



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

# Research Governance Service (RGS)

## Researcher User Guide

### Part B: Document Preparation and Submission



**Version 5.0**

**October 2018**

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## Suggested Citation

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

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# 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:

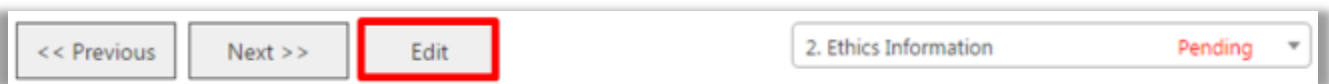
Project Details Section	Project Member Role
1. Project Header	CPI, CPI Delegate, PI, or PI Delegate
2. Ethics Information	CPI or CPI Delegate
3. Governance Information	PI or PI Delegate
4. Investigator Contact Information	CPI, CPI Delegate, PI or PI Delegate.

### 1.1 Fill Out the Project Details Tab (General Information)

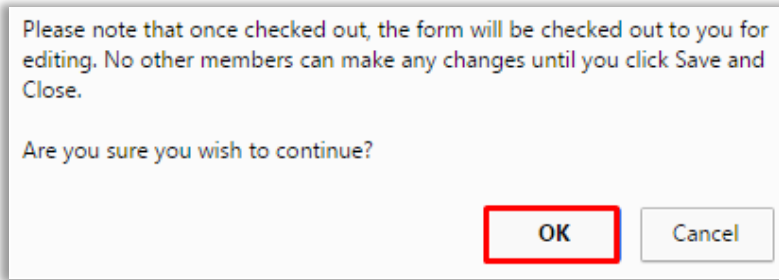
1. In the project's workspace, click on the 'Project Details' tab.



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 checked out 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 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, 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 (i) 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:

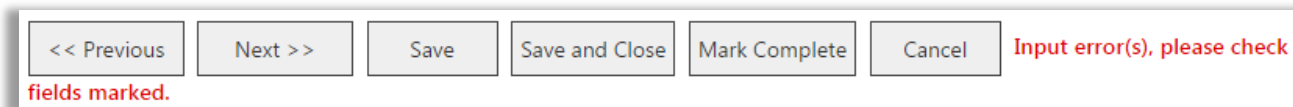
A screenshot of a web form titled "1. Project". At the top right, a red message says "This section is locked out by you for editing." Below this is a dropdown menu for "2. Ethics Information" with a "Pending" status. The form contains several fields with red asterisks indicating they are mandatory. These include: "Protocol version number", "Protocol version date", "Broad research area", "NHMRC group", "NHMRC fields of research", "Broad health condition", "Specific condition", "Research focus", "Keywords", and "Project summary". The "Project summary" field is a rich text editor with a toolbar containing icons for bold, italic, underline, list, and other text formatting options. Information icons (i) are present next to several fields. At the bottom right, a character count shows "Characters (including HTML): 0/2000".

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.*

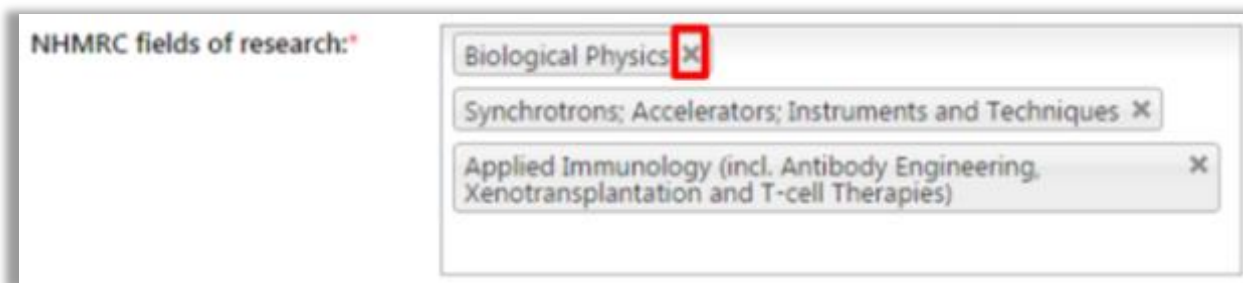
### Mandatory Fields

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.



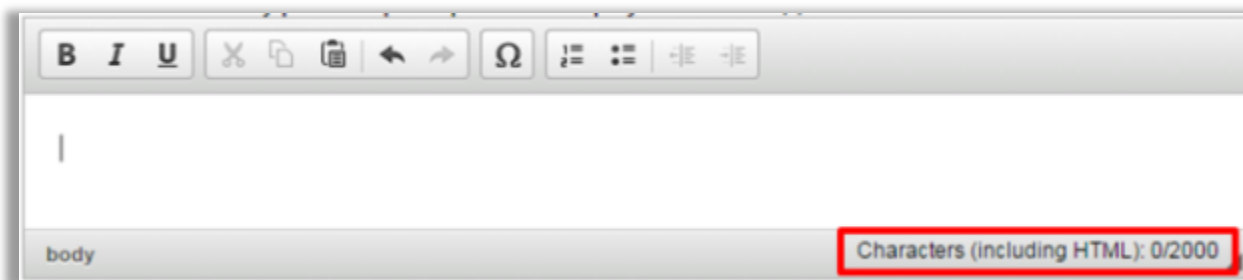
### Entering Data in Multi-select Fields

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.**

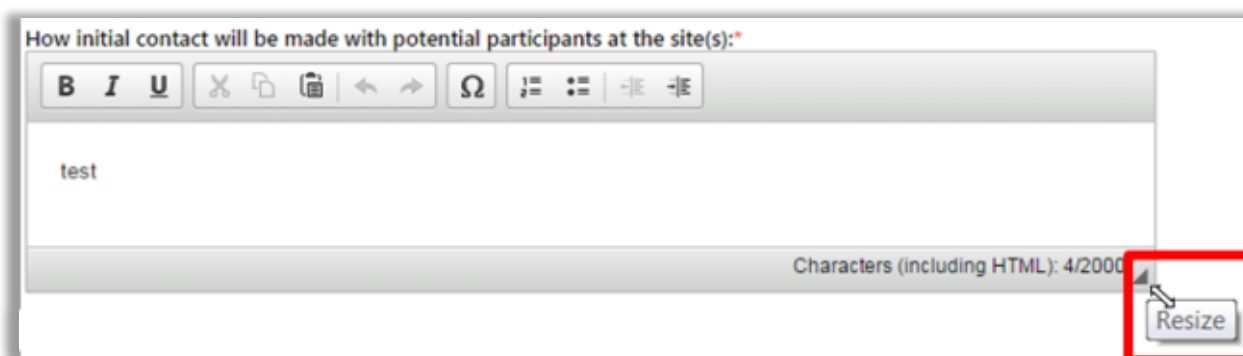


### Entering Data in Rich Text Fields

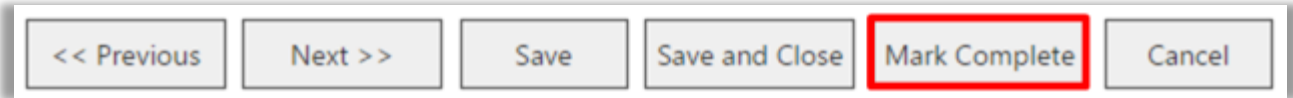
Rich text fields show a character or word count on the bottom left-hand corner of the box. Use this as guide to ensure you do not go beyond the limit; otherwise, you will be prompted with an error.



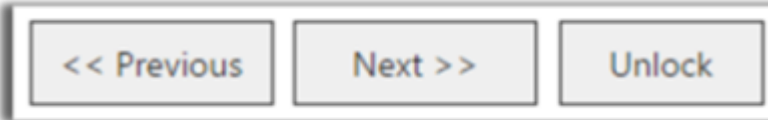
You may also drag the border of the box to extend its length.



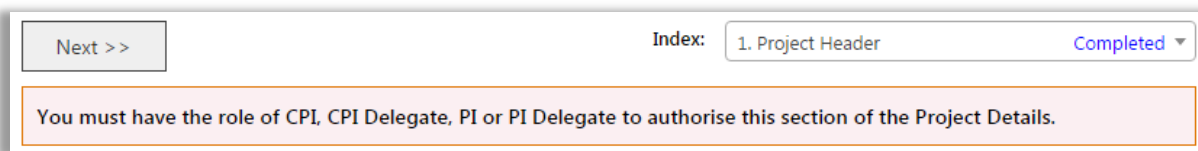
5. Click **Mark Complete** when all information in that section has been entered. The status of the section will update to 'Completed' to inform other Project Members that this section is now final and ready for authorisation. Any Project Member who is currently editing the section may click 'Mark Complete'.



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

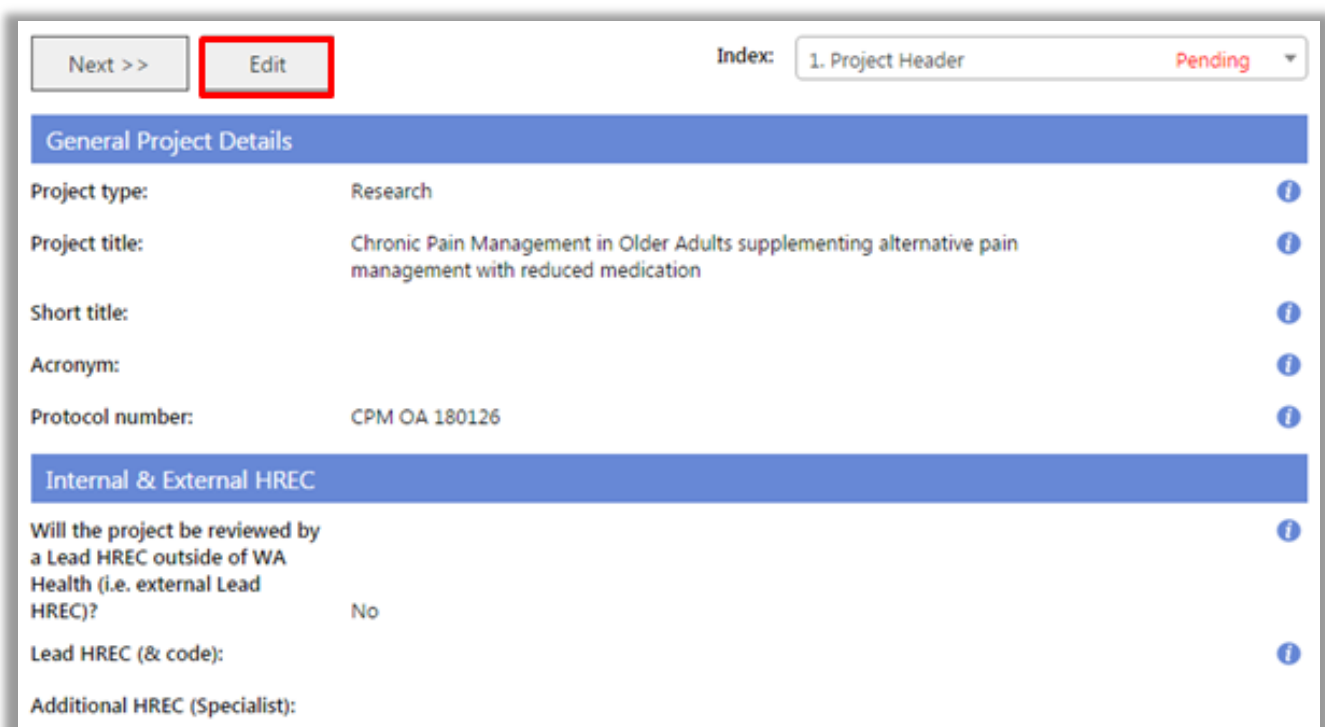


7. If you have the relevant role, click 'Authorise'.



## 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'.



General Project Details	
Project type:	Research
Project title:	Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication
Short title:	
Acronym:	
Protocol number:	CPM OA 180126

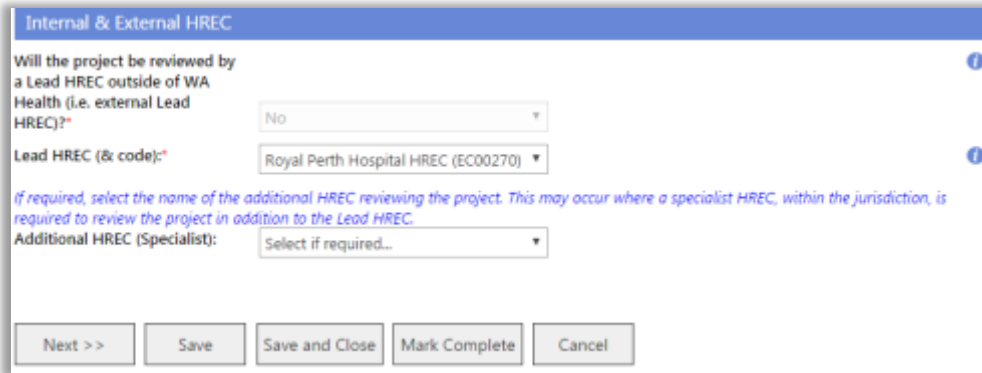
Internal & External HREC	
Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?	No
Lead HREC (& code):	
Additional HREC (Specialist):	



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 Health 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 Health 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 Health) 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 Health) 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.

**Internal & External HREC**

Will the project be reviewed by a Lead HREC outside of WA Health (i.e. external Lead HREC)?\*  i

*For projects submitted to WA Health sites, you will need to complete the WA Specific Module e-form within the RGS. It will not be accepted as an attached document.*

External Lead HREC Jurisdiction:\*  i

External Lead HREC (& code):  i

Additional HREC (Specialist):  i

External HREC reference number:  i

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.

**7. Funder Information (monetary and in-kind)**

*All funders need to be added, both monetary and in-kind, as these will be added to the Budget Form.*

Funder organisation type:  i

Funder organisation name:   i

Funder Organisation Name	Funder Organisation Type	ABN	Profile	Major Funder?	
Department of Health WA	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>
Royal Perth Hospital	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>
East Metropolitan Health Service Executive	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>
Pfizer Australia	Commercial company - industry / contract research organisation		<a href="#">View</a>	No	<input type="button" value="Remove"/>

Is there an external funding organisation?\*  i

*If you cannot find a funder, please contact RGS Support.*

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.

**7. Funder Information (monetary and in-kind)**

All funders need to be added, both monetary and in-kind, as these will be added to the Budget Form.

Funder organisation type:

Funder organisation name:

Funder Organisation Name	Funder Organisation Type	ABN	Profile	Major Funder?	
Department of Health WA	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>
Royal Perth Hospital	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>
East Metropolitan Health Service Executive	Government - state (WA)		<a href="#">View</a>	No	<input type="button" value="Remove"/>

Is there an external funding organisation?\*

### 1.5 Authorise or Unauthorise a Section of the Project Details Tab

#### Authorise

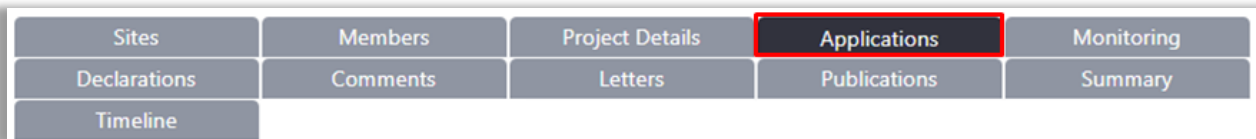
Only the CPI, CPI Delegate, PI or PI Delegate (refer to [‘Project Member Role to Authorise / Unauthorise Project Details’](#)) have the authority to authorise the Project Details sections once it has the ‘Completed’ status.

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 ‘Applications’ 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 (CPI Delegate can authorise the WASM)

### 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 Health 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 Health) 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](#)).

Applications Find information on Research Authorisation and Monitoring Forms

Ethics Approval

Active

Forms

*Forms must be authorised before they can be submitted by the CPI or CPI Delegate*

Form Name	Version	Status	Locked By	Updated By	Select
WA Specific Module (WASM)	1.0	Pending			<input type="checkbox"/>

Add Remove Authorise Unauthorise Print

Documents *Find recommended document templates here.*

*Documents must be authorised before they can be submitted by the CPI or CPI Delegate*

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
4440	HREA	1	Attached	<a href="#">William Gardner</a>	21/02/2018	<input type="checkbox"/>
4441	Research Protocol	1	Attached	<a href="#">William Gardner</a>	21/02/2018	<input type="checkbox"/>
4442	Lead HREC approval letter	0	Attached	<a href="#">William Gardner</a>	21/02/2018	<input type="checkbox"/>

Add Edit Remove Authorise Unauthorise Print

At this time, you are unable to submit ethics applications using the RGS to jurisdictions other than WA Health. Your forms and documents will only be submitted to the Additional WA Health HREC (Specialist).

Submit to Ethics

### 2.2.3 External Lead HREC Only

1. For NMA, if an External HREC (outside of WA Health) 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](#)).

Ethics Approval

Active

Forms

Form Name	Version	Status	Locked By	Updated By	Select
WA Specific Module (WASM)	1.0	Authorised		<a href="#">Katherine Coltrona</a>	<input checked="" type="checkbox"/>

Add Remove Authorise Unauthorise Print

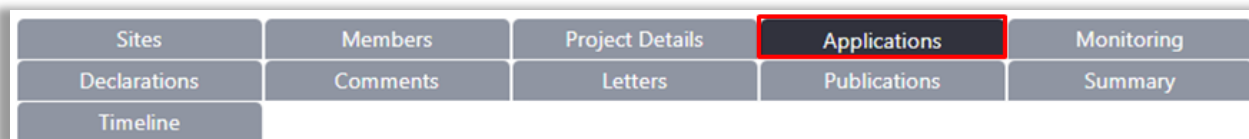
2. When the External Lead HREC has approved the ethics application, the CPI or CPI Delegate, must upload to the Ethics Approval Active section, the approved HREA and supporting documents (including the ethics approval letter) and submit them with the approved WASM to the RG Office. Refer to [Help Wiki: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

'Submit Ethics to RG Office' applies to projects reviewed by an external Lead HREC when there is no WA Health Additional HREC (Specialist) review.

Submit Ethics to RG Office

## 2.3 Add an Ethics Form

1. In the project workspace, click on the Applications tab.



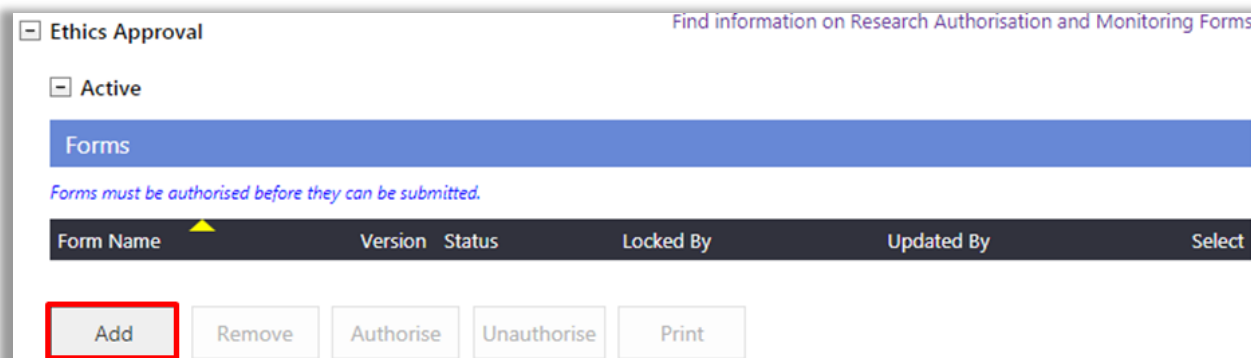
2. Click on the '+' sign next to the category (e.g. Ethics Approval, Site Authorisation) grouping to expand that section. To add an ethics form, you must click on 'Ethics Approval' and 'Active' groupings to see the 'Forms' grid and the corresponding buttons.

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 Applications 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](#)).

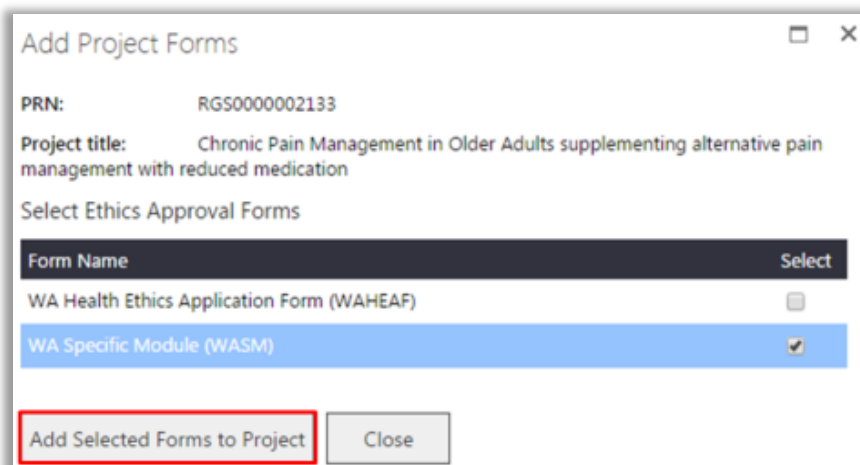
Project Header, Ethics Information or Investigator Contact Information section in [Project Details](#) is not authorised.

*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.



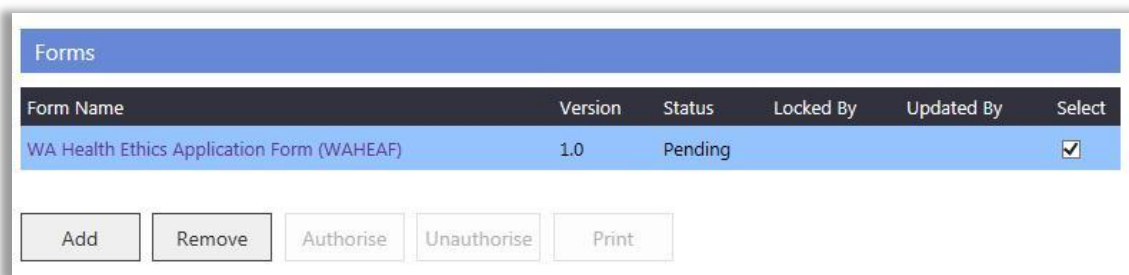
4. 'Select' either the WA Health Ethics Application (WAHEAF) OR WA Specific Module (WASM) and then click 'Add Selected Forms to Project'. The WASM should be selected if you are intending to use the HREA as your ethics application form. The [HREA](#) must be completed externally and uploaded to the RGS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



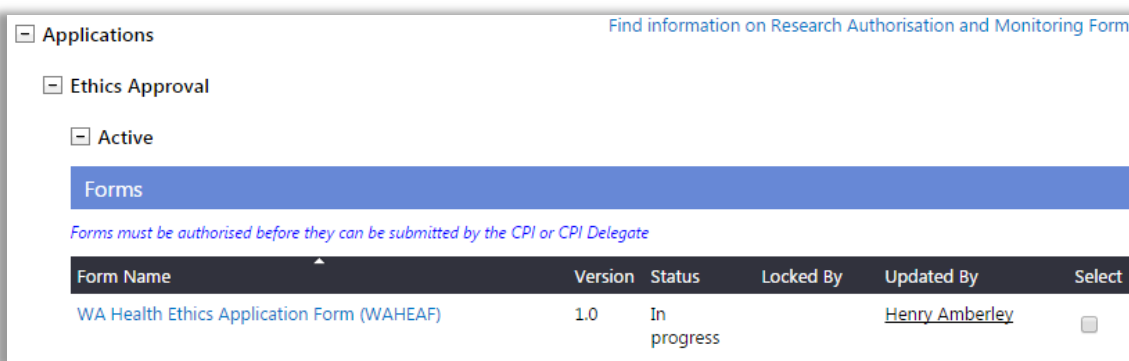


The RGS will only allow you to add either the WAHEAF or WASM. These form options will disappear from this screen once an ethics form has been added to the project.

5. When the form is successfully added, you will be directed back to the Applications tab. Version 1.0 of the selected ethics form now appears under the 'Ethics Approval', 'Active' section of the 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.



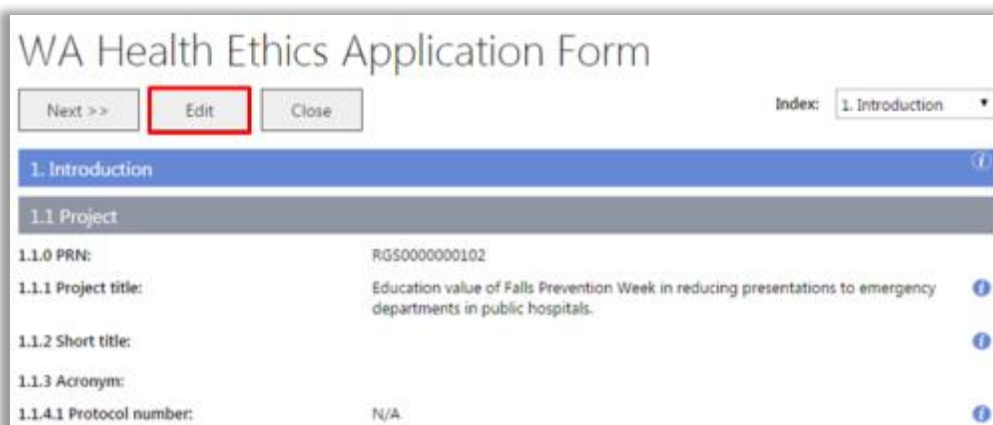
6. All Project Members can click on the embedded link in the form name to open it, allowing for viewing or editing.



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](#).

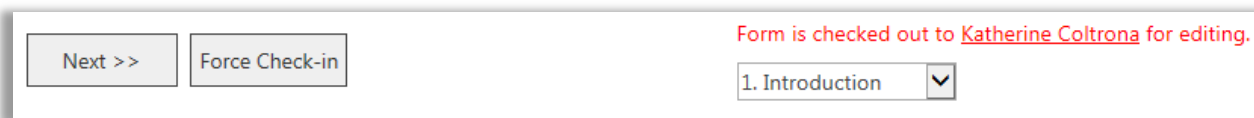
## 2.4 Fill Out an Ethics Form

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 Applications 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.

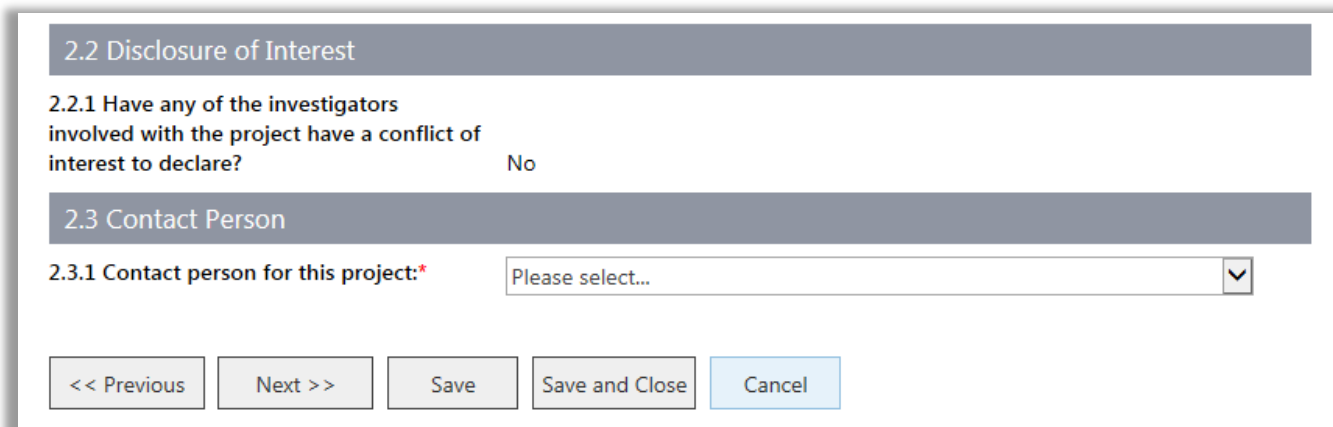


Next >> Force Check-in Form is checked out to [Katherine Coltrona](#) for editing.  
1. Introduction

- **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.



2.2 Disclosure of Interest

2.2.1 Have any of the investigators involved with the project have a conflict of interest to declare? No

2.3 Contact Person

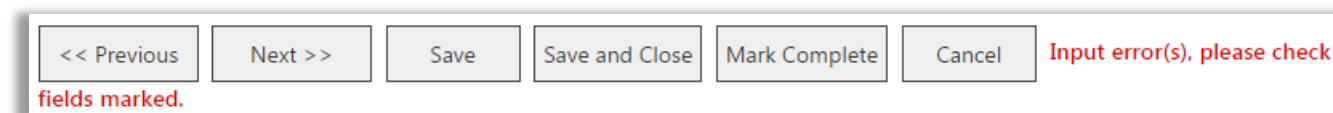
2.3.1 Contact person for this project:\* Please select...

<< Previous Next >> Save Save and Close Cancel

**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.

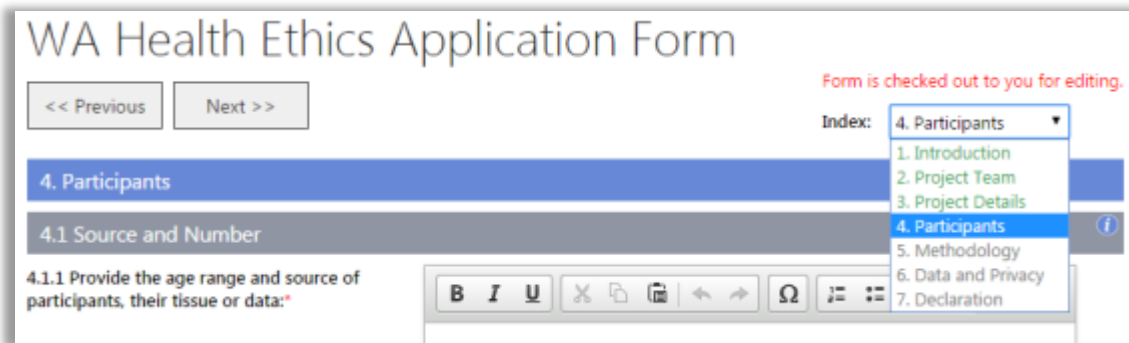


<< Previous Next >> Save Save and Close Mark Complete Cancel Input error(s), please check fields marked.

## 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.



The screenshot shows the 'WA Health Ethics Application Form' interface. At the top, there are navigation buttons for '<< Previous' and 'Next >>'. A status message indicates 'Form is checked out to you for editing.' Below this is the 'Form Index' dropdown menu, which is currently open, showing a list of sections: 1. Introduction, 2. Project Team, 3. Project Details, 4. Participants (highlighted in blue), 5. Methodology, 6. Data and Privacy, and 7. Declaration. The main content area shows the '4. Participants' section, with a sub-section '4.1 Source and Number' and a text field containing the instruction: '4.1.1 Provide the age range and source of participants, their tissue or data:'. A rich text editor toolbar is visible below the text field.

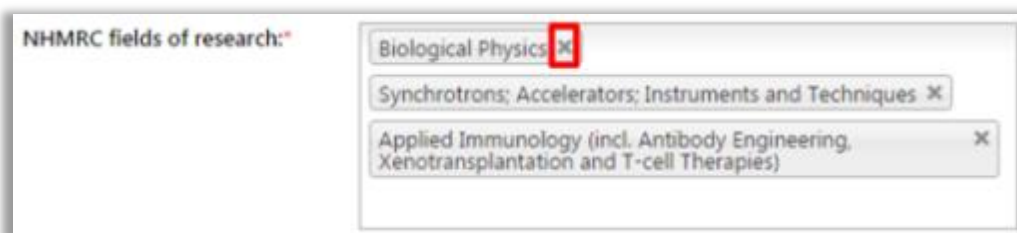
Whilst in edit mode, you can only use the index to navigate through the completed section (green) up to the black section of the form. When you click 'Edit' you will be taken to the last edited section of the form.

## 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

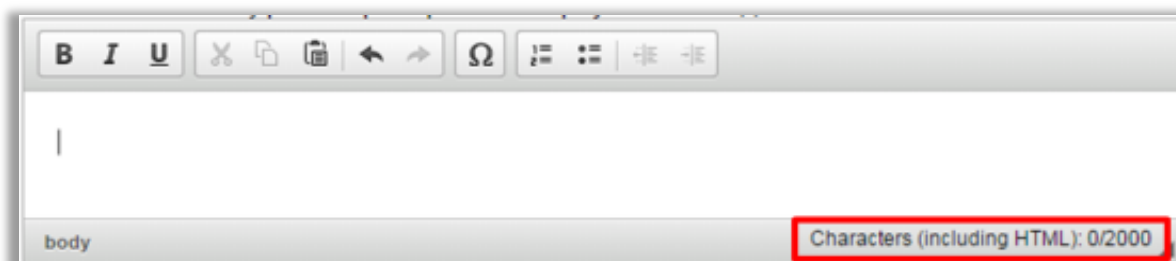
If a field allows multiple selections, click on the desired option to add it into the list. If you have selected an option in error and wish to remove it, click on the X beside the option.



The screenshot shows a multi-select field titled 'NHMRC fields of research:'. The field contains three selected options, each with a red 'X' button to its right for removal: 'Biological Physics', 'Synchrotrons; Accelerators; Instruments and Techniques', and 'Applied Immunology (incl. Antibody Engineering, Xenotransplantation and T-cell Therapies)'.

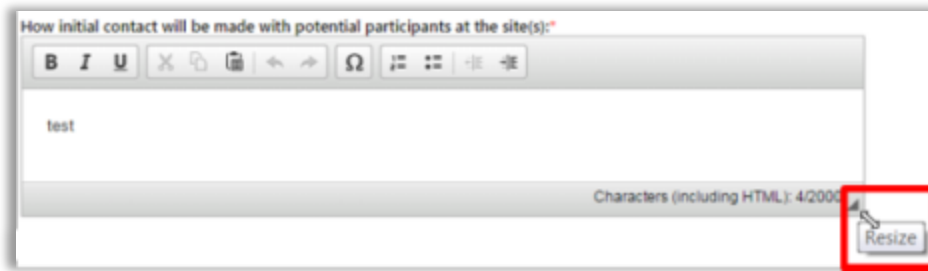
## Enter Data in Rich Text Fields

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.



The screenshot shows a rich text editor toolbar with various icons for bold, italic, underline, and other text formatting. Below the toolbar is a text area. At the bottom right of the text area, a red box highlights the character count: 'Characters (including HTML): 0/2000'.

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

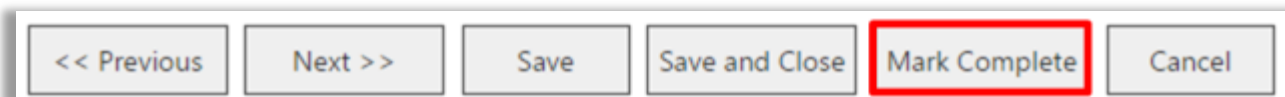


### Click on Your Web Browser's Refresh button to fetch the Latest Information

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.

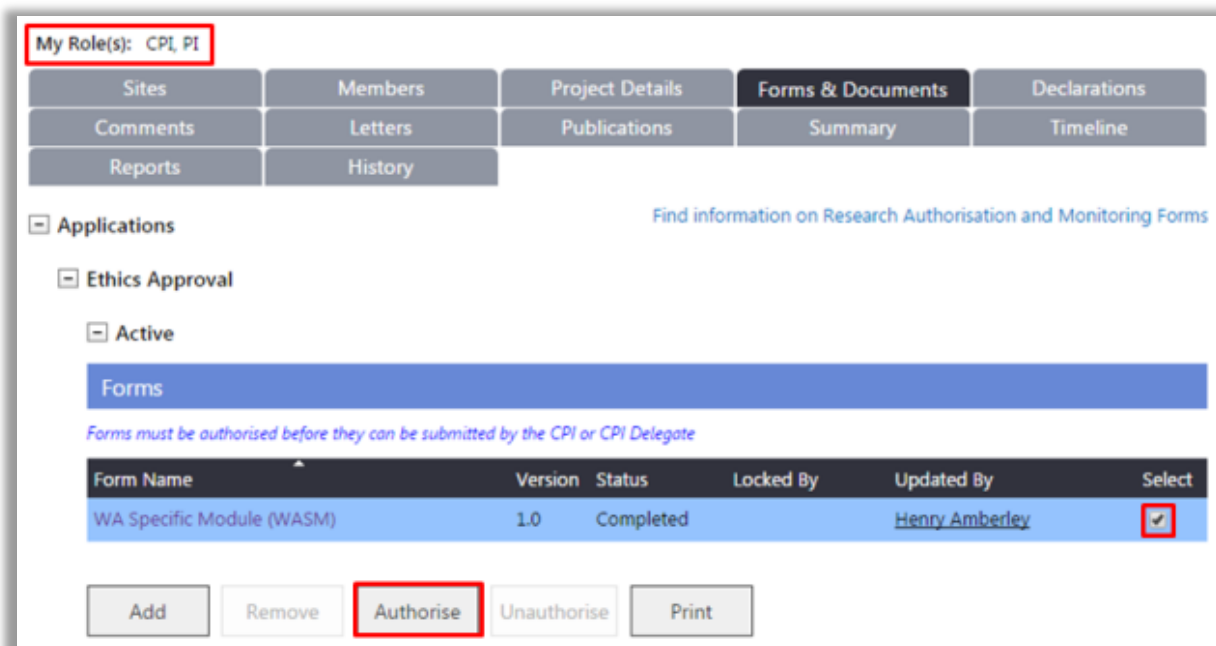


## 2.5 Sign, Authorise and Unauthorise an Ethics Form

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. **Only the CPI can authorise the WAHEAF.** The WASM has no required signatures and requires authorisation by either the CPI or CPI Delegate.



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

Name	Position	Signature	Date
<a href="#">Henry Amberley</a>	CPI, PI	(Automatically signed when form is Authorised)	
<a href="#">Jane Mitchell</a>	PI	<input type="button" value="Sign"/>	

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'.

Name	Position	Signature	Date
<a href="#">Henry Amberley</a>	CPI, PI	(Automatically signed when form is Authorised)	
<a href="#">Jane Mitchell</a>	PI	Signed	22/02/2018

After authorising a form, the 'Unauthorise' button should appear. To exit the form, click 'Close'.

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

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'.

Name	Position	Signature	Date
<a href="#">Henry Amberley</a>	CPI, PI	Signed	22/02/2018
<a href="#">Jane Mitchell</a>	PI	Signed	22/02/2018

*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:

<b>Location of changes made</b>	<b>WAHEAF</b>	<b>WA Specific Module</b>	<b>Site Specific Assessment Form</b>	<b>Access Request Form</b>
<b>Sites tab</b>	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
<b>Members tab</b>	Unauthorise	Keep as 'Authorised'	Unauthorise only the form(s) with changes	Unauthorise only when the CPI is changed
<b>Project Details tab - Project Header</b>	Unauthorise	Unauthorise	Unauthorise	Unauthorise
<b>Project Details tab - Ethics Information</b>	Unauthorise	Unauthorise	Unauthorise	Unauthorise
<b>Project Details tab - Governance Information</b>	Keep as 'Authorised'	Keep as 'Authorised'	Unauthorise	Keep as 'Authorised'
<b>Project Details tab - Investigator Contact Information</b>	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 'Applications' tab.

Sites	Members	Project Details	<b>Applications</b>	Monitoring
Declarations	Comments	Letters	Publications	Summary
Timeline	History			

2. Click on the '+' sign next to the 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 all 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 Applications 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](#)).

Project Header, Ethics Information, Governance Information or Investigator Contact Information section in [Project Details](#) is not authorised.

*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.

Site Authorisation

Active

Forms

Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.

Site / Organisation

Add Remove Authorise Unauthorise Print

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.



**Add Project Forms**

PRN: RGS0000001011

Project title: Input of a Multidisciplinary Device to Accompany the Announce of Diagnosis for Young Children With Serious Constitutional Hemorrhagic Disease and Their Families

Select Site Authorisation Forms

Form Name	Select
Access Request (AR) Form	<input type="checkbox"/>
Site Specific Assessment (SSA) Form	<input checked="" type="checkbox"/>

SSA form and Budget form for which site(s):

Add Selected Forms to Project

- Aboriginal Health
- Armadale Health Service
- Armadale Mental Health Service
- Bentley Health Service
- Department of Health
- Perth Children's Hospital
- Royal Perth Hospital

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.

**Add Project Forms**

PRN: RGS0000000028

Project title: Does cheese consumption make fat people even fatter?

Select Site Authorisation Forms

Form Name	Select
Access Request (AR) Form	<input type="checkbox"/>
Site Specific Assessment (SSA) Form	<input checked="" type="checkbox"/>

SSA form and budget form for which site(s): Bentley Health Service

Add Selected Forms to Project Close

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.

Site Authorisation

Active

Forms

*Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.*

Site / Organisation

- Department of Health
- Royal Perth Hospital
- Fiona Stanley Hospital

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Pending			<input type="checkbox"/>
Budget Form	1.0	Pending			<input type="checkbox"/>

Add Remove Authorise Unauthorise Print

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.

Site Authorisation

Active

Forms

*Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.*

Site / Organisation

- Fiona Stanley Hospital

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Pending			<input type="checkbox"/>
Budget Form	1.0	In progress		Henry Amberley	<input type="checkbox"/>

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 pending signatures', an email is sent to the PI to inform them that the form is ready to be signed.

### 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.**

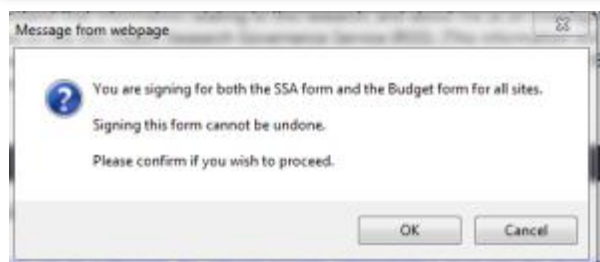
1. To sign a SSA Form, click on the embedded link in the form located in the project workspace's Forms & Documents tab, under 'Applications', 'Site Authorisation', 'Active' groupings, the form will have the status of Completed (Pending Signatures). You can navigate to the 'Declaration' page using the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

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Completed (Pending Signatures)		<a href="#">Henry Amberley</a>	<input type="checkbox"/>

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.

The screenshot shows the 'Site Specific Assessment (SSA) Form' for Fiona Stanley Hospital. The 'Index' is set to '18. Declarations'. The current section is '18.1 Declaration by All Responsible Principal Investigators'. It contains a list of 10 numbered statements regarding the researcher's responsibilities and commitments. Below the text is a table for signatures:

Name	Position	Signature	Date
Aron Clark	PI	<input type="button" value="Sign"/>	



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.

The screenshot shows the '18.2 Declaration by All Responsible Business Managers, Divisional Directors and Regional Directors' section. It includes a list of 3 numbered statements. Below the text is a table for invited signatories:

Name	Position	Signature	Date	Invitation Status	Invited By	Select
<input type="button" value="Add"/> <input type="button" value="Remove"/> <input type="button" value="Invite to Sign"/>						

*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 Position 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.**

Name	Position	Signature	Date	Invitation Status	Invited By	Select
<a href="#">Jonathon Sewell</a>	Business Manager - Fiona Stanley Hospital	<input type="button" value="Sign"/>		Invited	<a href="#">April Clark</a>	<input type="checkbox"/>

*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 or PI Delegate 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.

Name	Position	Signature	Date	Invitation Status	Invited By	Select
<a href="#">Jonathon Sewell</a>	Business Manager - Fiona Stanley Hospital	Signed	21/02/2018	Accepted	<a href="#">April Clark</a>	

*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 Applications tab.

Name	Position	Signature	Date	Invitation Status	Invited By	Select
<a href="#">Jonathon Sewell</a>	Business Manager - Fiona Stanley Hospital	Signed	21/02/2018	Accepted	<a href="#">April Clark</a>	

<< Previous    Close    **Unauthorise**

Alternatively, a PI can authorise and a PI or PI Delegate can unauthorise a form in the project workspace's Application 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.**

**Forms**

*Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.*

Site / Organisation

Sir Charles Gairdner Hospital

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Completed		<a href="#">Henry Amberley</a>	<input checked="" type="checkbox"/>
Budget Form	1.0	Authorised		<a href="#">Henry Amberley</a>	<input type="checkbox"/>

Royal Perth Hospital

Add    Remove    Authorise    Unauthorise    Print

### 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.

*Before this form can be authorised, the relevant hospital administrators must sign the declaration. Please invite them below.*

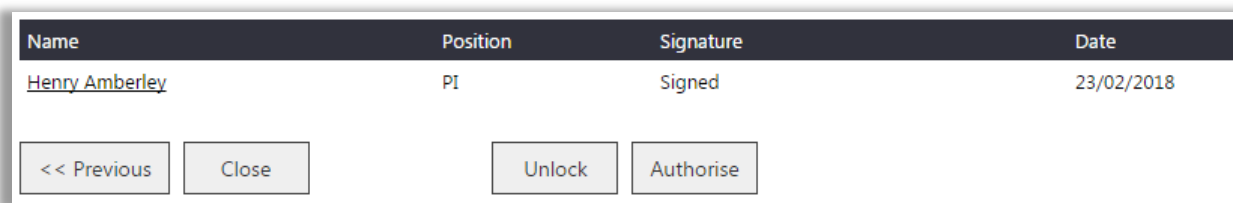
**3.2 Site Declaration of Support** i

Name	Position	Signature	Date	Invitation Status	Invited By	Select
<a href="#">Jonathon Sewell</a>	Head of Department	Signed	23/02/2018	Accepted	<a href="#">Henry Amberley</a>	

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*

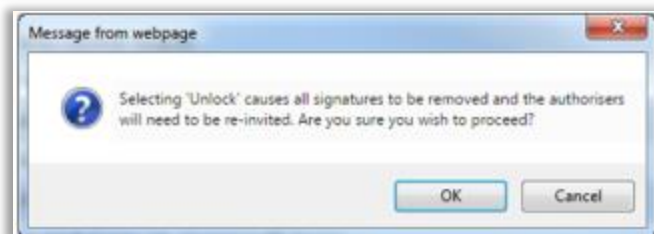
1. You can unauthorise a form in the project workspace's Applications tab after selecting a form or document. If you only need to obtain an additional signature on the form then you do not have to unlock or edit the form to do this only unauthorise it. The form can be authorised again when the signature/s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



*Note: Selecting 'Unlock' causes all signatures to be removed and the authorisers will need to be re-invited.*



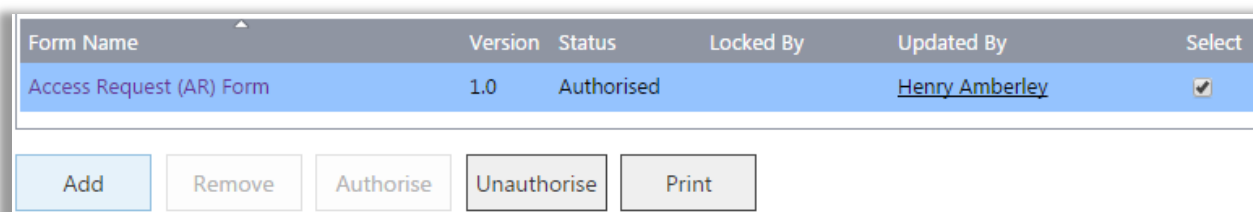
Click 'OK' on the message to proceed or 'Cancel' for the form to remain locked. If you click 'OK' it will remove all signatures from the form. If you click 'OK' you can then click 'Edit' to make any changes to the form. You will then have to go through the process of obtain any signatures needed.

### 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 'Close'.

### 3.5 Systematic Unauthorisation of the Governance Forms

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

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



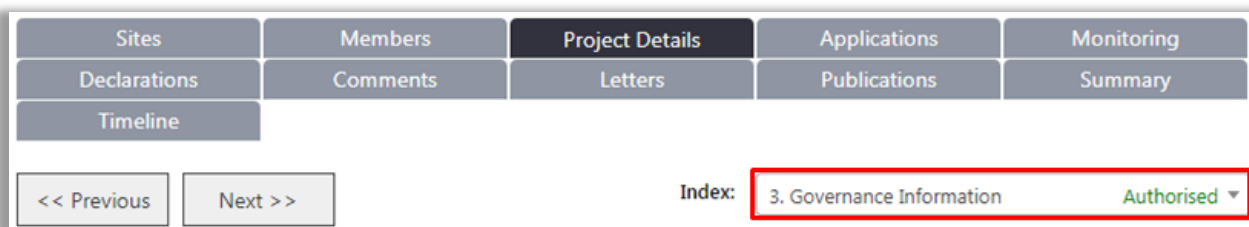
## 4. Add, Fill Out and Authorise a Budget Form

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](#).



Sites	Members	<b>Project Details</b>	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
Timeline				

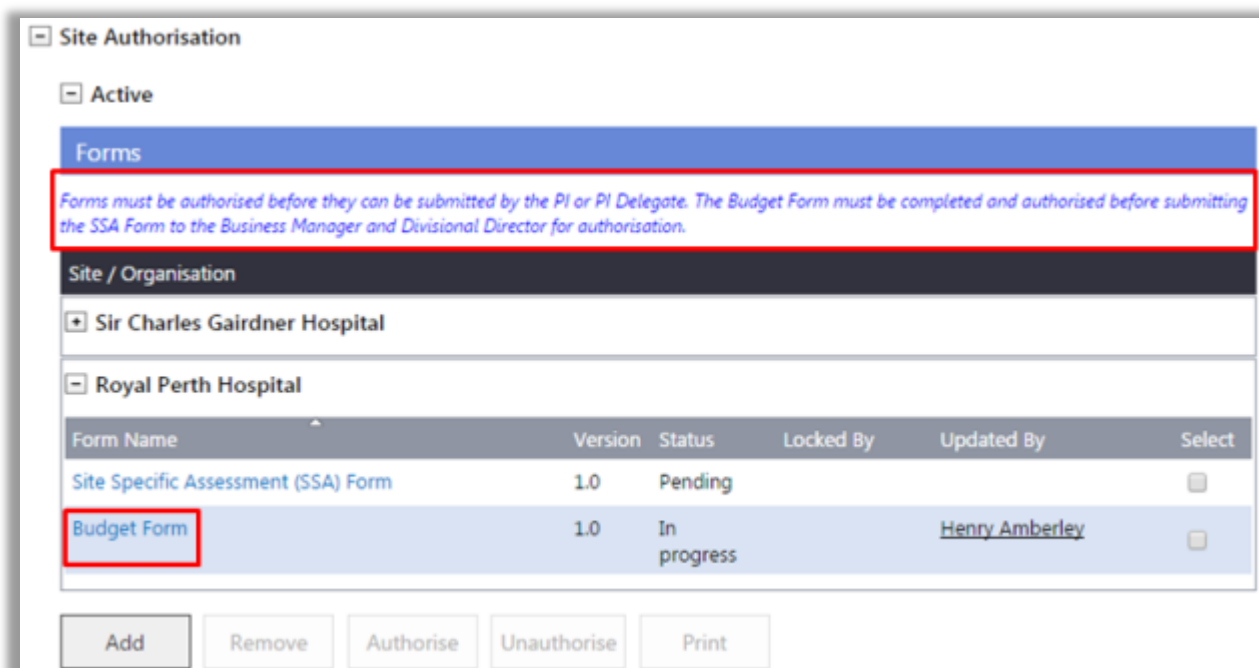
<< Previous      Next >>

Index: **3. Governance Information**      Authorised ▾

✓ **A SSA Form with a corresponding Budget Form has been added in the Applications 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](#).



Site Authorisation

Active

**Forms**

Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.

Site / Organisation

Sir Charles Gairdner Hospital

Royal Perth Hospital

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Pending			<input type="checkbox"/>
<b>Budget Form</b>	1.0	In progress		<a href="#">Henry Amberley</a>	<input type="checkbox"/>

Add    Remove    Authorise    Unauthorise    Print

### 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).**

The screenshot shows the 'Site Authorisation' interface. At the top, there is a 'Forms' section with a red box around a warning message: "Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation." Below this, there are sections for 'Site / Organisation' with 'Sir Charles Gairdner Hospital' and 'Royal Perth Hospital' listed. A table displays the following data:

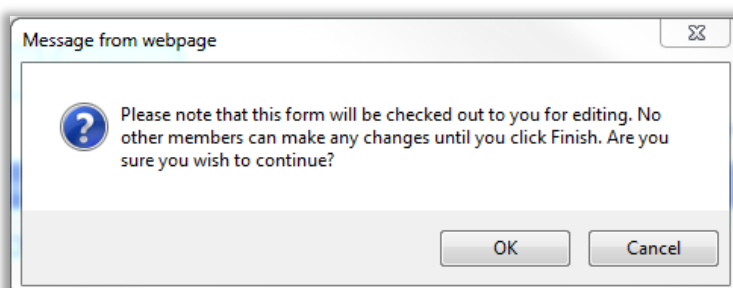
Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	1.0	Pending			<input type="checkbox"/>
Budget Form	1.0	In progress		Henry Amberley	<input type="checkbox"/>

At the bottom of the interface, there are buttons for 'Add', 'Remove', 'Authorise', 'Unauthorise', and 'Print'.

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

The screenshot shows the 'Budget Form' editing interface. At the top, there are buttons for 'Next >>', 'Edit', and 'Print'. A dropdown menu shows '1. Department(s) Selection'. Below this, there is a section titled 'Section 1 of 3 - Department(s) Selection' for 'Royal Perth Hospital'. It includes fields for 'Proposed number of participants in this site:' and 'Expected project timeframe for this site: year(s)'. A table below lists departments with columns: Department Name, Type, Head Of Dept, Invitation Status, Invited By, HoD Delegate, Invitation Status, Invited By, and Authorisation Status. At the bottom, there are buttons for 'Next >>' and 'Edit'.

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 Applications 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 Applications 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

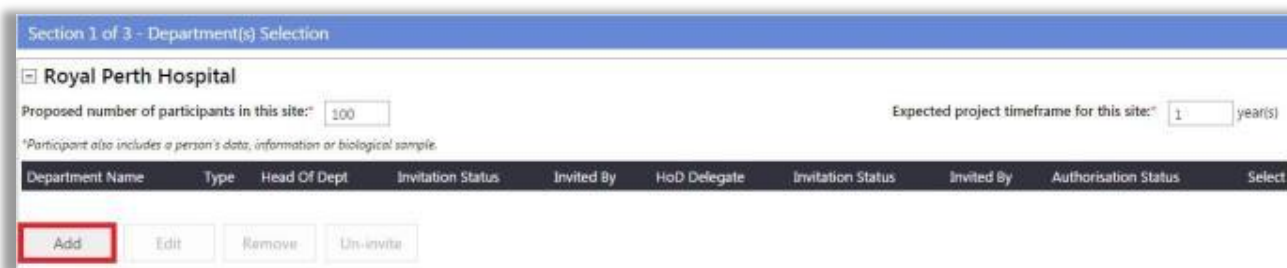
1. In the 'Department(s) Selection' section, enter the 'Proposed number of participants for this site' and the 'Expected project timeframe for this site' at the top of the form. **Note that participant also includes a person's data or biological sample.**

### 4.3.1.1 Add a Department

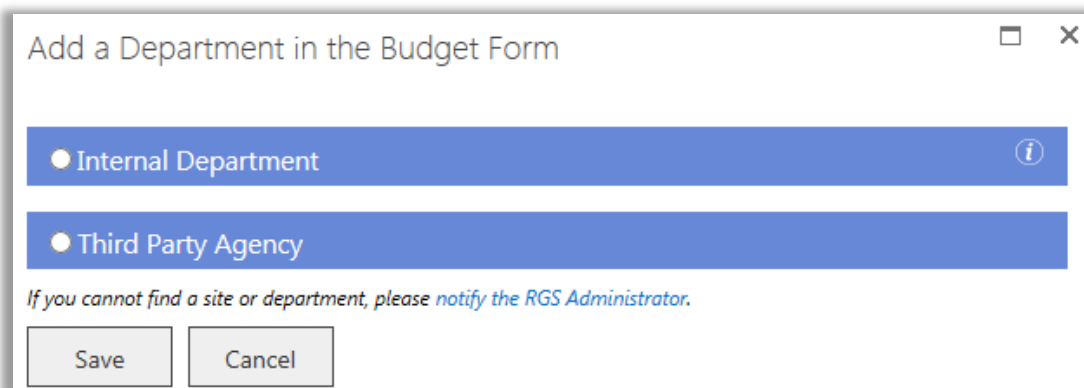
2. Select/nominate the departments that will be involved in the project at the site e.g. research department, supporting department (s) and any third party agency. **Add them to the Budget Form in the following order:**

- 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.

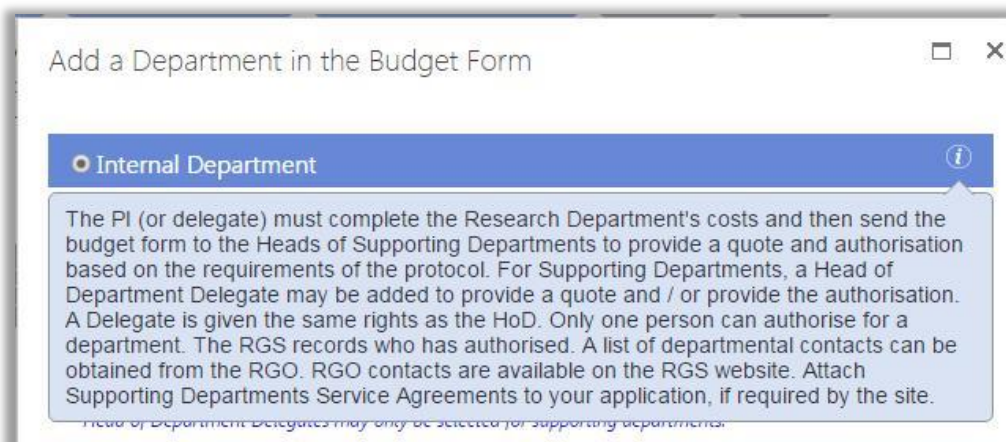


3. The 'Add a Department in the Budget Form' screen will launch. If you wish to add a research or supporting department at the site, select 'Internal Department'. Select 'Third Party Agency' if the supporting department will be external to the site.



### 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).

Add a Department in the Budget Form

**Internal Department**

Department:\* Gastroenterology

Is this a research department?\* Yes

You must add a research department first if one applies.

Head of Department:\* John O'Leary

Head of Department Delegates may only be selected for supporting departments.

**Third Party Agency**

If you cannot find a site or department, please notify the RGS Administrator.

Save Cancel

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.

Add a Department in the Budget Form

**Internal Department**

This site already has research department. This department will be added as supporting department.

Department:\* PathWest

Is this a research department?\* No

You must add a research department first if one applies.

Head of Department:\* Albert Macintosh

Head of Department Delegate: Jane Mitchell

Head of Department Delegates may only be selected for supporting departments.

**Third Party Agency**

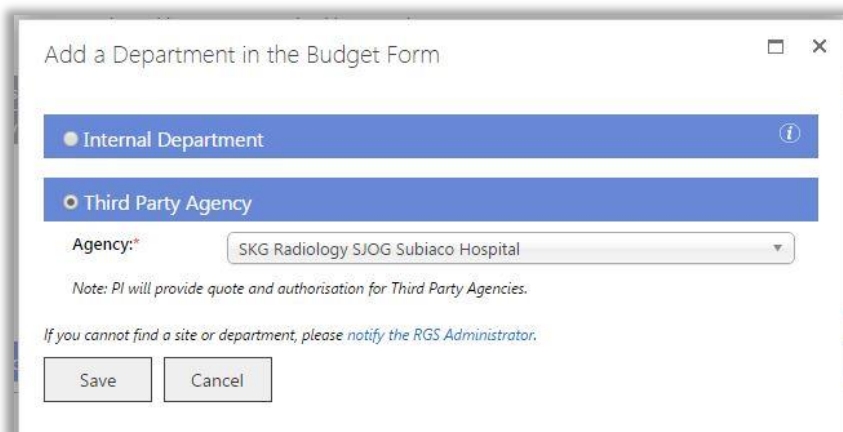
If you cannot find a site or department, please notify the RGS Administrator.

Save Cancel

### 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'.

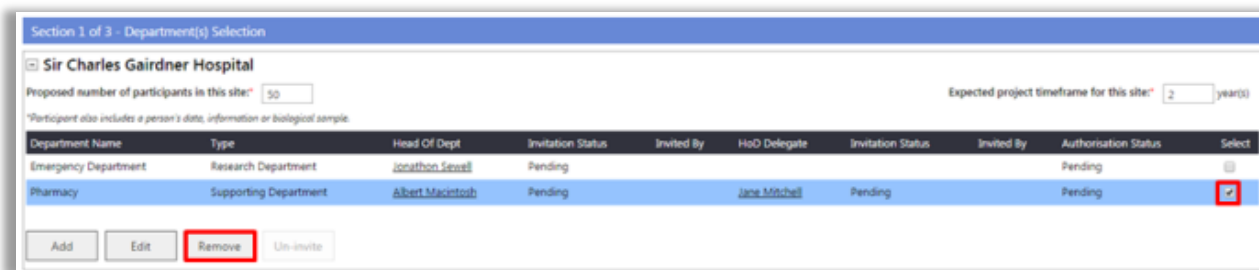
### 4.3.1.4 Edit and Remove a Department or Head of Department

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.*

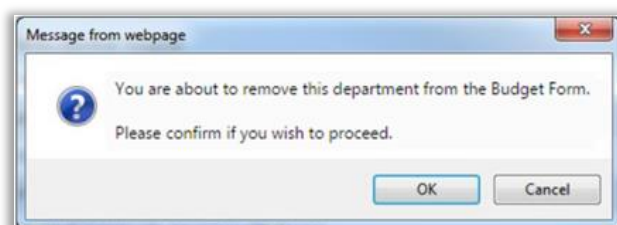
The Department and the HoD, HoSD or HoSD Delegate can be edited as long as the HoD, HoSD or HoSD Delegate has an Invitation Status of 'Pending'. If the Invitation Status is 'Invited', the HoD, HoSD or HoSD Delegate must be un-invited before the department/person can be changed (refer to Un-invite User).

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

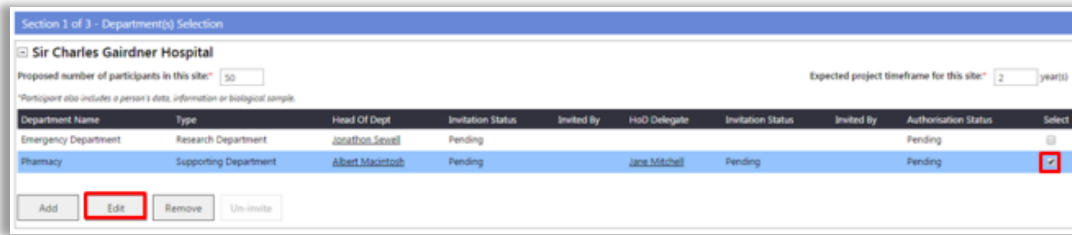


Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorization Status	Select
Emergency Department	Research Department	Jonathan Sewell	Pending					Pending	
Pharmacy	Supporting Department	Albert Macintosh	Pending		Jane Mitchell	Pending		Pending	<input checked="" type="checkbox"/>

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.*

Budget Form

Form is checked out to you for editing.

Index: 1. Department(s) Selection

Section 1 of 3 - Department(s) Selection

Sir Charles Gairdner Hospital

Proposed number of participants in this site: 50

Expected project timeframe for this site: 2 years

Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorisation Status	Select
General Medicine	Research Department	<a href="#">Jonathan Sewell</a>	Pending					Pending	<input type="checkbox"/>
Pharmacy	Supporting Department	<a href="#">Albert Macintosh</a>	Pending		<a href="#">Jane Mitchell</a>	Pending		Pending	<input type="checkbox"/>
SKG Radiology SJOG Subiaco Hospital	Third Party Agency	<a href="#">Henry Amberley</a>	Pending					Pending	<input type="checkbox"/>

Clicking **Invite to Quote** will create tasks assigned to selected HoDs and send corresponding email notification.

**Invite to Quote or Authorise**

Next >> Save Save and Close Cancel Authorise

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'.

Invite to Provide Quote and Authorise/Decline in Budget Form

Department Name	Department Type	Head of Department	Head of Dept Delegate	Select
General Medicine	Research Department	<a href="#">Jonathan Sewell</a>		<input type="checkbox"/>
Pharmacy	Supporting Department	<a href="#">Albert Macintosh</a>		<input checked="" type="checkbox"/>
Pharmacy	Supporting Department		<a href="#">Jane Mitchell</a>	<input checked="" type="checkbox"/>
SKG Radiology SJOG Subiaco Hospital	Third Party Agency	<a href="#">Henry Amberley</a>		<input type="checkbox"/>

Invite Cancel

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

Message from webpage

I acknowledge that the people I have requested to provide a quote are the appropriate people and are aware of the confidentiality requirements regarding this research project.

OK Cancel



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 \(for supporting department HA\)](#).

Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorisation Status	Select
General Medicine	Research Department	Jonathan Sewell	Invited	Henry Amberley				Pending	<input type="checkbox"/>
Pharmacy	Supporting Department	Albert Macintosh	Invited	Henry Amberley	Jane Mitchell	Invited	Henry Amberley	Pending	<input type="checkbox"/>
SKG Radiology SIOG Subiaco Hospital	Third Party Agency	Henry Amberley	Pending					Pending	<input type="checkbox"/>

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

Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorisation Status	Select
General Medicine	Research Department	Jonathan Sewell	Invited	Henry Amberley				Pending	<input type="checkbox"/>
Pharmacy	Supporting Department	Albert Macintosh	Invited	Henry Amberley	Jane Mitchell	Invited	Henry Amberley	Pending	<input type="checkbox"/>
SKG Radiology SIOG Subiaco Hospital	Third Party Agency	Henry Amberley	Pending					Pending	<input type="checkbox"/>

*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'.

Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorisation Status	Select
General Medicine	Research Department	Jonathan Sewell	Invited	Henry Amberley				Pending	<input type="checkbox"/>
Pharmacy	Supporting Department	Albert Macintosh	Invited	Henry Amberley	Jane Mitchell	Invited	Henry Amberley	Pending	<input checked="" type="checkbox"/>
SKG Radiology SIOG Subiaco Hospital	Third Party Agency	Henry Amberley	Pending					Pending	<input type="checkbox"/>

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.

Department Name	Department Type	Head of Department	Head of Dept Delegate	Select
Pharmacy	Supporting Department	Albert Macintosh		<input type="checkbox"/>
Pharmacy	Supporting Department		Jane Mitchell	<input checked="" type="checkbox"/>

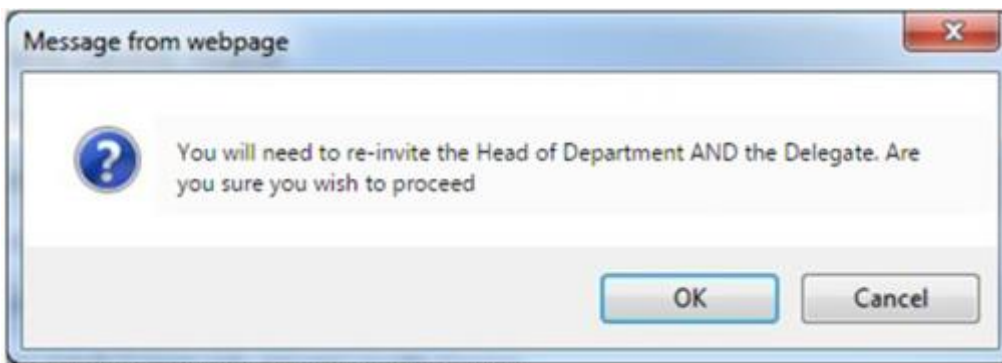
### 4.3.2.2 Edit an Authorised or Declined Section

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.



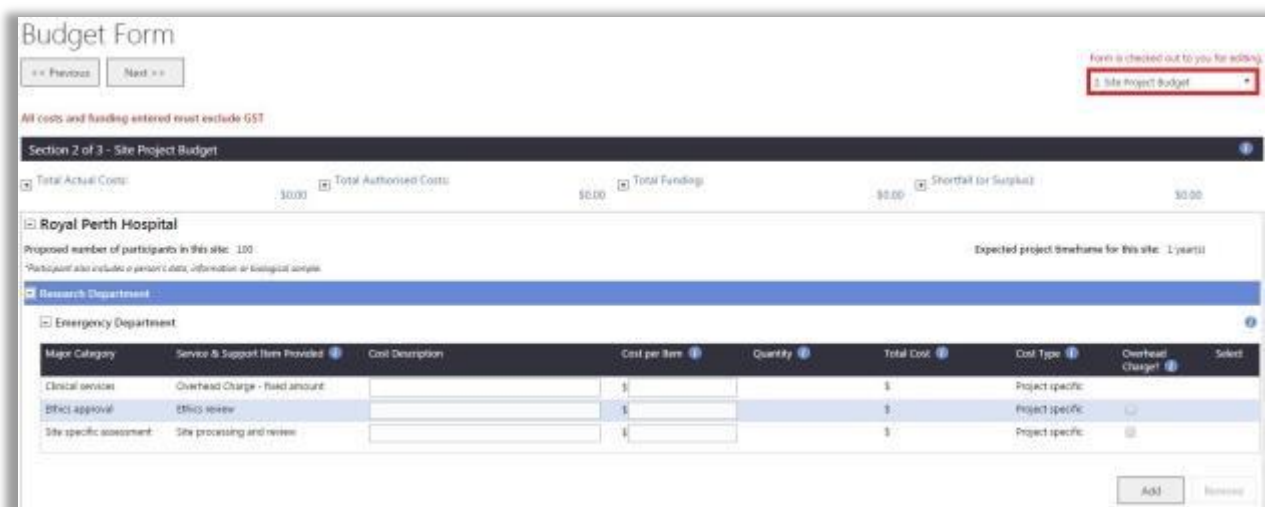
2. If the PI or PI Delegate unlocks the section they will receive a confirmation message that the HoD, HoSD or HoSD Delegate will need to be re-invited to provide authorisation. Click 'OK' to proceed.



### 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](#)).



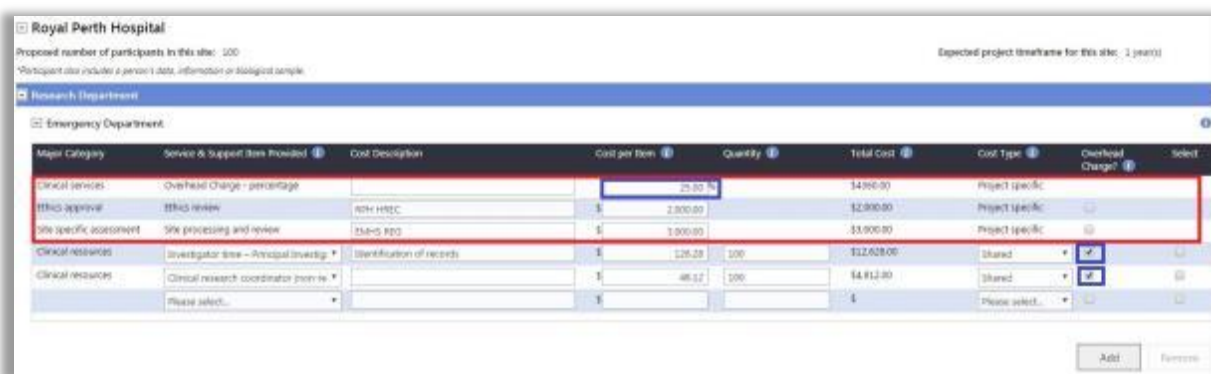
Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge	Selected
Clinical services	Overhead Charge - fixed amount		\$		\$	Project specific		
ethics approval	ethics review		\$		\$	Project specific		
Site specific assessment	Site processing and review		\$		\$	Project specific		

User tip: Refer to the [i](#) at any time.

### 4.3.3.1 Research Department Default Items

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

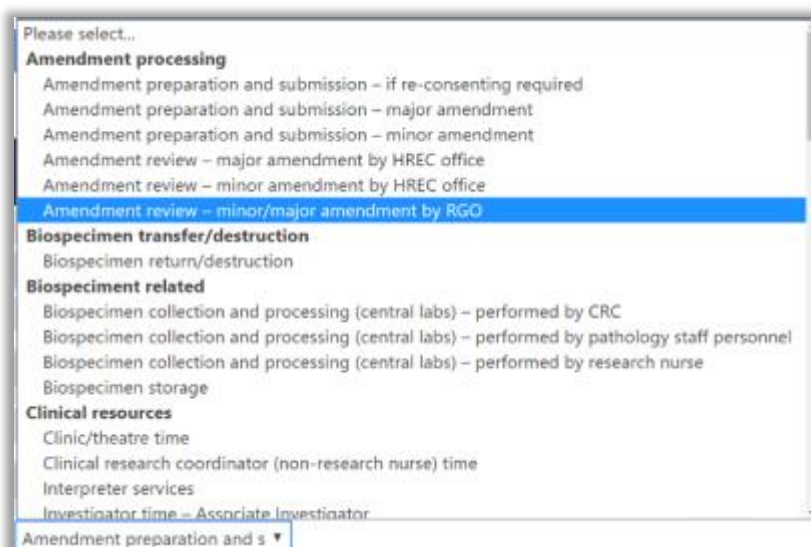
Major Category	Services
1. <b>Clinical services</b>	Overhead Charge – percentage <i>If 'Overhead charge' tick box is checked for one or more items, a percentage must be nominated</i> <b>OR</b> Overhead Charge – fixed amount <i>If none of the items' 'Overhead charge' is checked, a fixed amount must be provided</i>
2. <b>Ethics approval</b>	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. <b>Site specific assessment</b>	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

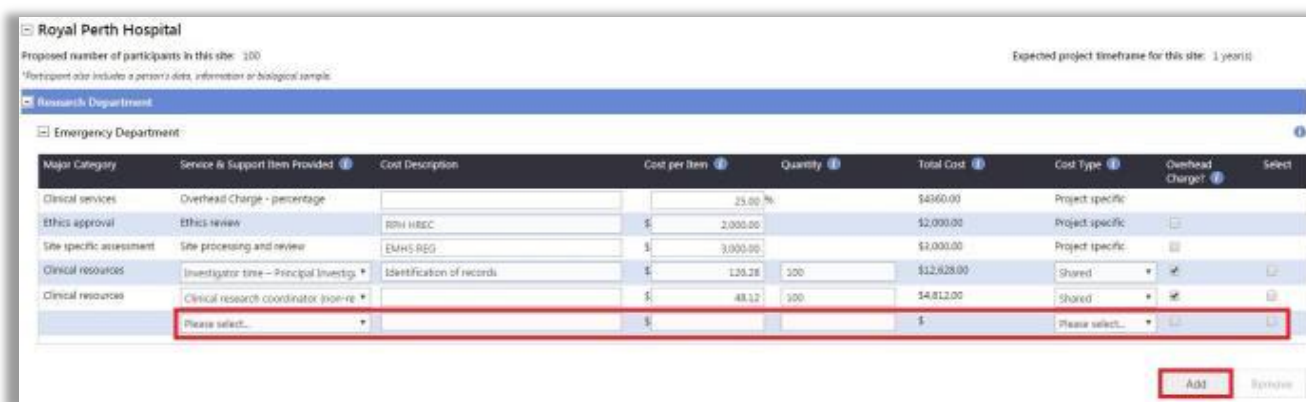
1. Ensure that you have clicked 'Edit'. The PI/PI Delegate can enter the following items as required for the research department and third party agency. They can also add items for the supporting departments (but cannot authorise the supporting department costs):

<b>Major Category</b> <b>Service &amp; Support Item Provided</b>	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.
---------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

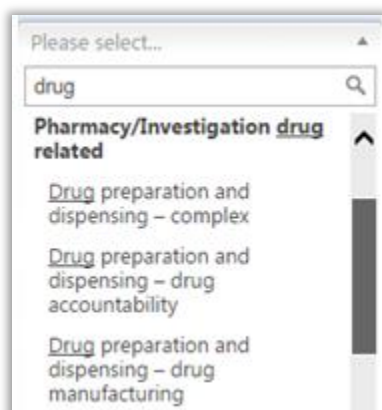


<b>Cost Description</b>	Provide comment or description of the service or support item provided if the Service & Support Item does not give enough detail.
<b>Cost per Item</b>	Provide the individual cost per service or support item e.g. cost per test/procedure or salary per participant.
<b>Quantity</b>	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).
<b>Total Cost</b>	This is calculated as the total cost per service or support item for the whole site, for the proposed number of participants.
<b>Cost Type</b>	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.
<b>Overhead Charge?</b>	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 <u>percentage</u> must be nominated in the 'Overhead charge' item found under the Research Department; otherwise, if none of the items is ticked, a <u>fixed amount</u> must be provided in the field.
<b>Select</b>	Tick this to remove an item. When an item is selected, the 'Remove' button will be enabled. <i>This does NOT have to be ticked when adding a service or support item, or authorising/declining the department.</i>

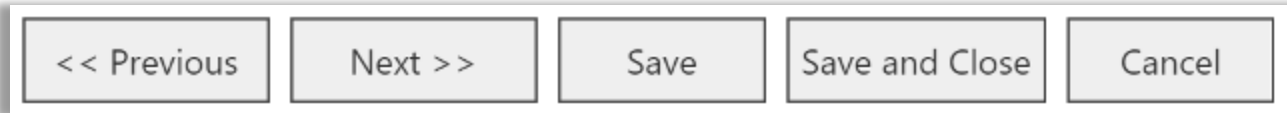
2. To add a service and support item click 'Add'. After clicking 'Add', a blank row will be added at the bottom of the list.



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:

Royal Perth Hospital  
Proposed number of participants in this site: 100  
\*Participant also includes a person's date, information or biological sample  
Expected project timeframe for this site: 1 year(s)

**Research Department**

**Emergency Department**

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?
Clinical services	Overhead Charge - percentage		25.00%	1	\$495.00	Project specific	No
Ethics approval	Ethics review	RPH HREC	\$2,000.00	1	\$2,000.00	Project specific	No
Site specific assessment	Site processing and review	EMHS RRG	\$3,000.00	1	\$3,000.00	Project specific	No
Clinical resources	Investigator time - Principal Investigator	Identification of records	\$128.28	100	\$12,828.00	Shared	Yes
Clinical resources	Clinical research coordinator (non-research market time)		\$48.12	100	\$4,812.00	Shared	Yes

**Supporting Department**

**Pharmacy**

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?
Pharmacy (Investigation drug related)	Drug preparation and dispensing - simple	Dispensing Fee	\$40.00	50	\$2,000.00	Project specific	No

**Third Party Agency**

**SRG Radiology SRG Subiaco Hospital**

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?
Clinical services	Imaging examinations and procedures	CT Scan	\$590.00	50	\$28,000.00	Project specific	No

### 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.

Royal Perth Hospital  
Proposed number of participants in this site: 100  
\*Participant also includes a person's date, information or biological sample  
Expected project timeframe for this site: 1 year(s)

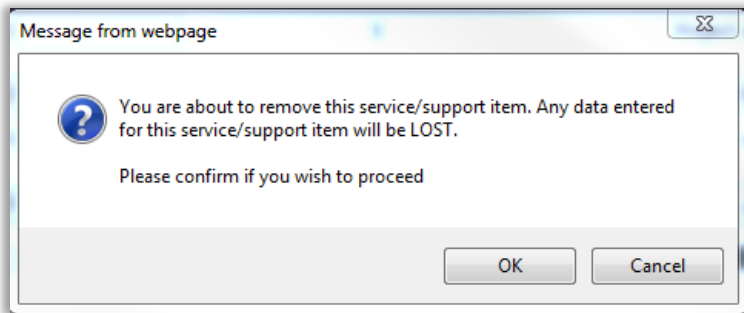
**Research Department**

**Emergency Department**

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?	Select
Clinical services	Overhead Charge - percentage		25.00%		\$495.00	Project specific		
Ethics approval	Ethics review	RPH HREC	\$2,000.00		\$2,000.00	Project specific		
Site specific assessment	Site processing and review	EMHS RRG	\$3,000.00		\$3,000.00	Project specific		
Clinical resources	Investigator time - Principal Investigator	Identification of records	\$128.28	100	\$12,828.00	Shared		<input checked="" type="checkbox"/>
Clinical resources	Clinical research coordinator (non-re)		\$48.12	100	\$4,812.00	Shared		<input checked="" type="checkbox"/>
	Please select...		\$		\$	Please select...		<input checked="" type="checkbox"/>

Add Remove

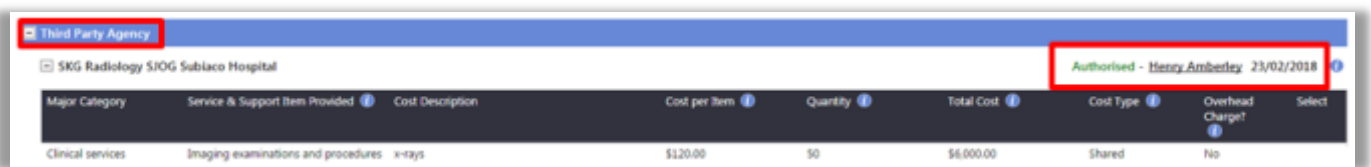
2. A confirmation message will be shown. Click 'OK' if you wish to proceed with the deletion; otherwise, click 'Cancel'.



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 completed 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):

<b>Amount of Funding by Sponsor or Funder</b>	Provide the dollar amount of funding per cost item.
<b>Sponsor Funder Name</b>	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.
<b>Amount of In-Kind Support</b>	Provide a dollar amount for all in-kind support provided per cost item.
<b>In-Kind Funder Name</b>	Provide the source of in-kind support i.e. sponsor or departmental support.
<b>Fund Description</b>	Provide comment or description of the service or support item funded if the funder describes it differently.

The screenshot displays the 'Section 3 of 3 - Site Project Funding / Support' section of the Budget Form. It includes a summary table at the top with the following data:

Total Actual Costs	\$56,800.00	Total Authorised Costs	\$28,000.00	Total Funding	\$57,060.00	Shortfall (or Surplus)	\$29,060.00
		Project specific costs	\$28,000.00	Funding amount	\$52,060.00		
		Shared costs	\$0.00	In-kind support	\$5,000.00		

Below this is a table of 'Available Funders' with columns for Name, Type of Funder, Funding by Sponsor or Funder, In-kind Support, Funding Status, and Remove. Funders listed include East Metropolitan Health Service Executive, Pfizer Australia, and Royal Perth Hospital.

The 'Research Department' section is expanded to show a table of cost items. A red box highlights the funding details for these items:

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Qty	Total Cost	Cost Type	\$ Funding by Sponsor or Funder	Sponsor Funder Name	\$ In-Kind Support	In-Kind Funder Name	Fund Description
Clinical services	Overhead Charge		25.00%	1	\$4,380.00	Project specific	\$ 4,380.00	Pfizer Australia	\$ 0.00	Please select...	
Ethics approval	Ethics review	RPM HREC	\$2,000.00	1	\$2,000.00	Project specific	\$ 0.00	Please select...	\$ 2,000.00	East Metropolitan He	
Site specific assessment	Site processing and review	EMHS RSG	\$3,000.00	1	\$3,000.00	Project specific	\$ 0.00	Please select...	\$ 3,000.00	East Metropolitan He	
Clinical resources	Investigator time - Principal Investigator	Identification of records	\$126.28	100	\$12,628.00	Shared	\$ 12,700.00	Pfizer Australia	\$ 0.00	Please select...	
Clinical resources	Clinical research coordinator (non-research nurse) time		\$48.12	100	\$4,812.00	Shared	\$ 5,000.00	Pfizer Australia	\$ 0.00	Please select...	

#### 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.

This screenshot shows the bottom portion of the Budget Form, including the summary table and navigation buttons. The summary table data is as follows:

Total Actual Costs	\$56,800.00	Total Authorised Costs	\$56,800.00	Total Funding	\$57,060.00	Shortfall (or Surplus)	\$29,060.00
--------------------	-------------	------------------------	-------------	---------------	-------------	------------------------	-------------

### 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 PI/Delegate 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.

Department Name	Type	Head Of Dept	Initiation Status	Initiated By	HoD Delegate	Initiation Status	Initiated By	Authorisation Status
General Medicine	Research Department	<a href="#">Jonathan David</a>	Accepted	<a href="#">Helen Armitage</a>				Authorised
Pharmacy	Supporting Department	<a href="#">Albert Woodcock</a>	Accepted	<a href="#">Helen Armitage</a>	<a href="#">Jane Mitchell</a>	Accepted	<a href="#">Helen Armitage</a>	Authorised
SIG Radiology: SIG Subbase Hospital	Third Party Agency	<a href="#">Helen Armitage</a>	Pending					Authorised

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 Applications 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

Supporting documents can be added at any time in the Applications tab after the project workspace has been approved. Project Details do not have to be authorised.

#### 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

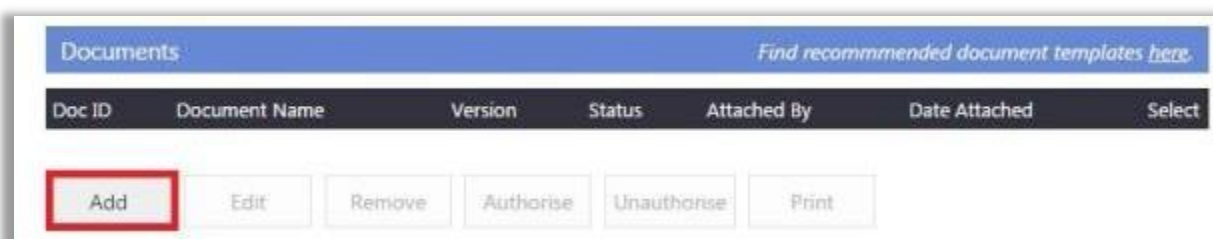
In addition to forms, you can add governance supporting documents relevant to your project (e.g. sponsor contracts, site participant information and consent forms, insurance certificates and indemnity forms).

#### Process for Ethics and Governance

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



2. Under the appropriate section (i.e. Ethics Approval or Site Authorisation), 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 'Applications' tab.

The screenshot shows the 'Add Project Documents' form for an 'Ethics Approval Document'. The PRN is RG5000002133 and the project title is 'Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication'. The document type is 'Participant Information Sheet and Consent Form (Master)'. The document name is 'Master Participant Information Sheet and Consent Form'. A note states: '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.' The status is 'Not attached'. Under 'Document Details', the version number is 1 and the version date is 19/02/2018. The document is identified as a 'Soft copy (electronic)'. A file named 'Master PICF ...y 2018.docx' is selected for upload.

The screenshot shows the 'Add Project Documents' form for a 'Site Authorisation Document'. The PRN is RG5000002103 and the project title is 'A Randomized, Double-Blind, Placebo Controlled Study of Venetoclax Co-Administered with Low Dose Cytarabine Versus Low Dose Cytarabine in Treatment Naive Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy'. The document category is 'Governance documents (drafts)'. The document type is 'CTRA - MA Standard Form (Form A)'. A note states: 'Please add a SSA form before attaching a draft supporting agreement. You don't have to submit the SSA form at this time with the draft agreement.' The document name is 'SCGH GSK Draft Agreement'. The associated form is 'Site Specific Assessment (SSA) Form (Sir Charles Gairdner Hospital)'. The status is 'Not attached'. Under 'Document Details', the version number is 1 and the version date is 10/01/2018. The document type is set to 'Please select...'. A file named 'RA University...ey draft.pdf' is selected for upload.

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

The screenshot shows the 'Hard Copy (Paper) Document' form. The question is 'Following submission, at what address/place will the hard copy be located?'. The answer entered is 'EMHS RG Office'.

The screenshot shows the 'Upload Soft Copy (Electronic) File' form. The question is 'Select file:'. The answer is 'RA University...ey draft.pdf'.

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 is set to 'Authorised'. If the document is a hardcopy then there will be no hyperlink in the name.

The screenshot shows the 'Documents' table with the following data:

Doc ID	Document Name	Version / Date	Status	Attached By	Date Attached	Select
8570	Master Participant Information Sheet and Consent Form	1 30/06/2018	Authorised	Joanna Smyth	26/09/2018	<input type="checkbox"/>
8571	Investigator Brochure	6 20/04/2018	Authorised	Joanna Smyth	26/09/2018	<input type="checkbox"/>

Below the table are buttons for 'Add', 'Edit', 'View', 'Remove', and 'Print'.

## 5.3 Edit a Supporting Document

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

Documents Find recommended document templates [here](#).

*Documents must have a status of authorised before they can be submitted.*

Doc ID	Document Name	Version / Date	Status	Attached By	Date Attached	Select
8570	Master Participant Information Sheet and Consent Form	1 30/06/2018	Authorised	<a href="#">Joanna Smyth</a>	26/09/2018	<input checked="" type="checkbox"/>
8571	Investigator Brochure	6 20/04/2018	Authorised	<a href="#">Joanna Smyth</a>	26/09/2018	<input type="checkbox"/>

Add Edit View Remove Print

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.

Edit Project Document

Ethics Approval Document

Document type: Recruitment Documents (letters)

Document name: Participant Introduction Letter

*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.*

Status: Attached

Latest Version

Document link/location: Participant Introduction Letter

Is hard copy (paper): No

Version number: 1      Version date: 10/01/2018      Document ID: 4437

Uploaded date: 19/02/2018      Uploaded by: Henry Amberley

Authorised date:      Authorised by:

Authorise

Update Document Details

Version number: 1      Version date: 09/01/2018

Is this a hard copy (paper) or soft copy (electronic) document? Soft copy (electronic)

Upload Soft Copy (Electronic) File

Select file: Choose file Pain Survey, ...ary 2018.pdf

Save Close

## 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.

Documents Find recommended document templates [here](#).

*Documents must be authorised before they can be submitted by the CPI or CPI Delegate. If you are unable to download documents, use Google Chrome.*

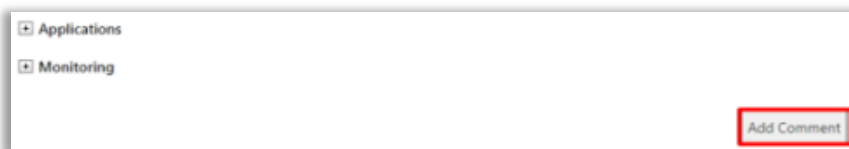
Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
8570	Master Participant Information Sheet and Consent Form	1	Authorised	<a href="#">Joanna Smyth</a>	26/09/2018	<input checked="" type="checkbox"/>
8571	Investigator Brochure	6	Authorised	<a href="#">Joanna Smyth</a>	26/09/2018	<input type="checkbox"/>

## 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.

Add Comment

Title\*

Category\* Please Select

Site(s) Please select...

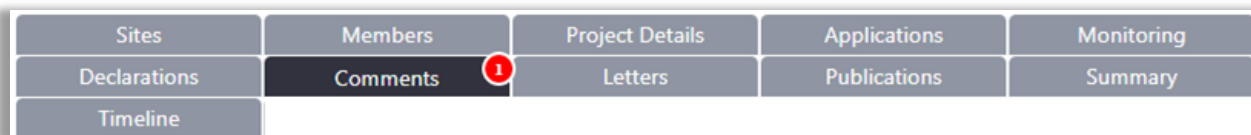
Description\* 

**B** *I* U

Words: 0/5000

Save Cancel

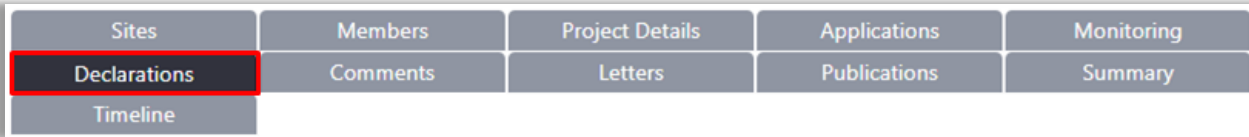
4. If the comment was successfully posted, it should appear under the category and the site(s) selected after clicking 'Save'. The Comments tab will notify anyone going to the project workspace that there is a new comment there for the next 7 days. The number of days is shown in the red circle.



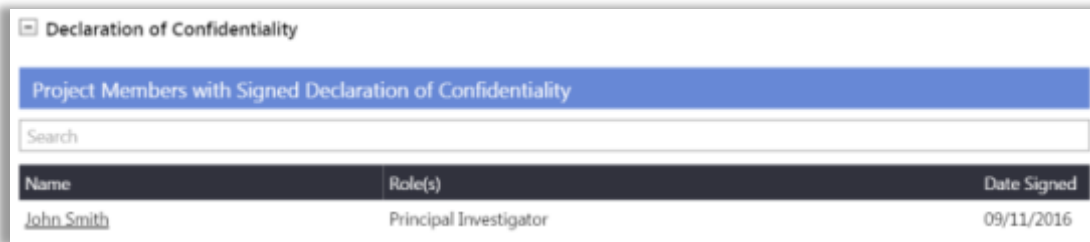
## 7. View or Add a Declaration

### View a Declaration

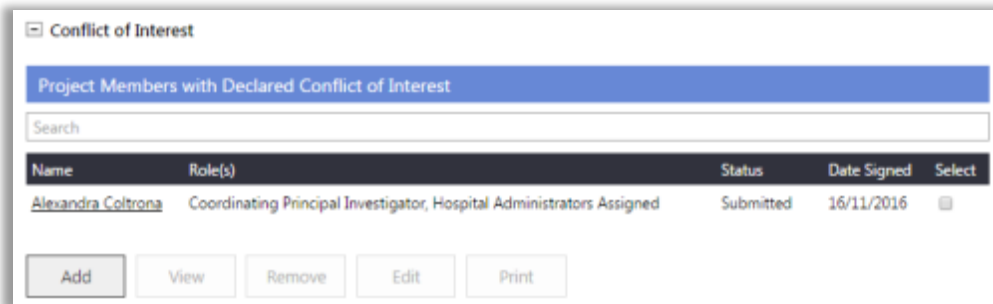
1. To view all Project Members who have signed the Declaration of Confidentiality (DOC) or Conflict of Interest (Col) Form, click on the 'Declarations' tab in the project's workspace.



2. The Declaration of Confidentiality section will show the list of Project Members who have signed the DOC. This is signed when accepting an invitation to the project. If the form has not been signed the person will have to be removed as a project member and then invited again.



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



### Add a Conflict of Interest Declaration

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

### WA Health Conflict of Interest Form

**1. Project Details**

1.1 PRN: RGS0000002104  
1.2 Project title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis

**2. Declaration of Interest**

2.1 Do you (or any relative or related entity) have an affiliation with the provider of the funding/support that may involve a financial or partiality conflict of interest?

2.2 Do you (or any relative or related entity of you) have an interest in the outcome of the research that may involve a financial or partiality conflict of interest?

**5. Declaration**

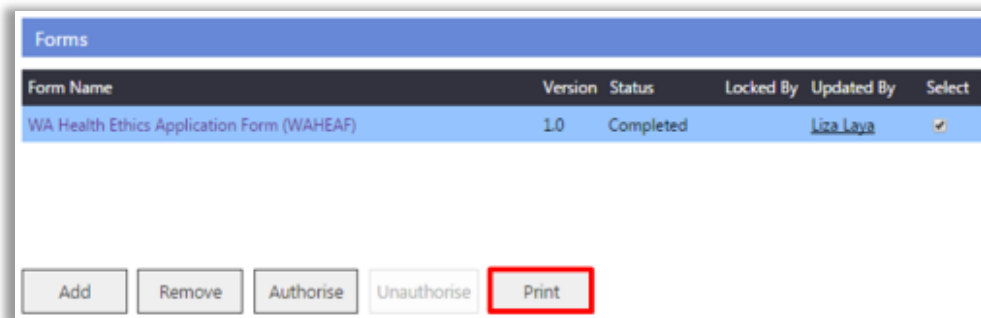
I declare the information in this form is truthful and accurate to the best of my knowledge.  
Please note that signing this COI will automatically submit the form. Please click 'Sign' to confirm.

Name	Role(s)	Signature
<a href="#">Alison French</a>	PI	<input type="text" value="Signature"/> <input type="button" value="Sign"/>

## 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 Applications tab (do not select a form or document at this stage).

The screenshot shows the 'Ethics Approval' interface. It has a header 'Ethics Approval' and a sub-header 'Active'. There are two main sections: 'Forms' and 'Documents'. Both sections have a table of authorised items and a 'Submit to Ethics' button at the bottom right.

**Forms**

Form Name	Version	Status	Locked By	Updated By	Select
WA Specific Module (WASM)	1.0	Authorised		Henry Amberley	<input type="checkbox"/>

**Documents**

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
4444	HREA	1	Authorised	Henry Amberley	23/02/2018	<input type="checkbox"/>
4435	Master Participant Information Sheet and Consent Form	1	Authorised	Henry Amberley	19/02/2018	<input type="checkbox"/>
4446	Pain Management Questionnaire	1	Authorised	Henry Amberley	23/02/2018	<input type="checkbox"/>
4437	Participant Introduction Letter	1	Authorised	Henry Amberley	19/02/2018	<input type="checkbox"/>
4445	Research Protocol	1	Authorised	Henry Amberley	23/02/2018	<input type="checkbox"/>

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'.

The screenshot shows the 'Submit Project To Ethics' screen. It has a title bar 'Submit Project To Ethics' and a close button. The screen is divided into several sections: 'Project title', 'Select the HREC for Submission', and 'Select the Forms and Documents for Submission'. The 'Project title' section contains the text 'Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication'. The 'Select the HREC for Submission' section shows 'Jurisdiction: Western Australia' and 'HREC: Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics C'. The 'Select the Forms and Documents for Submission' section contains two tables. The first table shows the 'WA Specific Module (WASM)' form selected. The second table shows several documents selected for submission.

**Project title:**  
Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication

**Select the HREC for Submission**

**Jurisdiction:**  
Western Australia

**HREC:**  
Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics C

**Select the Forms and Documents for Submission**

Form Name	Version	Status	Select
WA Specific Module (WASM)	1.0	Authorised	<input checked="" type="checkbox"/>

Document Type	Document Name	Version	Status	Select
Participant Information Sheet and Consent Form (Master)	Master Participant Information Sheet and Consent Form	1	Authorised	<input checked="" type="checkbox"/>
Recruitment Documents (letters)	Participant Introduction Letter	1	Authorised	<input checked="" type="checkbox"/>
Human Research Ethics Application (HREA)	HREA	1	Authorised	<input checked="" type="checkbox"/>
Protocol	Research Protocol	1	Authorised	<input checked="" type="checkbox"/>
Research Tools (questionnaires, surveys)	Pain Management Questionnaire	1	Authorised	<input checked="" type="checkbox"/>

If you wish to add comments about this submission, please go to the Comments tab.

Buttons: Cancel, Submit to Ethics

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 Applications tab.

Thank you. Your ethics submission was successful.

**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.

Submit Project To Ethics

Project

PRN: RGS0000002109

Project title: Test 1: National Mutual Acceptance - Lead WA Health HREC with Specialist HREC

Select the HREC for Submission

Jurisdiction: Western Australia

HREC: Please select

- Royal Perth Hospital HREC (EC00270)
- Department of Health WA Human Research Ethics Committee (EC00422)

If you wish to add comments about this submission, please go to the Comments tab.

Cancel Submit Project

2. The forms and documents will move to the 'Submitted' section of the Applications tab. Because you have nominated the specialist HREC the Submit to Ethics button is still enabled. Click 'Submit to Ethics'.

Submitted

Submit to Ethics

Forms

Royal Perth Hospital HREC

Form Name	Version	Status	Submission Date	Validation Date	Review Decision Date	Approval Decision Date	Select
WA Specific Module (WASM)	1.0	Submitted	16/06/2017				<input type="checkbox"/>



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.

Select the HREC for Submission

Jurisdiction: Western Australia

HREC: Department of Health WA Human Research Ethics Committee (EC00422)

Select the Forms and Documents for Submission

Form Name	Version	Status	Select
WA Specific Module (WASM)	1.0	Submitted	<input checked="" type="checkbox"/>

Document Type	Document Name	Version	Status	Select
Human Research Ethics Application (HREA)	Human Research Ethics Application	1.00	Submitted	<input checked="" type="checkbox"/>
Protocol	Protocol NMA Test 2	1.00	Submitted	<input checked="" type="checkbox"/>

If you wish to add comments about this submission, please go to the Comments tab.

Cancel Submit Project

4. The forms and documents will appear under the 'Submitted' section in the Applications tab, one set for each HREC.

Submitted

Forms

Royal Perth Hospital HREC

Form Name	Version	Status	Submission Date	Validation Date	Review Decision Date	Approval Decision Date	Select
WA Specific Module (WASM)	1.0	Submitted	16/06/2017				<input type="checkbox"/>

Department of Health WA Human Research Ethics Committee

Form Name	Version	Status	Submission Date	Validation Date	Review Decision Date	Approval Decision Date	Select
WA Specific Module (WASM)	1.0	Submitted	16/06/2017				<input type="checkbox"/>

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

1. For NMA, if an External HREC (outside of WA Health) 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.**

Submit Project To Ethics

Project

PRN: RGS000002113

Project title: Test 1: National Mutual Acceptance - External Lead HREC with Specialist HREC

Select the HREC for Submission

Jurisdiction: Western Australia

HREC: Department of Health WA Human Research Ethics Committee (EC00422)

Select the Forms and Documents for Submission

Form Name	Version	Status	Select
WA Specific Module (WASM)	1.0	Authorised	<input checked="" type="checkbox"/>

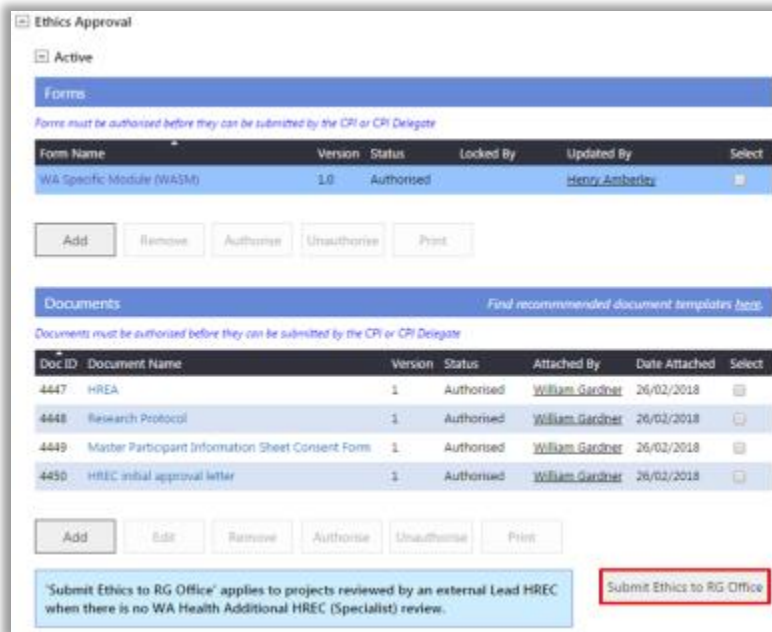
Document Type	Document Name	Version	Status	Select
Human Research Ethics Application (HREA)	Human Research Ethics Application	1.00	Authorised	<input checked="" type="checkbox"/>
Protocol	Protocol NMA Test 1	1.00	Authorised	<input checked="" type="checkbox"/>

If you wish to add comments about this submission, please go to the Comments tab.

Cancel Submit Project

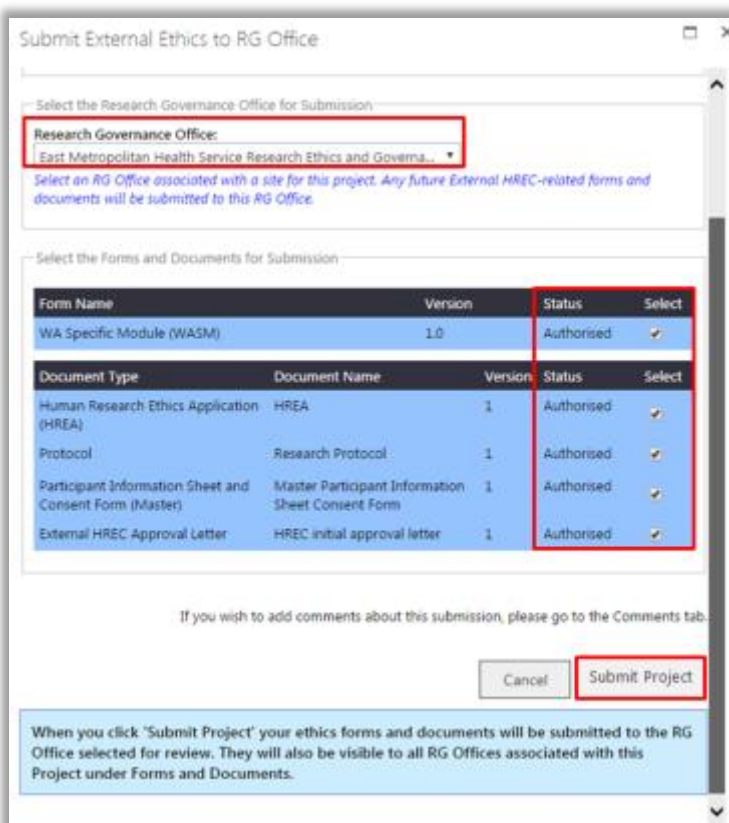
### 9.1.3 External Lead HREC Only

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.

Thank you. Your 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 Applications tab in the Submitted section. Click on the link (View) under 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'.

The screenshot shows the 'Submitted' section of a web application. It is divided into two main sections: 'Forms' and 'Documents'. Both sections are for the 'Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee'.

**Forms Section:**

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 <a href="#">View</a>			<input checked="" type="checkbox"/>

Below the table is a 'Print' button.

**Documents Section:**

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 <a href="#">View</a>			<input type="checkbox"/>
4437	Participant Introduction Letter	1	Valid	23/02/2018	26/02/2018 <a href="#">View</a>			<input type="checkbox"/>
4444	HREA	1	Valid	23/02/2018	26/02/2018 <a href="#">View</a>			<input checked="" type="checkbox"/>
4445	Research Protocol	1	Valid	23/02/2018	26/02/2018 <a href="#">View</a>			<input type="checkbox"/>
4446	Pain Management Questionnaire	1	Valid	23/02/2018	26/02/2018 <a href="#">View</a>			<input type="checkbox"/>

Below the table are 'View' and 'Print' buttons.

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

**View Validation Assessment**

PRN: RGS0000002133 Submission Date: 23/02/2018

Project: Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication

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

List of Forms and Documents

**Forms**

Name	Version	Validation Assessment	Comments
WA Specific Module (WASM)	1.0	Valid	

**Documents**

Name	Version	Version Date	Validation Assessment	Comments
Master Participant Information Sheet and Consent Form	1	19/02/2018	Valid	
Participant Introduction Letter	1	10/01/2018	Valid	
HREA	1	10/01/2018	Valid	
Research Protocol	1	10/01/2018	Valid	
Pain Management Questionnaire	1	10/01/2018	Valid	

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. **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 '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.

Active

**Forms**

Form Name	Version	Status	Locked By	Updated By	Select
WA Specific Module (WASM)	2.0	Pending			<input type="checkbox"/>

4. **If a document is given the validation status of 'AIR' in the 'Submitted' grid, then the additional information is provided in a new version of document which once uploaded can be submitted for validation and review.**

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			<input type="checkbox"/>

### 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:

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	06/12/2017	30/11/2017	

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	06/12/2017	30/11/2017	
3386	Study Protocol	1	Approved	14/08/2017	14/08/2017	06/12/2017	30/11/2017	
3385	Participant Information Sheet and Consent Form	2	Approved	26/09/2017	26/09/2017	06/12/2017	30/11/2017	
3385	Participant Information Sheet and Consent Form	1	AIR	14/08/2017	14/08/2017	14/08/2017		

- '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.

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 Committee for review at the next Committee meeting.

4. Following a review (at an ethics committee meeting) If the Committee requires revisions to a document and has marked it as **'Additional Information Required' (AIR) in the 'Submitted' grid.** You must upload the revised document version that addresses the Committee's review comments, which should then be submitted to the Committee for review at the next Committee meeting.

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

PROJECT | A pilot investigation into the early adjunctive use of virtual game therapy and the effects on patient motivation, pain management, coping behaviour and mobility of patients with burns

Feasibility Assessment | Document Preparation | Submission and Review | **Approval and Authorisation** | Monitoring | Archived

PRN: RGS0000000003	Project status: Active	<b>Project ethics approval status: Approved</b>
Project type: Research	Short title:	
Protocol number: 125load	Acronym:	CPI: <a href="#">Henry Amberley</a>
External HREC ref: None	Lead HREC: Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee (EC00271)	

## 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 Applications tab.

The screenshot displays the 'Site Authorisation' interface. It is divided into two main sections: 'Forms' and 'Documents'.  
**Forms Section:**  
- Header: 'Forms' (blue bar)  
- Note: 'Forms must be authorised before they can be submitted by the PI or PI Delegate. The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.'  
- Filter: 'Active'  
- Site: 'Sir Charles Gairdner Hospital' (expanded)  
- Table:  
| Form Name | Version | Status | Locked By | Updated By | Select |  
|---|---|---|---|---|---|  
| Site Specific Assessment (SSA) Form | 1.0 | Authorised | | Henry Amberley |  |  
| Budget Form | 1.0 | Authorised | | Alison French |  |  
- Site: 'Royal Perth Hospital' (collapsed)  
- Buttons: Add, Remove, Authorise, Unauthorise, Print  
**Documents Section:**  
- Header: 'Documents' (blue bar) with link: 'Find recommended document templates [here](#).'  
- Note: 'Documents must be authorised before they can be submitted by the PI or PI Delegate'  
- Filter: 'Form / Site(s)'  
- Site: 'Site Specific Assessment (SSA) Form (Sir Charles Gairdner Hospital)' (expanded)  
- Table:  
| Doc ID | Document Name | Version | Status | Attached By | Date Attached | Select |  
|---|---|---|---|---|---|---|  
| 88 | Research Agreement | 1.00 | Authorised | Henry Amberley | 20/10/2016 |  |  
| 108 | certificate of currency | 1.00 | Authorised | Henry Amberley | 20/10/2016 |  |  
| 116 | SCGH Participant Information Sheet and Consent Form | 1.00 | Authorised | Henry Amberley | 20/10/2016 |  |  
- Buttons: Add, Edit, Remove, Authorise, Unauthorise, Print  
- A red box highlights the 'Submit to Governance' button at the bottom right.

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 each 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**

Thank you. Your governance submission was successful.

**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.

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Site Specific Assessment (SSA) Form	1.0	Valid	07/03/2018	07/03/2018 <a href="#">View</a>			<input type="checkbox"/>
Budget Form	1.0	Valid	07/03/2018	07/03/2018 <a href="#">View</a>			<input type="checkbox"/>



The outcome of the validation process is viewable in the Applications tab in the Submitted section.

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

View Validation Assessment

PRN: RGS0000002133 Submission Date: 07/03/2018

Project: Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication

Site: Sir Charles Gairdner Hospital

List of Forms and Documents

**Forms**

Name	Version	Validation Assessment	Comments
Site Specific Assessment (SSA) Form	1.0	Valid	
Budget Form	1.0	Valid	

**Documents**

Name	Version	Version Date	Validation Assessment	Comments
------	---------	--------------	-----------------------	----------

Close

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.

Forms

The Budget Form must be completed and authorised before submitting the SSA Form to the Business Manager and Divisional Director for authorisation.

Site / Organisation

Department of Health

Royal Perth Hospital

Form Name	Version	Status	Locked By	Updated By	Select
Site Specific Assessment (SSA) Form	2.0	Pending			<input type="checkbox"/>

Add Remove Authorise Unauthorise Print

4. If a document is given the validation status of 'AIR' in the 'Submitted' grid. A new version of the document has to be added and submitted.

5. If the review assessment is 'Not Valid', 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:

Submission Date	Validation Date	Review Decision	Review Completion Date	Authorisation Decision	Authorisation Decision Date
02/08/2017	02/08/2017	Recommended	02/08/2017	Authorised	03/08/2017

2. You can track the approval of your projects forms & documents in Applications 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
- ‘Authorisation 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.

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Site Specific Assessment (SSA) Form	1.0	Approved	04/08/2017	04/08/2017 <a href="#">View</a>	18/01/2018	18/01/2018	<input type="checkbox"/>
Budget Form	1.0	Approved	04/08/2017	04/08/2017 <a href="#">View</a>	18/01/2018	18/01/2018	<input type="checkbox"/>

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.

Submitted

Forms

East Metropolitan Health Service Research Ethics and Governance Unit

Site / Organisation

Royal Perth Hospital

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Site Specific Assessment (SSA) Form	1.0	Under review	14/09/2017	14/09/2017 View	11/01/2018		<input type="checkbox"/>
Budget Form	1.0	AIR	14/09/2017	14/09/2017 View	11/01/2018		<input type="checkbox"/>

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

Submitted

Forms

East Metropolitan Health Service Research Ethics and Governance Unit

Site / Organisation

Royal Perth Hospital

Form Name	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Site Specific Assessment (SSA) Form	1.0	Under review	14/09/2017	14/09/2017 View	11/01/2018		<input type="checkbox"/>
Budget Form	1.0	AIR	14/09/2017	14/09/2017 View	11/01/2018		<input type="checkbox"/>

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.

Documents

Child and Adolescent Health Service Research Governance Office

Form / Site(s)

Perth Children's Hospital

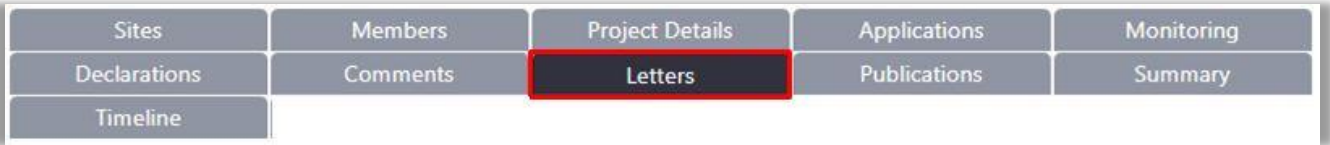
Doc ID	Document Name	Version	Status	Submission Date	Validation Date	Review Decision Date	Approval Decision Date	Select
1356	Insurance Certificate of Clumency	1.00	AIR	03/07/2017	03/07/2017	03/07/2017		<input type="checkbox"/>

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

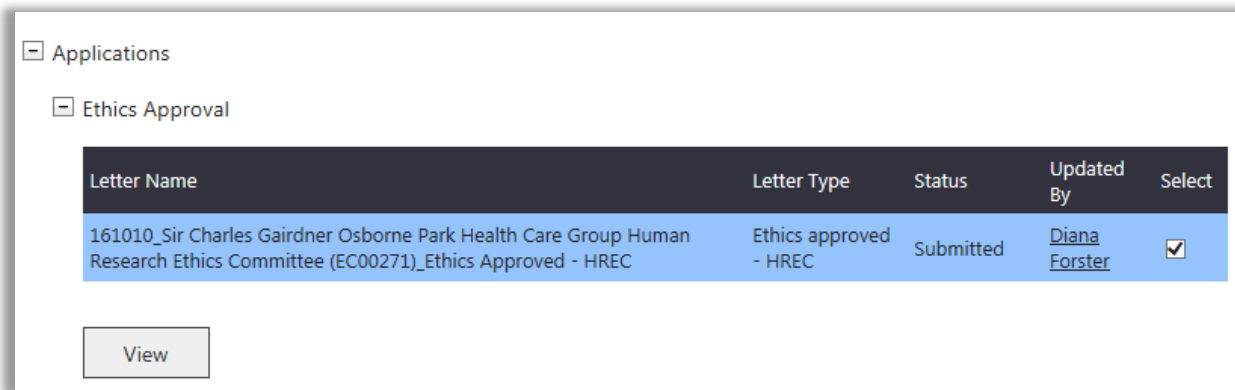
## 11. View Letters

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 and monitoring process, in the Letters tab. Any letter sent to the CPI or PI will have also been sent to them as an email.

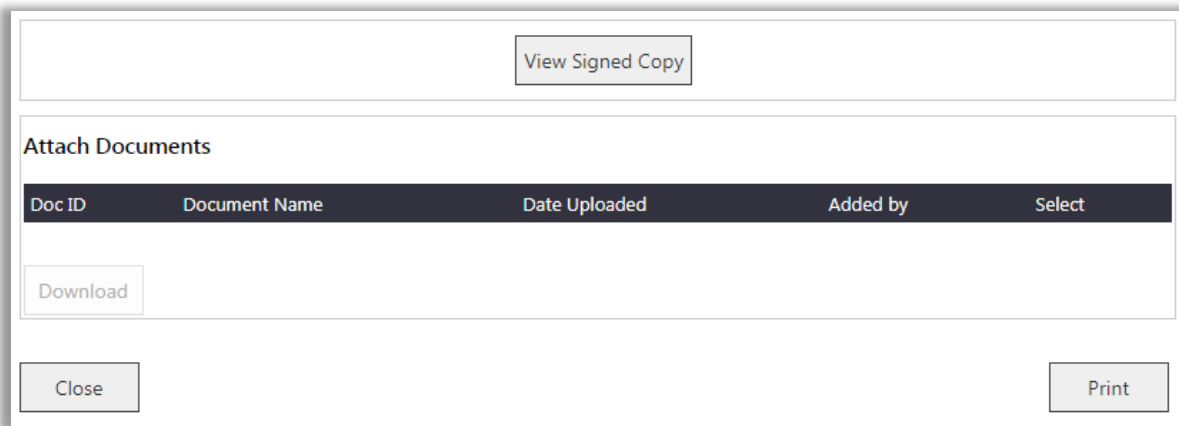
1. In the project workspace, click on the 'Letters' tab. The letters are divided, Applications has Ethics Approval and Site Authorisation and Monitoring has Ethics Monitoring and Governance Monitoring.



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. Clicking 'Close' will take you back to the Letters tab



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

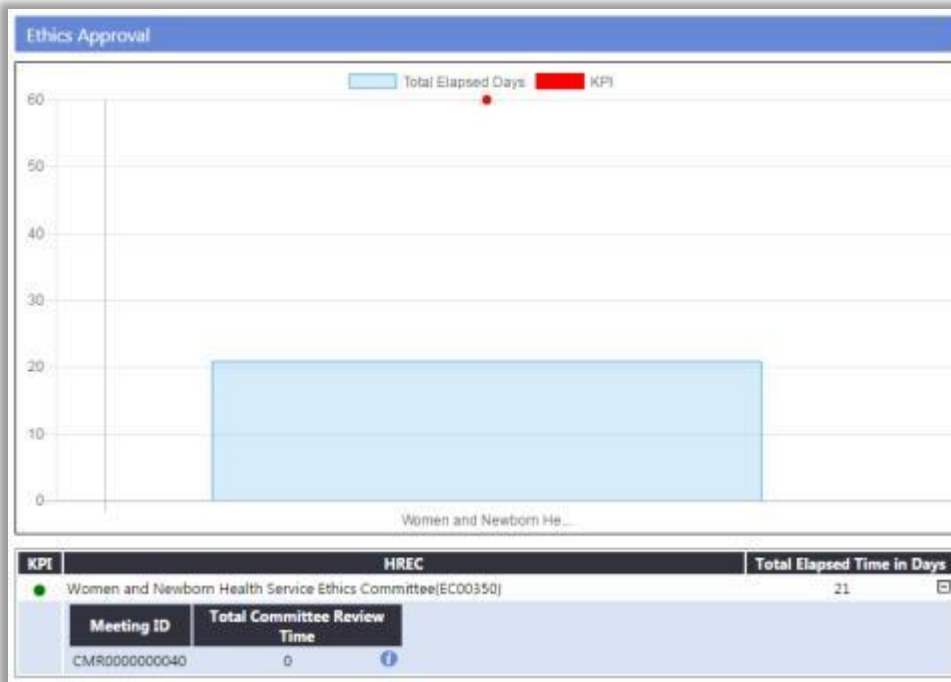
Project Members can track the review process of their project in the Timeline and Summary tabs.

### 12.1 Timeline

1. In the project workspace, click on the 'Timeline' tab.

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
<b>Timeline</b>				

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.

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	<b>Summary</b>
Timeline				

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

- General Project Details

General Project Details	
Project created date	04/08/2017
Single-centre or multi-centre project	Multi-centre
Broad research area	Public health research
NHMRC grouping of research	PUBLIC HEALTH AND HEALTH SERVICES
NHMRC fields of research	Health and Community Services
Broad health condition	Public Health
Specific condition	Health service research
Clinical trial phase	
Keywords	Multiple sites; Access Request; feasibility;
Research focus	Educational
Coordinating Principal Investigator organisation	Sir Charles Gairdner Hospital
Contact person for information and recruitment	Dr Henry Amberley
Contact person email	
Contact person phone	
Contact person address	Hospital Avenue, Nedlands, Western Australia 6009, Australia
Participant age group	18 - 70+;
Participant gender	All
Involves healthy volunteers	Yes
Publications	

Project Summary

- 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: \$0.00

+ Total Authorised Costs: \$0.00

+ Total Funding: \$0.00

+ Shortfall (or Surplus): \$0.00

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