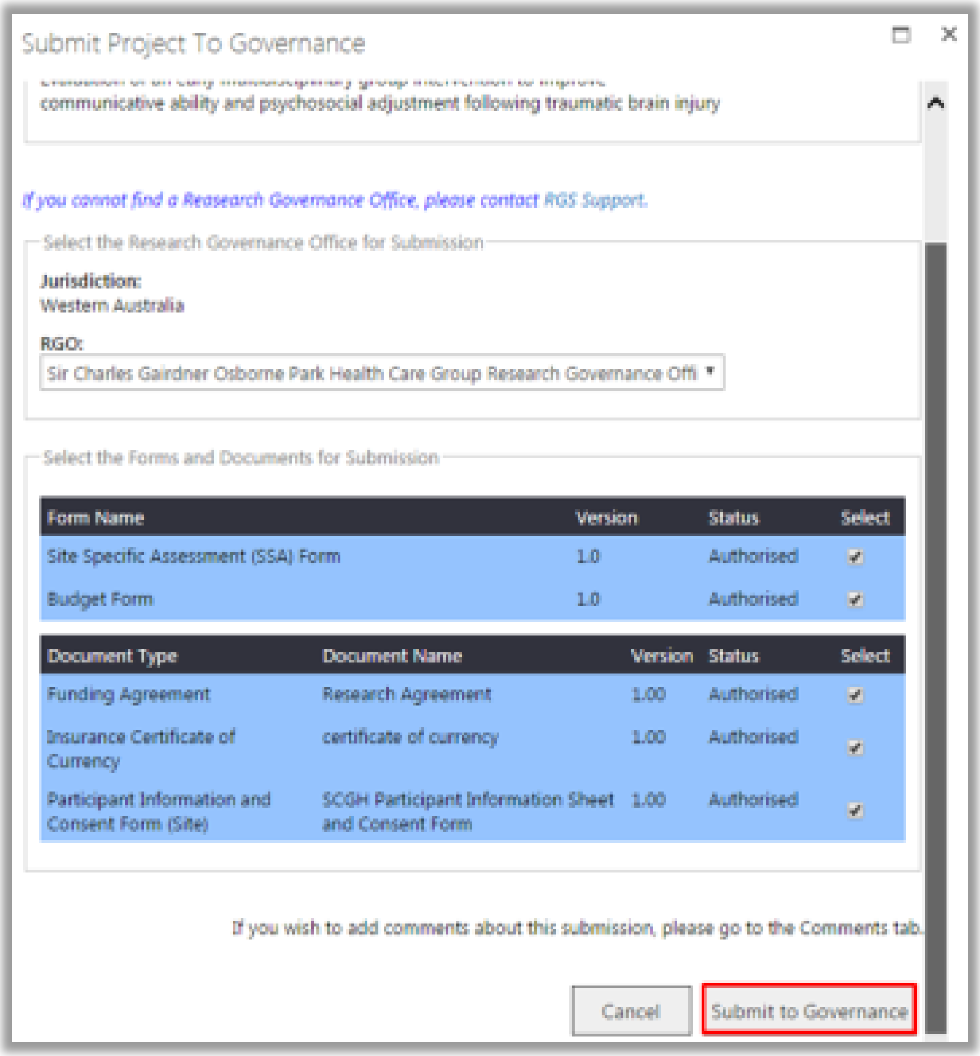
If the project is a multi-centre project, you must submit the SSA Form and any other additional governance documents for <u>each</u> site.

If after selecting a RG Office, you cannot find an expected form or document in the 'Submit Project to Governance' screen, check if:

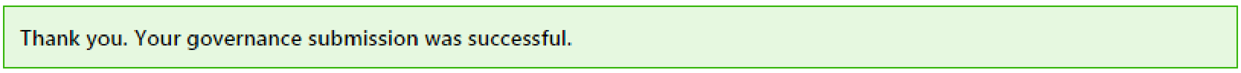
- *you are the PI or PI Delegate of the site associated to the form or document, and*
- *the form or document has a status 'Authorised'.*

If you cannot find the RG Office you wish to submit the application to, notify the [RGS Administrator](#).

3. You will receive a screen message advising the successful submission of your governance application.

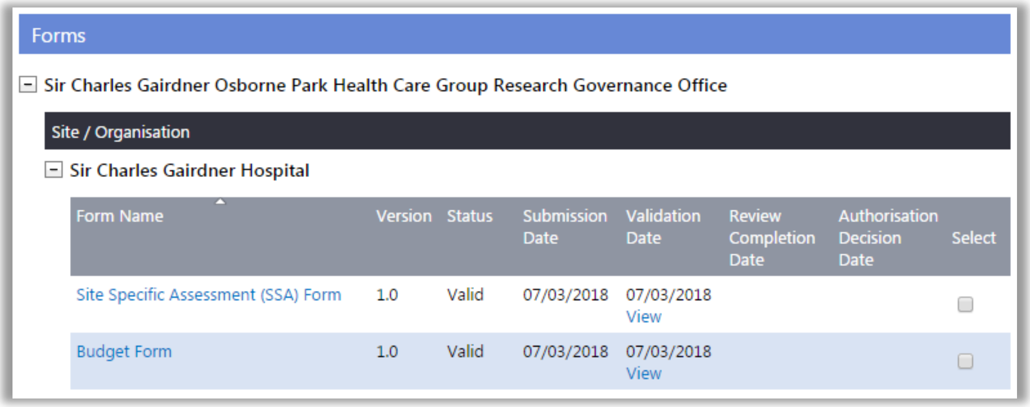


Note that you cannot submit another form or document until the validation of any previous submission has been completed.



10.2 Validation

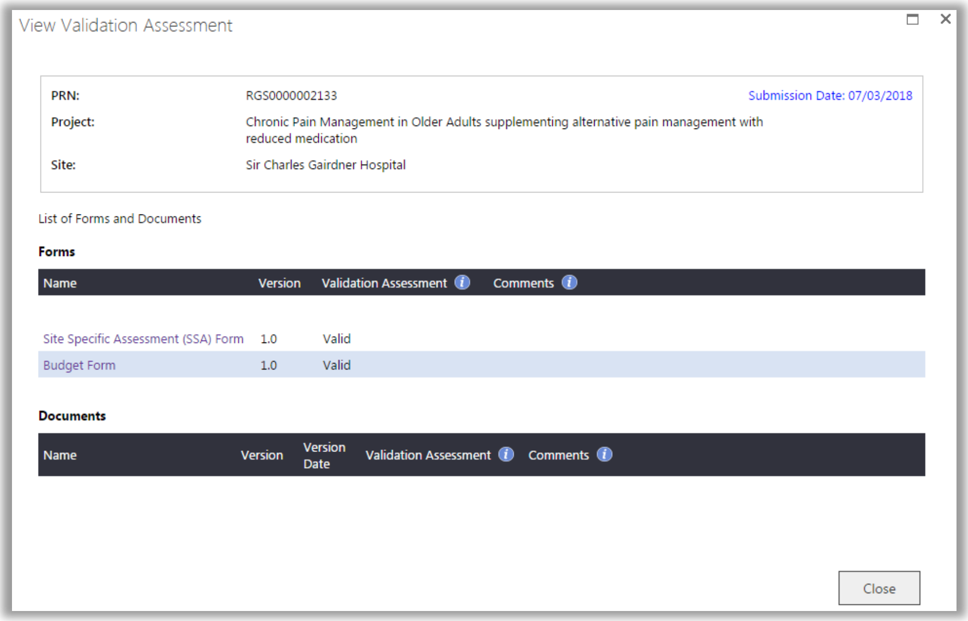
1. Following the successful submission of the governance forms and documents, the RGO will validate the application. Once completed, the PI and PI Delegate will receive an email informing them that the application has been through the validation process and to review the outcome in



RGS.

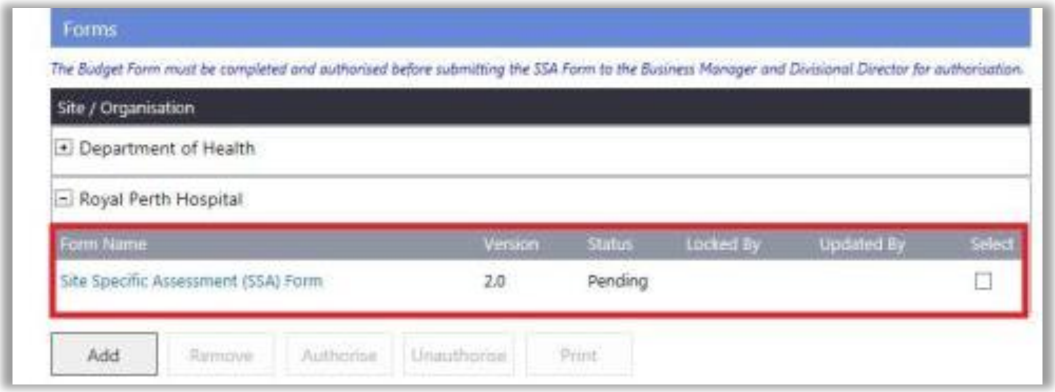
The outcome of the validation process is viewable in the Forms & Documents tab in the Submitted section.

2. Click on ‘View’ under the ‘Validation Date’ to open the ‘View Validation Assessment’ screen.



The RGO may decide that **addition information is required (AIR)** from the PI/PI Delegate if a form or document contains insufficient or incorrect information. The RGO will assign the form or document an 'AIR' status (or Not Valid) and provide information in the ‘Comments’ box. The PI/PI Delegate can read the comment and address this when resubmitting the updated or the correct form/document.

3. **If a form is given the validation status of 'AIR' in the ‘Submitted’ grid, a new version of the form is created in the ‘Active’ section of the ‘Site Authorisation’.** The PI will need to provide the information requested and submit the new version of the form for validation and review.

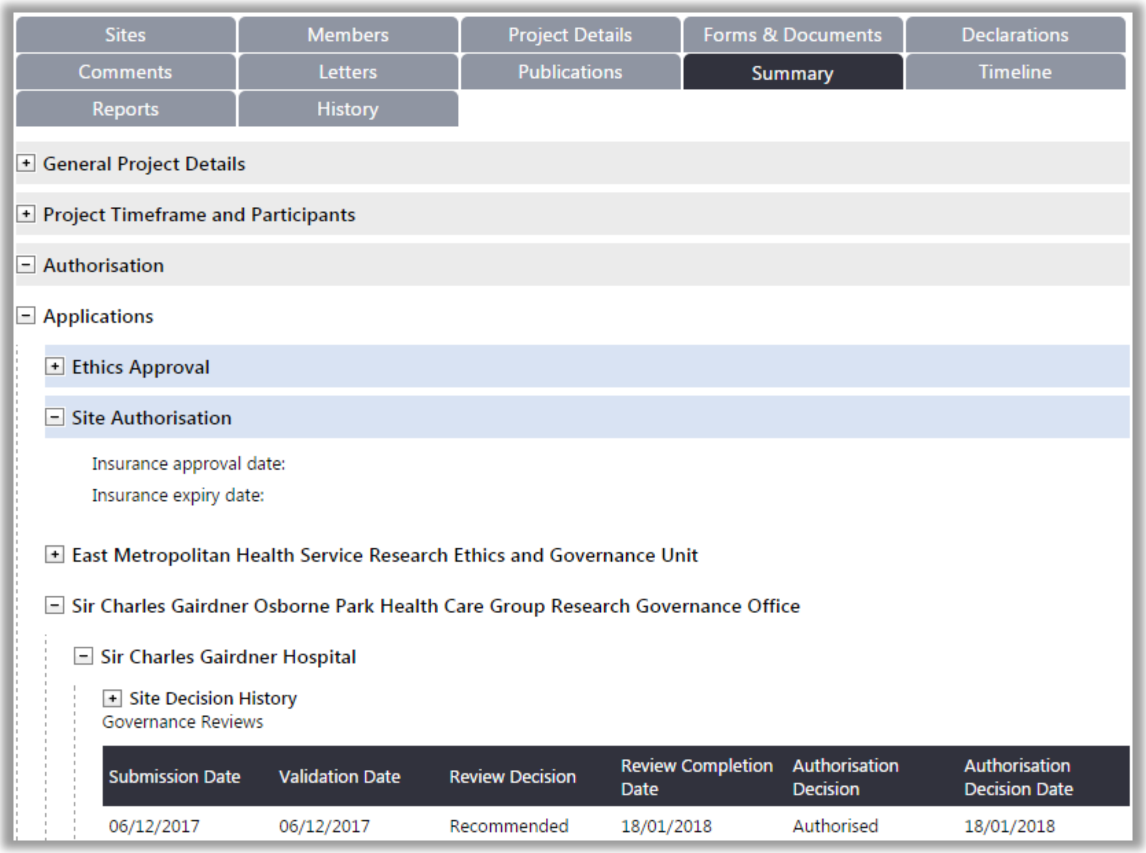


4. **If a document is given the validation status of 'AIR' in the ‘Submitted’ grid, a placeholder is created for the document in the ‘Active’ grid.** The PI can then provide the additional information and submit a new version of document.

5. If the review assessment is 'Not Valid', then no place holder is created, so another version of the form or document cannot be resubmitted.

10.3 Review Assessment

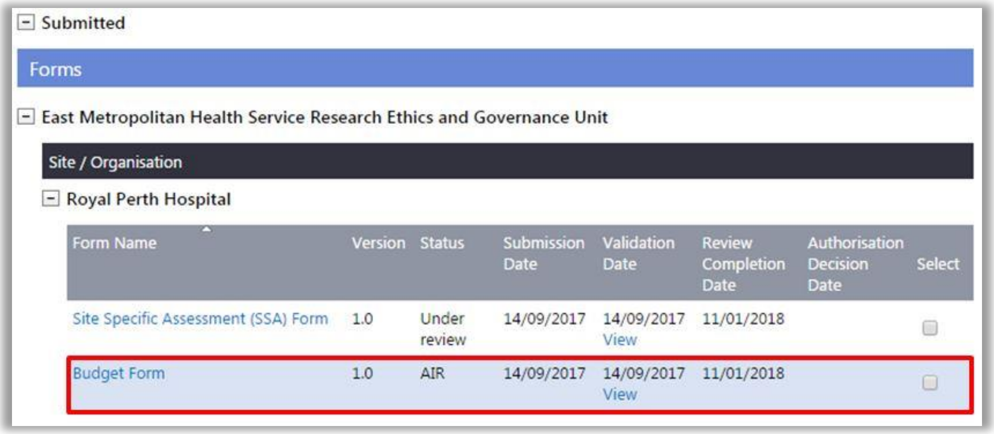
1. If all the forms and documents are valid, they will be reviewed by the RGO and a recommendation will be made to the Chief Executive (CE) / Delegate for site authorisation. You can track your project's RG Office review in the Summary tab:



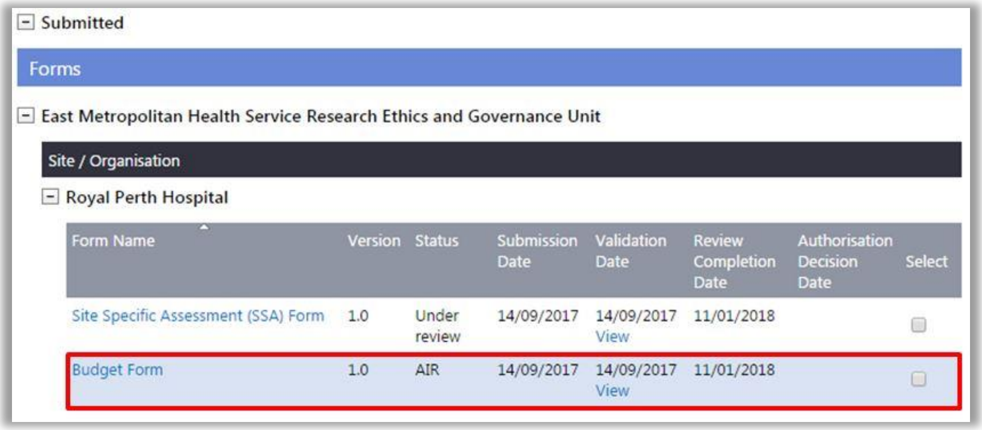
2. You can track the approval of your projects forms & documents in Forms & Documents tab:

- 'Review Decision Date' is when the RGO review is completed and the RGO enters the decision of the review (i.e. generates a letter).
- 'Status' reflects either the validation or RGO review decision
- 'Approval Decision Date' is the date the forms and documents were approved by the CE / Delegate. The Approval Decision Date for the SSA Form or AR Form is the same date as the site authorisation date.

3. Following a review, if the RGO requires revisions to a form and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid**; **a new version of the form will automatically be created under the 'Active' grid.**



You must implement the required changes to this version, which should then be submitted to the RGO for review prior to site authorisation.



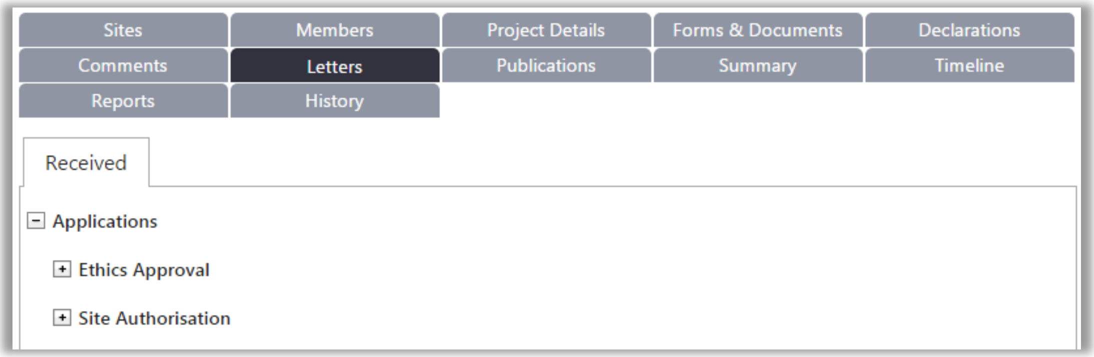
4. Following a review, if the RGO requires revisions to a document and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid**; **a placeholder for the new document version will automatically be created under the 'Active' grid.**

You must upload the revised document version to this placeholder that addresses the RGO review comments, which should then be submitted to the RG Office for review prior to site authorisation.

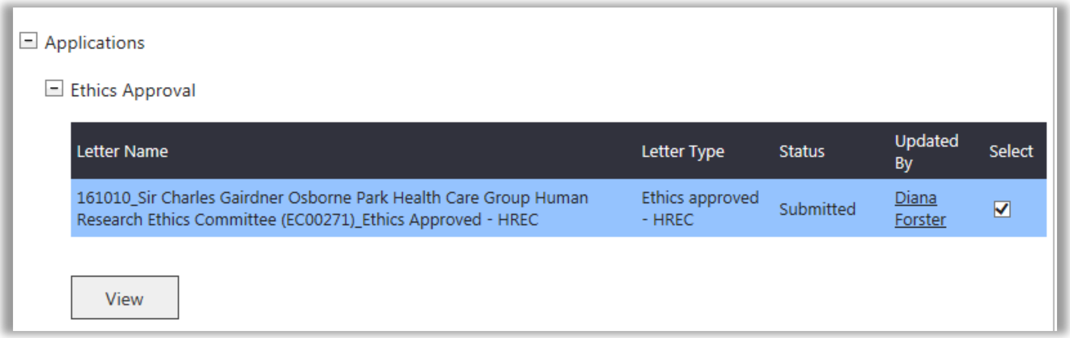
11. View Letters

Project Members can view letters sent to the CPI or PI from the HREC, RG Office and Chief Executive related to the project's review, approval/authorisation process, in the Letters tab. Any letter sent to the CPI or PI will have also be sent to them as an email.

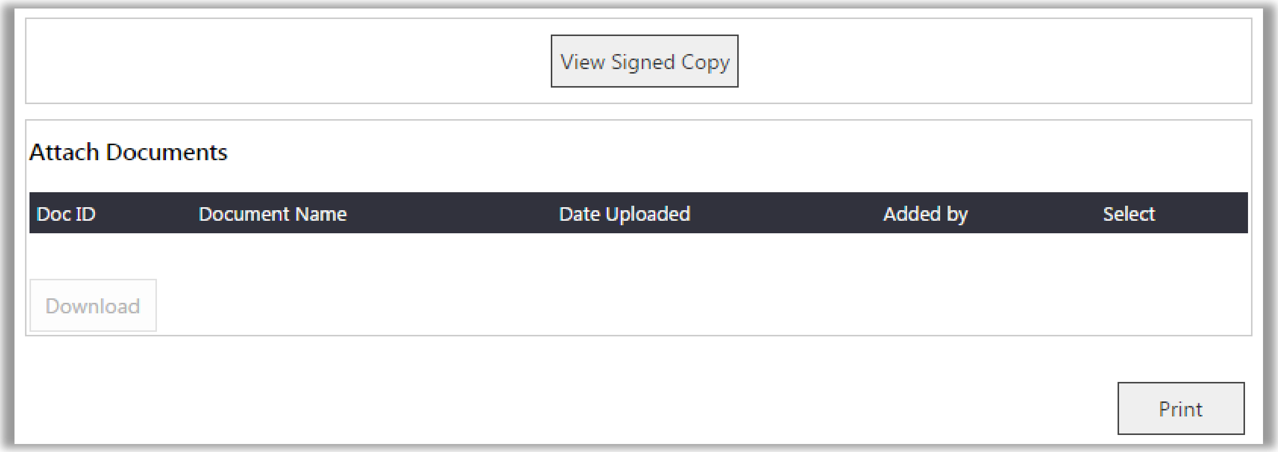
1. In the project workspace, click on the 'Letters' tab. Letters will be viewable in the 'Sent' section of the screen.



2. Expand the relevant section by clicking on the '+' sign. Select the letter and click 'View'.



3. The letter will be available for viewing and printing. Select the letter and click 'View'. When the letter opens scroll to the bottom and click 'View Signed Copy' to open the signed copy of the letter. Click 'Print' to print the letter. If there are any attachment other than the signed copy they will be under Attached Document.



The 'Letter Type' will be dependent on the decision. The options available are:

- **AIR –** will be used to request additional information from the CPI/PI.
- **Approved or Authorised -** will be used to notify the CPI/PI that ethics approval or site authorisation has been granted and if there are any special conditions.
- **Not Approved or Not Authorised** – will be used to notify the CPI/PI that ethics approval or site authorisation has NOT been granted and it cannot be resubmitted to the HREC/RG Office for any future review.

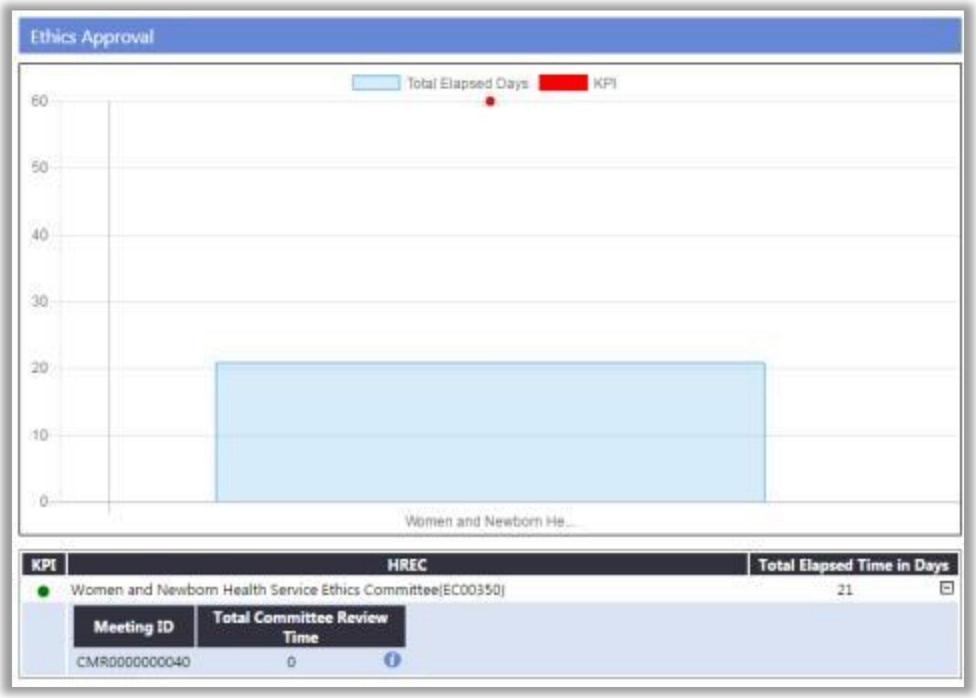
12. Track a Project through the Review Process

Project Members can track the review process of their project in the Timeline and Summary tabs.

12.1 Timeline

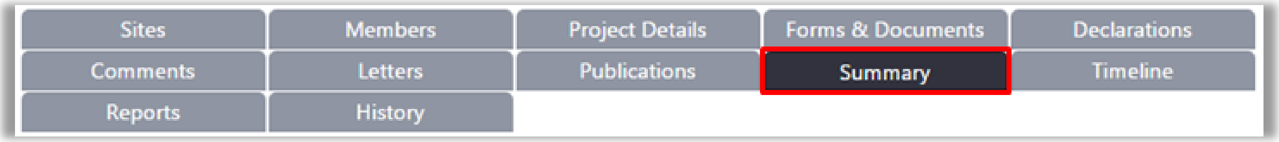
1. In the project workspace, click on the ‘Timeline’ tab.

The ‘Timeline’ provides the overall performance for your application’s validation and review based on a 60 day key performance indicator (KPI) for both Ethics Approval and Site Authorisation. It can be filtered by ‘Validation and ‘Review’.



12.2 Summary

1. In the project workspace, click on the ‘Summary’ tab. This is the default tab when you enter the project workspace.



Expand the sections by clicking on the ‘+’ sign. The ‘Summary’ provides details on:

- General Project Details

General Project Details

Project created date	03/03/2017
Single-centre or multi-centre project	Single-centre
Broad research area	Public health research
NHMRC grouping of research	PUBLIC HEALTH AND HEALTH SERVICES
NHMRC fields of research	Public Health and Health Services not elsewhere classified
Broad health condition	Other
Specific condition	Research that is not of generic health relevance and not applicable to specific health categories listed above
Clinical trial phase	
Keywords	hospital discharge; readmission; consumers;
Research focus	Educational
Project summary	This is where the project summary would be.
Coordinating Principal Investigator organisation	Sir Charles Gairdner Hospital
Contact person for information and recruitment	Dr Henry Amberley
Publications	
Particpant Age Group	18 - 70+;
Participant Gender	All
Involves Healthy Volunteers	No

- Project Timeframe and Participants (for the project as a whole and for all sites)

Project Timeframe and Participants

Expected Start Date	Actual Start Date	Expected Finish Date	Actual Finish Date	Expected Participant Numbers	Actual Participant Numbers	Expected Date of First Participant Recruitment	Recruitment Status
Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee (EC00271)							
01/05/2017		01/05/2020		40		01/06/2017	
Fiona Stanley Hospital							
01/05/2017		01/05/2020		40		01/06/2017	
Royal Perth Hospital							
01/05/2017		01/05/2020		10		01/06/2017	Active, not recruiting
Sir Charles Gairdner Hospital							
01/05/2017		01/05/2020		24		01/06/2017	

- Authorisation. – Ethics Approval & Site Authorisation

Applications

Ethics Approval

Risk type:	Low risk
Specific conditions of approval:	No specific conditions specified
Sites under approval:	Royal Perth Hospital

Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee (EC00271)

HREC Approval History

Committee Meetings

Committee Type	Submission Date	ACD	Validation Date	Meeting Date	Review Completion Date	Approval Decision	Approval Decision Date	Approval Expiry Date
HREC	08/05/2017		15/05/2017	25/05/2017	31/05/2017	AIR		
HREC	08/05/2017		15/05/2017	16/08/2017				
SC	08/05/2017		15/05/2017	19/05/2017	19/05/2017	SC Recommended	19/05/2017	
ARC	08/05/2017	02/08/2017	15/05/2017	04/08/2017	04/08/2017	Approved	04/08/2017	04/08/2022

Site Authorisation

Insurance approval date:

Insurance expiry date:

East Metropolitan Health Service Research Ethics and Governance Unit

Royal Perth Hospital

Site Decision History

Governance Reviews

Submission Date	Validation Date	Review Decision	Review Completion Date	Authorisation Decision	Authorisation Decision Date
04/08/2017	04/08/2017	Recommended	18/01/2018	Authorised	18/01/2018

Specific conditions of authorisation: No specific conditions specified

- Project Funding

Project Budget Summary

Governance

GlaxoSmithKline Australia Pty Ltd

Major funding organisation type	Commercial company - industry / contract research organisation
Major funder organisation address	1061 Mountain Highway, Boronia, Victoria 3155, Australia
Major funder country	Australia

Expected funding: $0.00

Actual funding: $0.00

Total Actual Costs:	Total Authorised Costs:	Total Funding:	Shortfall (or Surplus):
$0.00	$0.00	$0.00	$0.00

You can only see the budget relevant to the role you have in the project.