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

Research Governance Service (RGS)

Hospital Administrator (HA)
User Guide

Version 3.0

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1. Role of Hospital Administrator (HA)

This role is allocated to a person, who is appointed to, or acting in, a position within the organisation that has to decide whether to provide resources or services to support a research project; or authorise the commencement of a project at a site. This may involve one or more of the following:

- Provision of information, including quotes, for departmental resources and/or services to enable the development of a budget for a project.
- Provision of either an authorisation or decline decision to provide departmental resources and/or services for a project on the governance application and budget.
- Review and decide whether to provide authorisation to conduct a project within a department or at a site.

This person can be a Head of Research Department (HoD), Head of Supporting Department (HoSD), Business Manager (BM), Divisional Director (DD), Regional Director (RD) or Chief Executive (CE).

1.1 Head of Research Department (HoD)

This role applies to a person that has been appointed to, or acting as a Head of Department within an organisation where the research project will be conducted i.e. the department which is spearheading the project at a site. The role has the following responsibilities:

- Reviews the project including the feasibility of conducting it within their department.

- Provides authorisation for the project to be conducted within the research department, including agreeing with the resources, services, costs and funding outlined in the budget form.

1.2 Head of Supporting Department (HoSD)

This role applies to a person that has been appointed to, or acting as a Head of a Supporting Department within an organisation where the project will be conducted i.e. the department which is providing resources or services to support the project. The role has the following responsibilities:

- Provides information and estimated costs in the budget, for their department to provide resources and/or services required for the conduct of the project.

- Provides either an authorisation or decline decision to provide departmental resources and/or services for a project on the budget form.

1.3 Business Manager (BM)

This role applies to a person that has been appointed to, or acting as a Business Manager responsible for the department intending to conduct a research project. The role has the following responsibilities:

- Reviews the budget to ensure that the costs that impact on the site is accurately reflected and funding for services and resources are identified and agreed to.

- Provides authorisation on the research governance form.

1.4 Divisional Director (DD)

This role applies to a person that has been appointed to, or acting as a Divisional Director with responsibility for the Division intending to conduct a research project. The role has the following responsibilities:

- Reviews the project to ensure that the services and resources are adequate to conduct the research project within the Division.

- Provides authorisation on the research governance form.

1.5   Regional Director (RD)

This role applies to a person that has been appointed to, or acting as, a Regional Director, within WA Country Health Services (WACHS), with responsibility for the site(s) where the research project will be conducted. The role has the following responsibilities:

- Reviews the project to ensure that the services and resources are adequate to conduct the research project within the Region.

- Provides authorisation on the research governance forms.

1.6   Chief Executive (CE)

This role applies to a person that has been appointed to, or acting as, the Chief Executive of the organisation. The role has the following responsibilities:

- Decides whether site authorisation should be given to a project, based on the HREC and research governance reviews, at a site to which they have responsibility.

- Provides site authorisation related to monitoring forms and supporting documents.

- Can suspend a project at a site if required.

1.7   CE Delegate

The CE can delegate their authorisation rights to a person within their organisation. The CE Delegate has the same access/security rights as the CE within RGS.

2.   Hospital Administrator Access

2.1   Sign Up as Hospital Administrator

All HAs will be required to complete the New User Sign Up form to gain access to the RGS. Refer to Help Wiki: Sign up as RGS User (for WA Health Employees).

All users of RGS are assigned the default of 'RGS User'. In addition, you must select 'Hospital Administrator' as well as any other applicable roles. Refer to Help Wiki: Roles in RGS.

2.2   Update an Existing User to a Hospital Administrator

The RGS Support can update the roles of RGS users. Users that require a HA role assigned to them after signing up to RGS, must email the RGS Support to request HA access.

3.   Fill Out and Authorise a Budget Form (Supporting Department)

Principal Investigators (PI) that require either a service or support for a research project from a supporting department (department which is providing resources or services to support the research department) must request a quote and authorisation from the Head of the Supporting Department (HoSD) or their delegate. The type of service/support, cost and funding (whether monetary or in-kind support) must be documented in the RGS Budget Form.

The PI will nominate the HoSD (or delegate) when they select the supporting departments in the Budget Form and send them an invitation to provide a service. This will allow the HoSD to:

- decline the request to provide a service
- edit and authorise the service/support items and costs in their departmental costing section of the form
- indicate in their departmental funding section whether they wish to provide a service in-kind.

PIs (or delegates) who wish to nominate a HoSD for a supporting department should refer to the Select the departments section within the Help Wiki: Fill out a Budget Form.

3.1   Invitation to Provide a Service

1. Once you are invited as a HoSD, you will receive an email. Click on the link to the RGS Task provided in the email. *Note that if you have not done so, you will need to login to RGS use the link to access the Tasks page.*

I am currently looking into the feasibility of conducting the research project above. In order to conduct this project, I will need to utilise the services and/or resources from your department.

This invitation through a 'Task', gives you access to the project, including the project's protocol and Budget Form associated with this site.

If you are the Head of the Research Department:

Please review the 'Site Project Budget' and 'Site Project Funding / Support' pages in the Budget Form to assess whether you are happy to provide authorisation for this project to be carried out in your Department. This can be done by clicking 'Authorise' under the Research Department section of the 'Site Project Budget'.

If you are unable to provide the service or resources, please click the 'Decline' button on the 'Site Project Budget' page and provide a comment why you are unable to provide the service and/or resources.

If you are the Head of a Supporting Department or Delegate:

As Head of a Supporting Department you may delegate some or all of the requirement for completing your department's section of the budget to a delegate, if you have nominated a delegate please be aware that within the budget they have the same rights as you. Only one person can authorise the department's costs. Please ensure your delegate is aware of what part of this task they are being allocated, it is implied that if a delegate authorises the department's cost within a budget they do so with your authority.

Please review the protocol to make an assessment of what services (e.g. imaging or pathology tests) and/or resources (e.g. staff to provide information or perform procedures) your department is able to provide to meet the requirements of the protocol.

Please detail the relevant services, resources and their costs, which will be provided by your department, in the 'Site Project Budget' page of the Budget Form. Once you have entered the information, please click the 'Authorise' button on your quote.

If you are unable to provide the service or resources, please click the 'Decline' button on the 'Site Project Budget' page and provide a comment why you are unable to provide the service and/or resources.

This project may be either commercially, non-commercially or investigator (self) funded. Please consider this when you are providing your quote as to whether any services can be provided in-kind. If you wish to provide in-kind support for a service, you can enter the amount under the '$ Amount of In-Kind Support' against the relevant cost item in the 'Site Project Funding /Support' page of the Budget Form, or alternatively, provide a comment.

Any comments related to costs and in-kind support can be added to the 'General Comments' field, or alternatively, please feel free to contact me directly.

Services and costs provided that will be subject to a payment from an external funder will be documented in an agreement with the external funder.

Please use the link below to action the task associated with this project.
RGS Task: | https://rgs.health.wa.gov.au/Pages/task-form.aspx?fm=V&tud=9325

Thank you for considering my project.

If you are not taken directly to the task, click on 'Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: All about Tasks.

2. In the Tasks page, click on the 'Request to Quote/Authorise' link found under My Tasks. If it is overdue it will be in the overdue section of Tasks and be coloured 'red'.

3. The Task Form will open, click 'Action' which will direct you to the project's Budget Form for the site which is requesting your department's services or support, or 'Cancel' to return to Tasks.

Click 'Decline the task' if you have received the task in error. You will unable to access the project Budget Form or related documentation.

3.2   Agree to Provide a Service and Authorise

Provide a Quote in a Budget Form

The Budget Form has 3 screens:

1. **Departmental Selection** – this section is completed by the PI and lists the Research Department, Supporting Departments and Third Party Agencies that will be involved in supporting the project and their nominated Heads of Department/delegates.

2. **Site Project Budget** – this section contains the costs of the project. It is:
   a. completed by the PI for the Research Department and Third Party Agency and authorised by the HoD
   b. completed and authorised by the HoSD.

3. **Site Project Funding / Support** – this section contains the costs of the project. It can be completed by the PI and HoSD.

1. In the Budget Form, click 'Edit'.
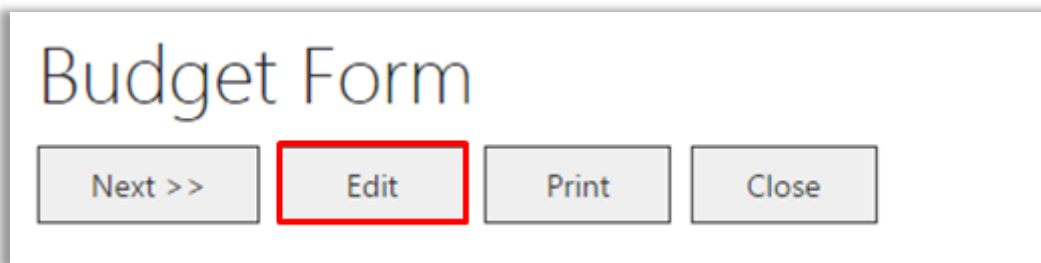
2. A confirmation message will appear. Click 'OK' to proceed.
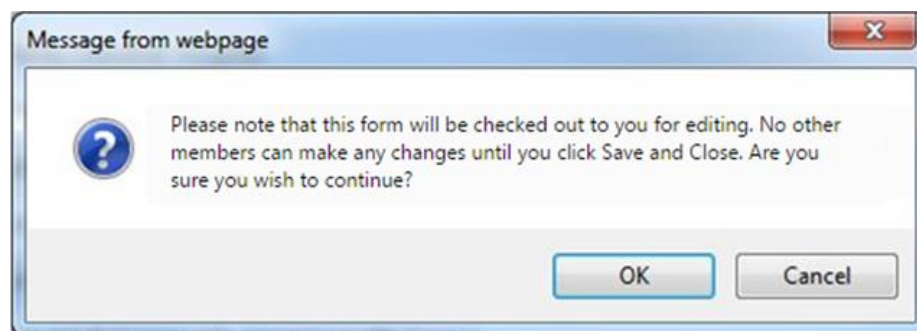
Take note that you are now on 'Edit' mode, and the form will be checked out to you until you click 'Save & Close'.
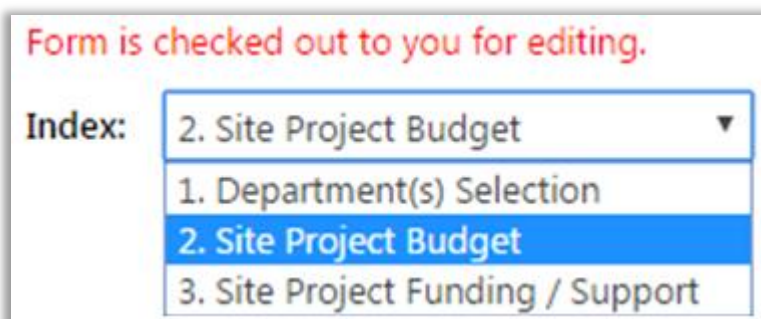
3. You can go to any section of the Budget by using the Index and selecting the section you want. Alternately you can click 'Next' or 'Previous' located at the top and bottom of the page.
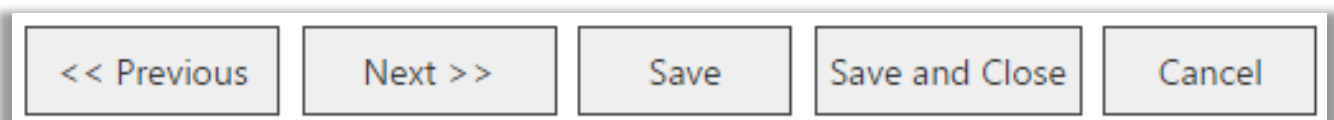
If you want to go to the 'Forms & Documents' tab to review the project's protocol or other documents in order to determine what services are required. You can right click on the tab and open a new tab or window.


4. In the 'Site Project Budget' you can add an item by clicking the 'Add' button. The Service & Support drop down menu has a search facility and will tailor the results based on what you type; the results will be any item with word in it. The list of service and support items that are available on the Help Wiki: Fill out and authorise a Budget Form (for a supporting department)
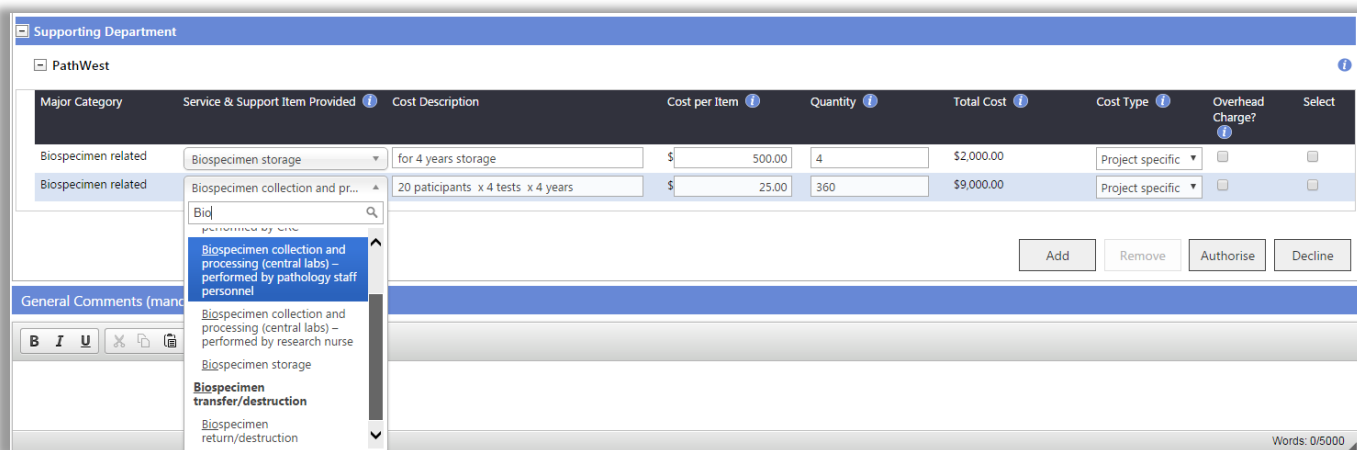
5. Based on the protocol, enter the service/support item, a cost description if required (i.e. the usual name of the item), cost and quantity. To calculate the quantity you should review, the number of participants and time frame of the project which is listed on the 'Department Selection' screen.

The PI may have already entered the service/support items and quantity; these can be edited before authorisation. If so, review the items against the protocol and enter the cost per item. **The screen can be expanded or you can drag the scroll bar found at the bottom of the grid to view the other columns.**

6. To remove an item prior to authorising, select the item and click 'Remove'.
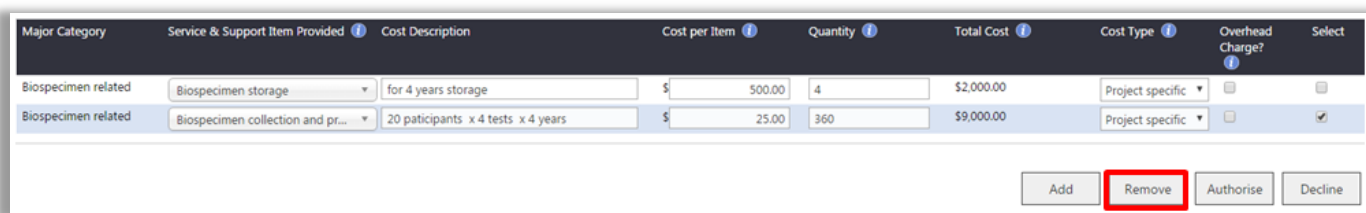
7. You can add a comment in the comments box at the bottom of the screen to notify the PI of any concerns related to the provision of services/support or nominate if any services will be provided as in-kind support. Any in-kind support can then be added against this item by you or the PI in the **Site Project Funding / Support** section of the Budget Form.
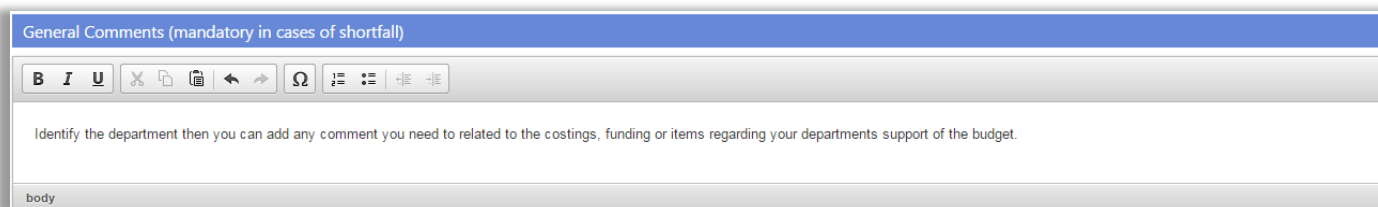
Authorise a Budget Form

 1. When you are ready to authorise, click on the 'Authorise' button, which is located at the bottom right hand side of your department's list of items.
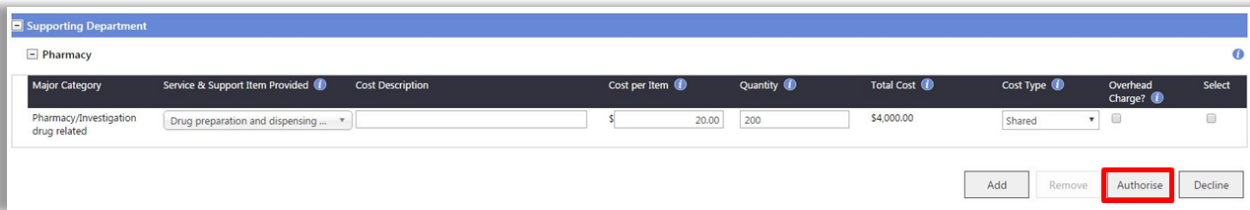

To confirm that you authorised your department's costs successfully, the department will display 'Authorised' with your name and the date of authorisation. No further items can be added to this section of the budget unless it is unlocked.

If you wish to make changes, click 'Unlock' and the previous authorisation will be removed. The items under the supporting department can be edited at this point. Remember that if the section of the budget is unlocked it will have to be authorised again. Press 'Save & Close' to save your changes and close the budget, this will make the budget available to other users.

3.3   Decline a Request to Provide a Service

1. If your department is unable to provide the services or support from your department for the research project, click on 'Decline'.
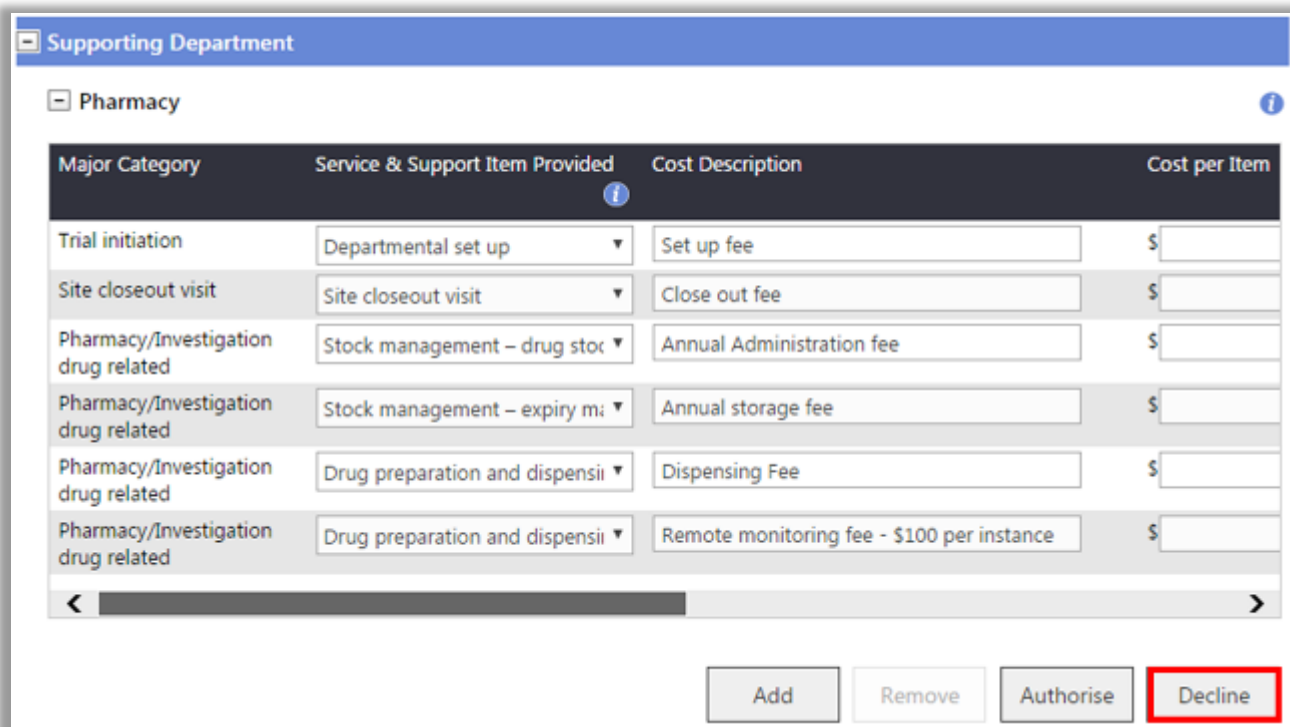
2. A comment screen will launch. You will need to provide a reason to the PI for declining the request to provide a service/support for the project.

3. Click 'Save' to proceed with declining the use of the services for your department.

After saving, if you wish to remove the comment or provide a new one, you will have to unlock this department, click 'Decline' again and provide a new comment.

To confirm that you declined the provision of your service successfully, the department will display 'Declined' with your name and the date of declining. If you hover-over the word 'Declined', the reason will be shown.

If you wish to make changes, click 'Unlock' and the previous authorisation will be reset. The items under the supporting department can be edited again at this point.

4. Authorise a Budget Form (Research Department HA)

The Head of the Research Department is required to authorise the Budget Form after reviewing:

- the Site Specific Assessment (SSA) Form to ensure they agree with the research project being conducted in their department
- the Budget Form (Section 2) for the costs of conducting the research project in their department
- the Budget Form (Section 3) to ensure that the costs for the whole site budget are covered by equivalent funding (whether monetary or in-kind support).

Note: If you are the PI and the Head of the Department for the research department you must have the research department budget authorised by your line manager.

The HoD will be invited to review and authorise the Budget Form once:

- the service department costs have been authorised by the **HoSD** in the **Site Project Budget**
- the research department, ethics/governance and third party agency costs have been entered by the PI/delegate in the **Site Project Budget**
- the funding has been entered against the research department and supporting departments costs in the **Site Project Funding / Support** by the PI/delegate

Third party agency

A third party agency is an external organisation that is providing a service for the research project. The PI should provide supporting documentation for the service and costs (i.e. a service agreement). This document should be available in the forms and documents tab.

PIs (or delegates) who wish to nominate a HoD for a research department should refer to the Select the departments section within the Help Wiki: Add, fill out and authorise a Budget Form.

4.1 Invitation to Authorise a Budget Form

1. Once you are invited as a HoD, you will receive an email. Click on the link to the RGS Task provided in the email. Note that if you have not done so, you will need to login to RGS to access the Tasks page.

I am currently looking into the feasibility of conducting the research project above. In order to conduct this project, I will need to utilise the services and/or resources from your department.

This invitation through a 'Task', gives you access to the project, including the project's protocol and Budget Form associated with this site.

If you are the Head of the Research Department:

Please review the 'Site Project Budget' and 'Site Project Funding / Support' pages in the Budget Form to assess whether you are happy to provide authorisation for this project to be carried out in your Department. This can be done by clicking 'Authorise' under the Research Department section of the 'Site Project Budget'.

If you are unable to provide the service or resources, please click the 'Decline' button on the 'Site Project Budget' page and provide a comment why you are unable to provide the service and/or resources.

If you are the Head of a Supporting Department or Delegate:

As Head of a Supporting Department you may delegate some or all of the requirement for completing your department's section of the budget to a delegate, if you have nominated a delegate please be aware that within the budget they have the same rights as you. Only one person can authorise the department's costs. Please ensure your delegate is aware of what part of this task they are being allocated, it is implied that if a delegate authorises the department's cost within a budget they do so with your authority.

Please review the protocol to make an assessment of what services (e.g. imaging or pathology tests) and/or resources (e.g. staff to provide information or perform procedures) your department is able to provide to meet the requirements of the protocol.

Please detail the relevant services, resources and their costs, which will be provided by your department, in the 'Site Project Budget' page of the Budget Form. Once you have entered the information, please click the 'Authorise' button on your quote.

If you are unable to provide the service or resources, please click the 'Decline' button on the 'Site Project Budget' page and provide a comment why you are unable to provide the service and/or resources.

This project may be either commercially, non-commercially or investigator (self) funded. Please consider this when you are providing your quote as to whether any services can be provided in-kind. If you wish to provide in-kind support for a service, you can enter the amount under the '$ Amount of In-Kind Support' against the relevant cost item in the 'Site Project Funding /Support' page of the Budget Form, or alternatively, provide a comment.

Any comments related to costs and in-kind support can be added to the 'General Comments' field, or alternatively, please feel free to contact me directly.

Services and costs provided that will be subject to a payment from an external funder will be documented in an agreement with the external funder.

Please use the link below to action the task associated with this project.
RGS Task: | https://rgs.health.wa.gov.au/Pages/task-form.aspx?fm=V&tud=9325

Thank you for considering my project.

If you are not taken directly to the task, click on 'Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: All about Tasks.

2. In the Tasks page, click on the 'Request to Quote/Authorise' link found under My Tasks. If it is overdue it will be in the overdue section of Tasks and be coloured 'red'.

Task Name	Task Outcome	Initiator	Created	Due Date
My Tasks				
▲ Task Type : Invitation to Provide Quote and Authorise/Decline in Budget Form (1)				
RGS0000002133 General Medicine - Request to Quote/Authorise	Pending	Henry Amberley	22/02/2018	1/03/2018

3. Upon opening the task, click 'Action' which will direct you to the project's Budget Form for the site you have been nominated as the Research Department HoD, or 'Cancel' to return to Tasks.

Task Form

Group task?	No
Task type:*	Invitation to Provide Quote and Authorise/Decline in Budget Form
PRN:*	RGS0000002133
Project title:*	Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication
Department:*	Pharmacy
Start date:	22/02/2018
Due date:*	1/03/2018
Assignee:*	Albert Macintosh
Task description:*	Invite HOD and HoSD to provide a quote and/or authorise/decline the Budget Form.

Action	Decline Task	Cancel

Please click "Action" to take you to the relevant screen to undertake a task.

Click 'Decline the task' if you have received the task in error. You will unable to access the project Budget Form or related documentation. If you have actioned the task already, click 'Finish Task'.

4.2   Authorise a Budget Form

The Budget Form has 3 screens:

a. **Departmental Selection** – this section is completed by the PI and lists the Research Department, Supporting Departments and Third Party Agencies that will be involved in supporting the project and their nominated Heads of Department/delegates.

b. **Site Project Budget** – this section contains the costs of the project. It is:
   - completed by the PI for the Research Department and Third Party Agency and authorised by the HoD
   - completed and authorised by the HoSD.

c. **Site Project Funding / Support** – this section contains the costs of the project. It can be completed by the PI and HoSD.

1. In the Budget Form, click 'Edit'.
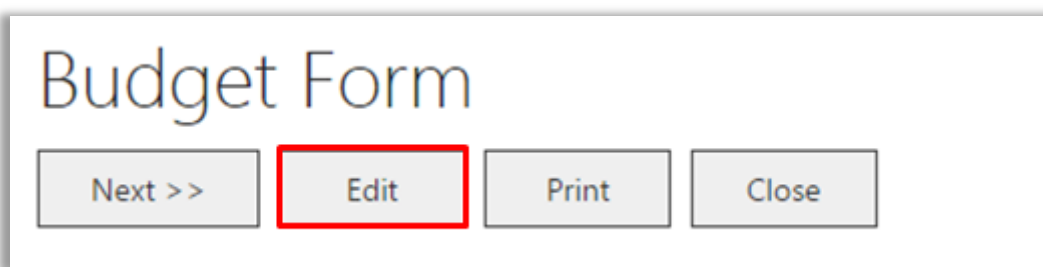
2. A confirmation message will appear. Click 'OK' to proceed.
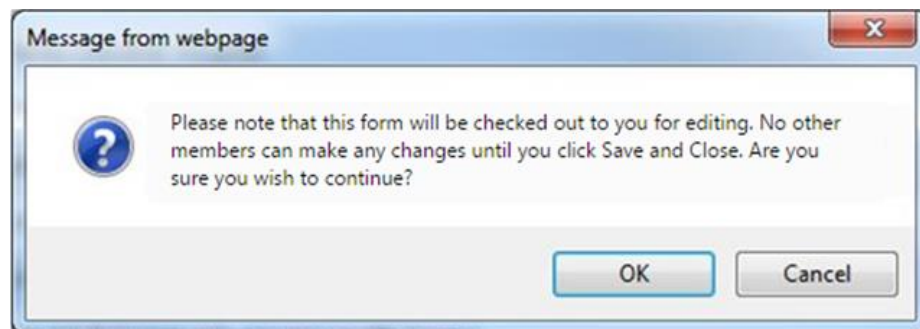
Take note that you are now on 'Edit' mode, and the form will be checked out to you until you click 'Save & Close'.
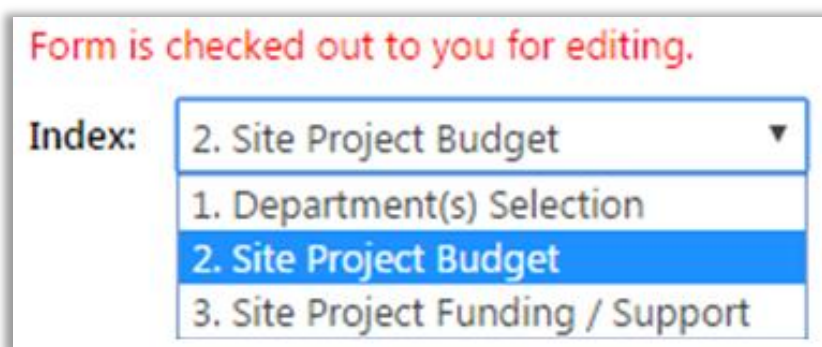
3. You can go to any section of the Budget by using the Index and selecting the section you want. Alternately you can click 'Next' or 'Previous' located at the top and bottom of the page

4. At any time you can click on 'Forms & Documents' tab to review the project's protocol or other documents in order to determine what services are required.

Sites	Members	Project Details	Forms & Documents	Declarations	Comments
Summary	Timeline	Reports	History		
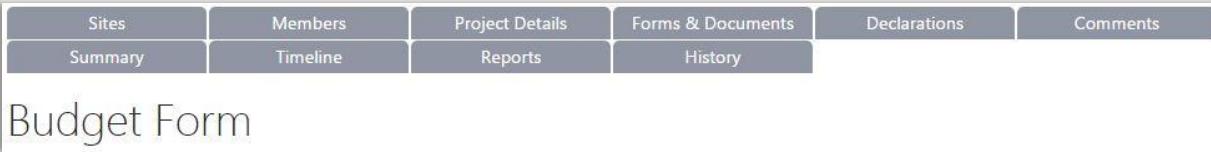
Budget Form

5. The 'Site Project Budget' lists down the service and support items previously provided by the PI (or delegate). Expand the Research Department section by clicking on the '+' sign. **The screen can be expanded or you can drag the scroll bar found at the bottom of the grid to view the other columns.**

These items are added by default under a Research Department:

- Overhead Charge:

  - ***Clinical services: Overhead Charge – percentage*** - *If 'Overhead charge' tick box is checked for one or more items, a percentage must be nominated; OR*
  - ***Clinical services: Overhead Charge – fixed amount*** - *If none of the items' 'Overhead charge' is checked, a fixed amount must be provided.*

- Ethics approval: Ethics review

  This is the amount charged by an Ethics Office for an ethical review. Under single ethical review, an amount should be entered by the site that conducted the ethical review; all other sites would enter $0.00 cost. The ethical review cost should be covered by in-kind support attributed to the site managing the Ethics Office, if there is no monetary payment by the funder of the project (e.g. non-commercial projects).

- Site specific assessment: Site processing and review

  This is the amount charged by a RG Office for a governance review. The governance review cost should be covered by in-kind support attributed to the site managing the RG Office, if there is no monetary payment by the funder of the project (e.g. non-commercial project).

Research Department

─ Anaesthesia and Pain Medicine

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 %		$21100.00	Project specific		
Ethics approval	Ethics review	SMHS HREC	$ 0.00		$0.00	Project specific	☐	
Site specific assessment	Site processing and review	EMHS RGO	$ 2,500.00		$2,500.00	Project specific	☐	
Feasibility assessment	Preliminary assessment ▾	PI & Clinical Trials Coordinator	$ 1,000.00	1	$1,000.00	Shared ▾	☑	☐
Site specific assessment	Preparation of the SSA applicat... ▾	Clinical Trials Coordinator	$ 2,000.00	1	$2,000.00	Shared ▾	☑	☐
Trial initiation	Departmental set up ▾	all staff	$ 3,000.00	1	$3,000.00	Shared ▾	☑	☐
Patient accrual	Recruitment activity ▾	PI & Research Nurse	$ 200.00	40	$8,000.00	Shared ▾	☑	☐
Clinical resources	Investigator time – Principal Inv... ▾	Protocol review, safety reports etc	$ 120.00	20	$2,400.00	Shared ▾	☑	☐
Clinical resources	Clinical research coordinator (n... ▾	Administration of trial	$ 80.00	200	$16,000.00	Shared ▾	☑	☐
Clinical resources	Outpatient time ▾	all visits	$ 200.00	240	$48,000.00	Shared ▾	☑	☐
Site closeout visit	Site closeout visit ▾	all staff	$ 3,000.00	1	$3,000.00	Shared ▾	☑	☐
Record archiving	Archiving of records ▾	Clinical Trials Coordinator	$ 1,000.00	1	$1,000.00	Shared ▾	☑	☐

Add   Remove   Authorise   Decline

6. If you wish to remove a budget item prior to authorising, select a particular item and click 'Remove'.

Major Category	Service & Support Item Provided ⓘ	Cost Description	Cost per Item ⓘ	Quantity ⓘ	Total Cost ⓘ	Cost Type ⓘ	Overhead Charge? ⓘ	Select
Biospecimen related	Biospecimen storage ▾	for 4 years storage	$ 500.00	4	$2,000.00	Project specific ▾	☐	☐
Biospecimen related	Biospecimen collection and pr... ▾	20 paticipants x 4 tests x 4 years	$ 25.00	360	$9,000.00	Project specific ▾	☐	☑

Add   Remove   Authorise   Decline

7. Click 'Next' to review the **Site Project Funding / Support** section of the Budget Form. **Drag the scroll bar found at the bottom of the grid to view the other columns.** For each support/service item there should be a cost and equivalent funding amount.

8. When you are ready to authorise, return to the 'Site Project Budget' screen by clicking 'Previous', click on the 'Authorise' button located under the last item of the Research Department's costs.

9. To confirm that you authorised the Research Department successfully, the department will display 'Authorised' with your name and the date of authorisation.

If you wish to make changes, click 'Unlock' and the previous authorisation will reset. The items under the research department can be edited at this point. Press 'Save & Close' to save your changes and close the budget, this will make the budget available to other users.

4.3   Decline Authorisation of a Budget Form

1. If the research department is unable to provide the services or support or approve the budget for the research project, click on 'Decline'.

2. A comment screen will launch. You will need to a provide reason to the PI for declining to authorise the Budget Form.

3. Click 'Save' to proceed with declining the authorisation.

After saving, if you wish to remove the comment or provide a new one, you will have to unlock this department, click 'Decline' again and provide a new comment.

To confirm that you declined your authorisation successfully, the department will display 'Declined' with your name and the date of declining. If you hover-over the word 'Declined', the reason will be shown.

5. Sign the Declaration on a SSA Form

Prior to Hospital Administrators signing the Site Specific Assessment (SSA) Form the PI should ensure the following have been completed:

- The Budget Form has been completed and authorised by the PI
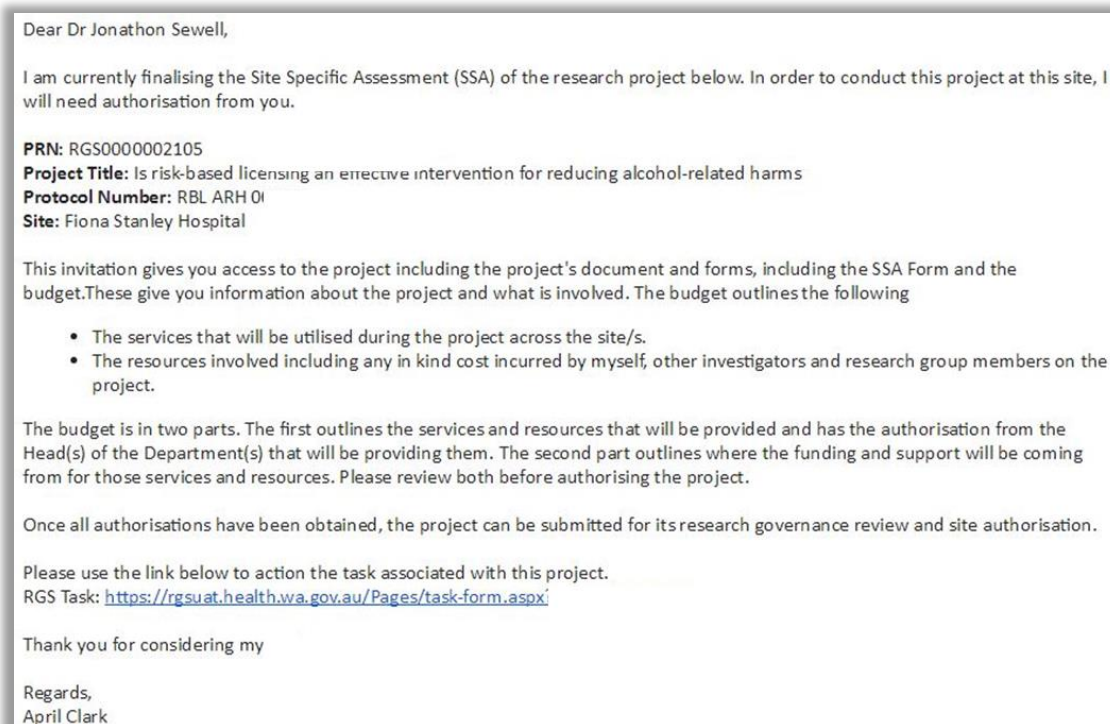- The SSA Form has been completed and signed by the PI

Following this, the PI must invite in the following order: the Business Manager (BM), Divisional Director (DD) and Regional Director (RG) (for WACHS only) to review the SSA Form and Budget Form and sign the form's authorisation declaration.

The PI will nominate the BM, DD and RG on the SSA Form and sent them an invitation to sign.

5.1 Invitation to Sign a SSA Form

1. Once you are invited as a BM, DD or RG, you will receive an email. Click on the link to the RGS Task provided in the email.

Note that if you have not done so, you will need to login to RGS to access the Tasks page.

Dear Dr Jonathon Sewell,

I am currently finalising the Site Specific Assessment (SSA) of the research project below. In order to conduct this project at this site, I will need authorisation from you.

PRN: RGS0000002105
Project Title: Is risk-based licensing an effective intervention for reducing alcohol-related harms
Protocol Number: RBL ARH 0
Site: Fiona Stanley Hospital

This invitation gives you access to the project including the project's document and forms, including the SSA Form and the budget.These give you information about the project and what is involved. The budget outlines the following

- The services that will be utilised during the project across the site/s.
- The resources involved including any in kind cost incurred by myself, other investigators and research group members on the project.

The budget is in two parts. The first outlines the services and resources that will be provided and has the authorisation from the Head(s) of the Department(s) that will be providing them. The second part outlines where the funding and support will be coming from for those services and resources. Please review both before authorising the project.

Once all authorisations have been obtained, the project can be submitted for its research governance review and site authorisation.

Please use the link below to action the task associated with this project.
RGS Task: https://rgsuat.health.wa.gov.au/Pages/task-form.aspx

Thank you for considering my

Regards,
April Clark

If you are not taken directly to the task, click on 'Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: All about Tasks.

2. In the Tasks page, click on the 'Request to Quote/Authorise' link found under My Tasks. If it is overdue it will be in the overdue section of Tasks and be coloured 'red'.

My Tasks				
Task Name	**Task Outcome**	**Initiator**	**Created**	**Due Date**
▲ Task Type : Invitation to Sign Declaration (1)				
Invitation to Sign Declaration for SSA Form for RGS0000002105	Pending	April Clark	21/02/2018	28/02/2018

3. Upon opening the task, click 'Action' which will direct you to the project's SSA form for the site or 'Cancel' to return to Tasks.

Task Form

Group task?	No
Task type:*	Invitation to Sign Declaration
PRN:*	RGS0000000012
Project title:*	A randomised double-blind, placebo and active-control, parallel-arm phase III trial with controlled adjustment of dose to evaluate the efficacy and safety of CG5503 extended-release (ER) in subjects with moderate of severe chronic pain due to osteoarthritis
Start date:	9/04/2018
Due date:*	16/04/2018
Initiator:	Jane Mitchell
Assignee:*	John O'Leary
Task description:*	Invite Signatory to sign the declaration in the Governance Form.
Assignee comments:	**B** *I* U X ↶ ↷ Ω := :≡ ⊣≣ ⊣≣
	Words: 0/5000
Task status:	**Pending**

[Action] [Decline Task] [Cancel]

Please click "Action" to take you to the relevant screen to undertake a task.

Click 'Decline the task' if you have received the task in error. You will unable to access the project or related documentation. If you have actioned the task already, click 'Finish Task'.

5.2   Authorise a SSA Form

1. In the SSA Form, you can use the Index to go to the different sections of the form, alternately you can click 'Next' and 'Previous'. At any time you can click on 'Forms & Documents' tab to review the project's documentation. From the Forms & Documents tab you can also go to the other tabs in the project workspace. To return to the SSA Form click on the SSA Form in the Active section of Forms & Documents tab.

Sites	Members	Project Details	Forms & Documents	Declarations
Comments	Letters	Publications	Summary	Timeline
Reports	History			

Site Specific Assessment (SSA) Form
Royal Perth Hospital

Next >>	Print	Close

Index: 1. Project Details ▼

1. Project Details
2. Broad Research Area, NHMRC Group and Field of Research
3(1). Investigators (for sites covered by this form) - Royal Perth Hospital
4. Credentialing and Training
5. Participants
6-11. Questions
12. Indemnity and Insurance
13. Research Agreements
14. Intellectual Property
15. Biosafety, Chemical and Radiation Safety
16. Resource and Budget Information
17. Funds Management Details
18. Declarations

1. Project Details

1.1 Project

1.1.0 PRN: RGS000000001

1.1.1 Project title: A randomised with controlled extended-relea osteoarthritis

1.1.2 Short title:

2. You can send a Project General Task to the PI if you need further details before signing the SSA Form. Refer to the Help Wiki: All about Tasks.

3. Go to the Declarations page. Click on the 'Budget Form' in blue text on point 3 of the declaration to review the budget. This will open in a new window/tab which can be closed when you have finished reviewing it. The 'Sign' button for your name will be enabled, when you click it, the date that you signed is recorded on the form. 'Close' to close the form.

18.2 Declaration by All Responsible Business Managers, Divisional Directors and Regional Directors ⓘ

In addition, for WACHS a declaration from the relevant **Regional Director** is required.

1. I certify that I have read the research project details covered by this form and that the research is appropriate to be conducted within this Department and at the site(s).
2. I certify that there are suitable and adequate facilities, resources and funding for the research project to be conducted at the site(s).
3. My signature indicates that I support this research project being carried out using such resources and funding, as documented in the Budget Form associated with this form.

Name	Position	Signature	Date	Invitation Status	Invited By	Select
Albert Macintosh	Business Manager - Sir Charles Gairdner Hospital	Sign		Accepted	Henry Amberley	☐
Jonathon Sewell	Divisional Director - Sir Charles Gairdner Hospital	Sign		Invited	Henry Amberley	☐

<< Previous	Close

6. Authorise or Not Authorise a Project at a Site

Once a Research Governance Officer (RGO) has conducted their governance review of a project to be conducted at a site or requesting access to participants, their tissue or data, they will make a recommendation for site authorisation to the Chief Executive (CE) or Delegate (e.g. Executive Director).

The RGO will nominate the CE/Delegate and send them an invitation to review the recommendation and provide an authorisation decision.

6.1 Invitation for Site Authorisation

1. Once you are invited as a CE/Delegate, you will receive an email. Log into RGS and then click on the link to the Authorisation page provided in the email.

If you are not taken directly to the task, click on 'Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: All about Tasks.

2. In the Tasks page, click on the 'Request for CE/Delegate Authorisation' link found under My Tasks. If it is overdue it will be in the overdue section of Tasks and be coloured 'red'.

My Tasks				
Task Name	**Task Outcome**	**Initiator**	**Created**	**Due Date**
◢ Task Type : Request for CE/Delegate Authorisation (2)				
Request for CE/Delegate Authorisation: RGS0000002103	Pending	Emma Forster	4/04/2018	4/08/2018

3. Upon opening the task, click 'Action' which will direct you to the project's Authorisation page for the site you have been nominated as the CE/Delegate, or 'Cancel' to return to Tasks. If you have actioned the task already, click 'Finish Task'.

6.2 Review RGO Recommendation

1. In the Authorisation page locate the 'CE/Delegate Authorisation' section under 'Site Authorisation', the 'RG Office' and your site. Expand sections by clicking on the + sign. Click on the ID to review the RGO's recommendation.

2. The RGO's recommendation screen will launch. The following will be available:

a. **RGO Recommendation Decision –** this will provide the RGO's recommendation regarding authorisation.

b. **Comments** – this field may contain comments from the RGO regarding their recommendation decision.

c. **Site Specific Conditions for Authorisation –** this is any site specific condition that the RGO recommends placing on the project (e.g. increased frequency of reporting).

d. **Forms and Documents -** this is the project documentation reviewed by the RGO. Refer to: Request additional information, Authorise a project for a site and Not Authorise a project for a site to change the 'Review Assessment' for each form and document.

Click on the name of a form or documents if you wish to view them. Forms will open in a new window. Documents will download to your computer. Close the tab once you have finished looking at the form or document. You can view the whole project workspace by clicking on the SSA Form to open it.

At the top of the SSA Form click on 'Forms & Documents' tab which will take you to the project workspace. You can browse through the project's tabs to review all the projects details. Refer to Help Wiki: Navigate the project workspace for help on navigating the project.

e. **CE/Delegate Review Comments –** this section allows you to provide comments to the RGO regarding your authorisation decision.

f. **CE/Delegate Authorisation Decision -** select your authorisation decision by choosing AIR (additional information required), authorise or not authorise. Refer to Refer to: Request additional information, Authorise a project for a site and Not Authorise a project for a site.

g. **Site Specific Conditions for Authorisation –** these are populated from the RGO's specific conditions. This section allows you to edit them as required.

6.3   Request Additional Information

1. If additional information is required (AIR) prior to making an authorisation decision, you have the following options:

   a. Select **'AIR'** in the 'Review Assessment' against a form or document that requires amending. For the remaining forms and documents either:

      ○ Retain as '**RGO recommended'** if you are not comfortable giving approval at this time (i.e. the AIRed form or document may impact on this decision).

      ○ Select '**Approved'** – if you approve this form or document.

      ○ Select '**Not Approved'** – if you do not approve this form or document (i.e. it can no longer be resubmitted with amendments).

   The CE/Delegate Authorisation Decision will automatically be marked as AIR.

   b. If you do not wish to AIR a form or documents but require additional information prior to making an authorisation decision you should:

      ○ Select **'RGO recommended', 'Approved'** or **'Not Approved'** against each form or document.

      ○ Select **'AIR'** against the CE/Delegate Authorisation Decision.

2. Add a comment in the comments section to notify the RGO of the reason for your decision.

3. Click 'Sign & Finish'. The RGO will be notified of your decision and comments and convey them to the PI through a letter.

Your decision will be displayed as AIR and the review status will be completed.

	CE/Delegate Authorisation				
ID	RGO Recommendation Decision	CE / Delegate Authorisation Decision	Status	Authorisation Decision Date	CE / Delegate
9	Recommended	AIR	Completed		Jonathon Sewell
10	Recommended	Not Authorised	Completed	09/10/2016	Jonathon Sewell

A new CE/Delegate authorisation task will be generated after the RGO review when the PI has addressed the issues. At this time, you will be able to see a new version of the forms and documents you have marked as AIR and all those you have previously reviewed and have gone through another RGO review (re-assessment) i.e. the RGO has marked them as RGO Recommended or Under Review for your consideration.

6.4   Authorise a Project for a Site

1. To authorise a project, change the status of all forms and documents in the Review Assessment to 'Authorised' (you have the ability to mark an individual document as not approved if you do not wish it to be part of site authorisation). Select 'Authorised' in CE/Delegate Authorisation Decision.

	Forms and Documents						
Forms							
Form Name ⓘ	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	Review Assessment ⓘ
Site Specific Assessment (SSA) Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	Authorised
Budget Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	Authorised

Documents							
Doc ID	Document Name ⓘ	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	Review Assessment ⓘ
4455	GSK CTRA final	0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	Authorised
4454	Indemnity Form	0	04/04/2018	04/04/2018	05/04/2018		RGO recommended	Authorised
4453	Ace Insurance Certificate	0	04/04/2018	04/04/2018	05/04/2018		RGO recommended	Authorised

CE / delegate review comments

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Words: 0/5000

2. Click 'Sign & Finish' at the bottom of the screen. Your decision will be displayed as authorised and the review status will be completed.

	Authorisation by CE / Delegate		
CE / delegate authorisation decision:	Authorised		ⓘ
Site specific conditions for authorisation (if any):			ⓘ

Name	Position ⓘ	Signature	Date
John O'Leary	Head of Department	Signed	06/04/2018

The RGO will be notified of your decision and create an authorisation letter.

This can be sent to the PI along with any other documents. If required the letter can be printed for your signature before it is sent to the PI. The project status will be displayed on the Summary tab in the project workspace.

6.5   Not Authorise a Project for a Site

1. If you decide not to authorise the conduct of the project at the site, change the status of all forms and documents in the Review Assessment to 'Not Approved'. Select 'Not Authorised' as your decision. **If not authorised is selected the project application cannot be reconsidered at the site.** If you are of the opinion that there is a possibility to resolve the issues then it is better to AIR the project, refer to the 'Request Additional Information' process.

2. Add the reason for not authorising the conduct of the project at your site in the 'CE/Delegate Review Comments' section.

3. Click 'Sign' next to your name and 'Finish'. Click 'Sign' next to your name and 'Finish'. Your decision will be displayed as Not Authorised (as per ID 10 below) and the review status will be completed

The project status will be displayed on the Summary tab in the project workspace. The RGO will be notified of your decision and create a Not Authorised letter for you to sign.