



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

Research Governance Service (RGS)

Hospital Administrator (HA) User Guide



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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.

1.2.1 Head of Supporting Department (HoSD) Delegate

The HoSD can appoint a delegate who can complete the supporting department's section of the budget, they have the same rights as the HoSD.

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 Investigator (PI) that requires 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 'My Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: [All about Tasks](#).



On the My Tasks page, click the 'Request to Quote/Authorise' link found under Tasks Type.

My Tasks [Need help using this page?](#)

Group	Task Type	Subject	From	Due Date	Notes	Q
!	Invitation to Provide Quote and Authorise/Decline in Budget Form	RGS0000002151, Medical Oncology	Henry Amberley	29/10/2018		

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.

Task Form

Group task? No

Task type:* Invitation to Provide Quote and Authorise/Decline in Budget Form

PRN:* RGS0000002151

Project title:* A phase 2, open-label, single-arm, multi-centre study to evaluate the efficacy and safety of TWA 386 and Lifeablinib as first line therapy for subjects with advanced or inoperable Hepatocellular Carcinoma

Department:* Medical Oncology

Start date: 22/10/2018

Due date:* 29/10/2018

Assignee:* Albert Macintosh

Task description:* Invite HoD and HoSD or their delegates to provide a quote and or authorise/decline the Budget Form.

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

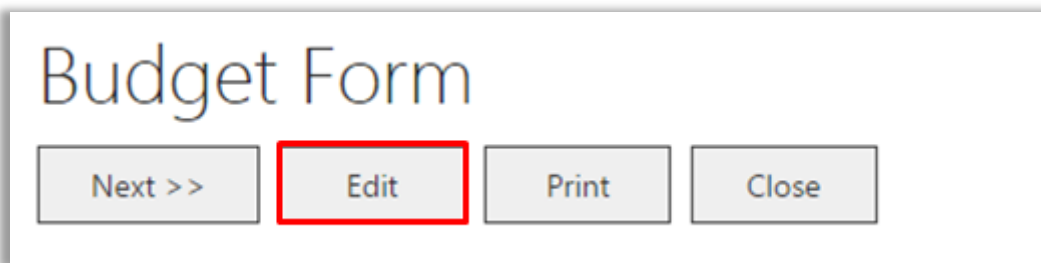
Click 'Decline the task' if you have received the task in error. You will be unable to access the project Budget Form or related documentation.

3.2 Agree to Provide a Service and Authorise

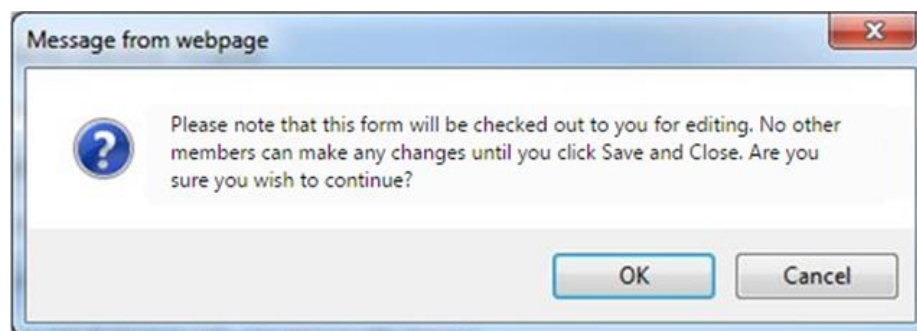
Provide a Quote in a Budget Form

The Budget Form has 3 screens:

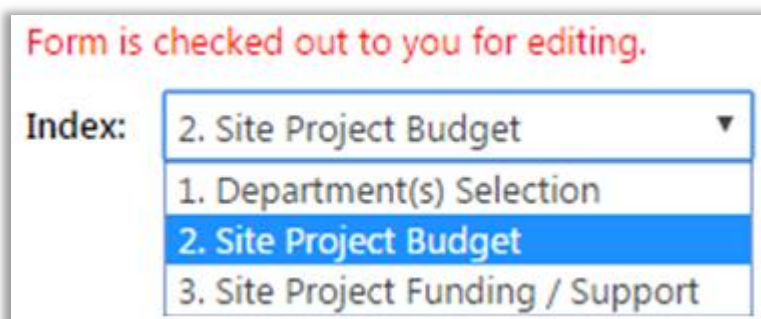
1. **Departmental Selection** – this section is completed by the PI and lists the Research Department, Supporting Departments and Third Party Agencies that will be involved in supporting the project and their nominated Heads of Department/delegates.
 2. **Site Project Budget** – this section contains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



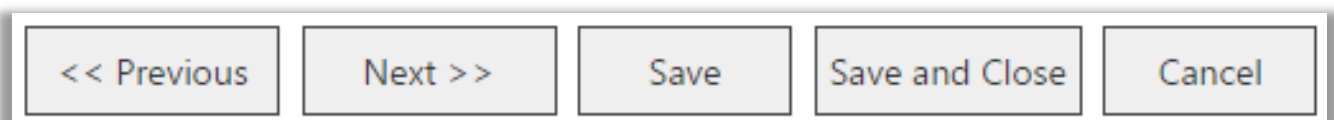
2. A confirmation message will appear. Click 'OK' to proceed.



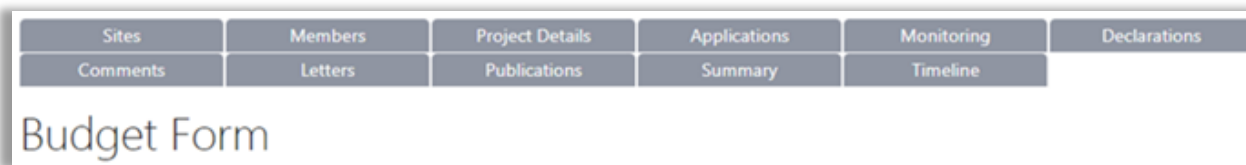
Take note that you are now on 'Edit' mode, and the form will be checked out to you until you click 'Save & Close'.



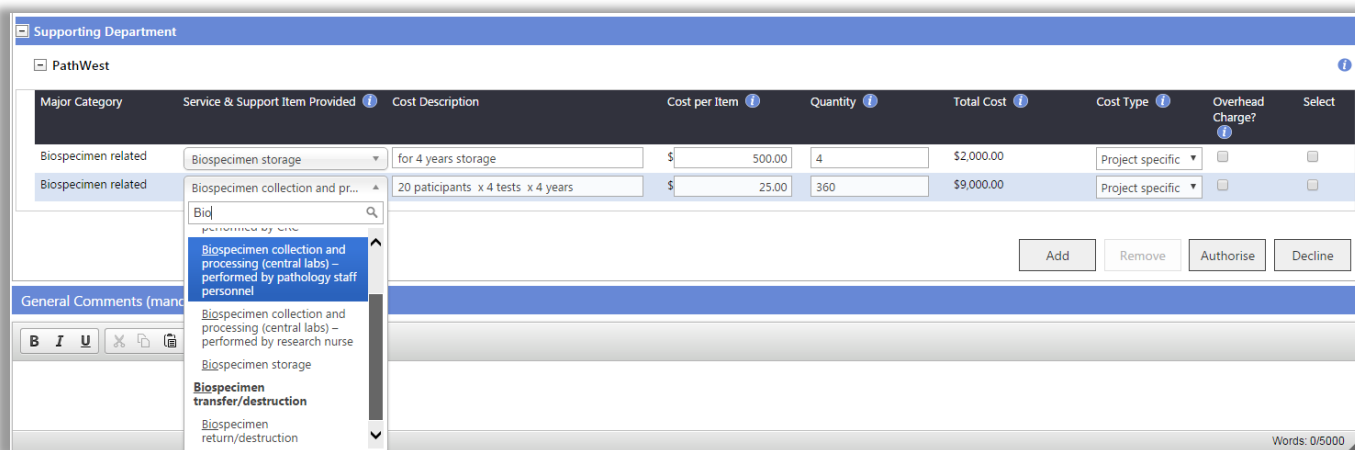
3. You can go to any section of the Budget by using the Index and selecting the section you want. Alternately you can click 'Next' or 'Previous' located at the top and bottom of the page.



If you want to go to the 'Applications' 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.



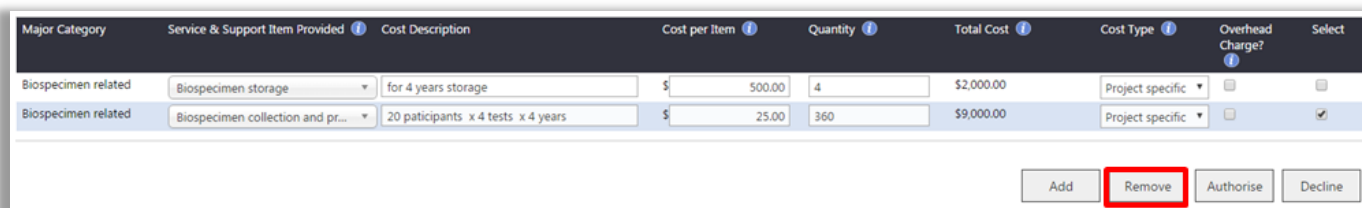
4. In the 'Site Project Budget' you can add an item by clicking the 'Add' button. The Service & Support drop down menu has a search facility and will tailor the results based on what you type; the results will be any item with word in it. The list of service and support items that are available on the Help Wiki: [Fill out and authorise a Budget Form \(for a supporting department\)](#)



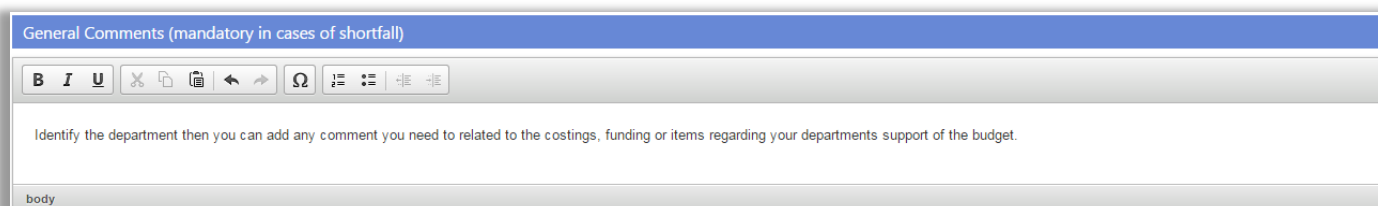
5. Based on the protocol, enter the service/support item, a cost description if required (i.e. the usual name of the item), cost and quantity. To calculate the quantity you should review, the number of participants and time frame of the project which is listed on the 'Department Selection' screen.

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.

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?	Select
Pharmacy/Investigation drug related	Drug preparation and dispensing		\$ 20.00	200	\$4,000.00	Shared		

Buttons: Add, Remove, **Authorise**, Decline

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.

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	No	
Biospecimen related	Biospecimen collection and processing (central labs) – performed by pathology staff personnel	20 participants x 4 tests x 4 years	\$25.00	360	\$9,000.00	Project specific	No	

Buttons: **Authorised - Jane Mitchell 06/04/2018**, Unlock

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'.

Major Category	Service & Support Item Provided	Cost Description	Cost per Item
Trial initiation	Departmental set up	Set up fee	\$
Site closeout visit	Site closeout visit	Close out fee	\$
Pharmacy/Investigation drug related	Stock management – drug stock	Annual Administration fee	\$
Pharmacy/Investigation drug related	Stock management – expiry management	Annual storage fee	\$
Pharmacy/Investigation drug related	Drug preparation and dispensing	Dispensing Fee	\$
Pharmacy/Investigation drug related	Drug preparation and dispensing	Remote monitoring fee - \$100 per instance	\$

Buttons: Add, Remove, Authorise, **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.

The screenshot shows a dialog box titled "Add Comment". At the top, there is a "Title:" field containing the text "Costing Declined". Below this is a paragraph of instructions: "Provide a reason for declining the cost provided for the department. Note that when you click 'Save', your comments will be FINAL and visible to other users. After saving, if you wish to remove the comment, you will have to unlock this department quote, select decline again and provide a new comment." Below the instructions is a "Comment:" field with a rich text editor toolbar (bold, italic, underline, link, unlink, undo, redo, insert link, insert image, list, indent, outdent) and a text area containing the text "Enter the reasons for declining here, this will be included in an email to the PI and PI Delegate". At the bottom right of the text area, it says "Words: 19/5000". At the bottom of the dialog box, there are two buttons: "Save" (highlighted with a red box) and "Cancel".

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.

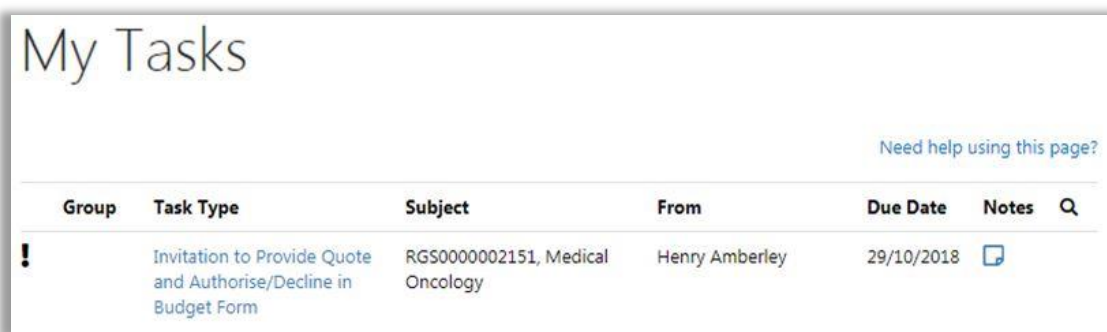
Please use the link below to action the task associated with this project.
RGS Task: | <https://rgs.health.wa.gov.au/Pages/task-form.aspx?fm=V&tud=9325>

Thank you for considering my project.

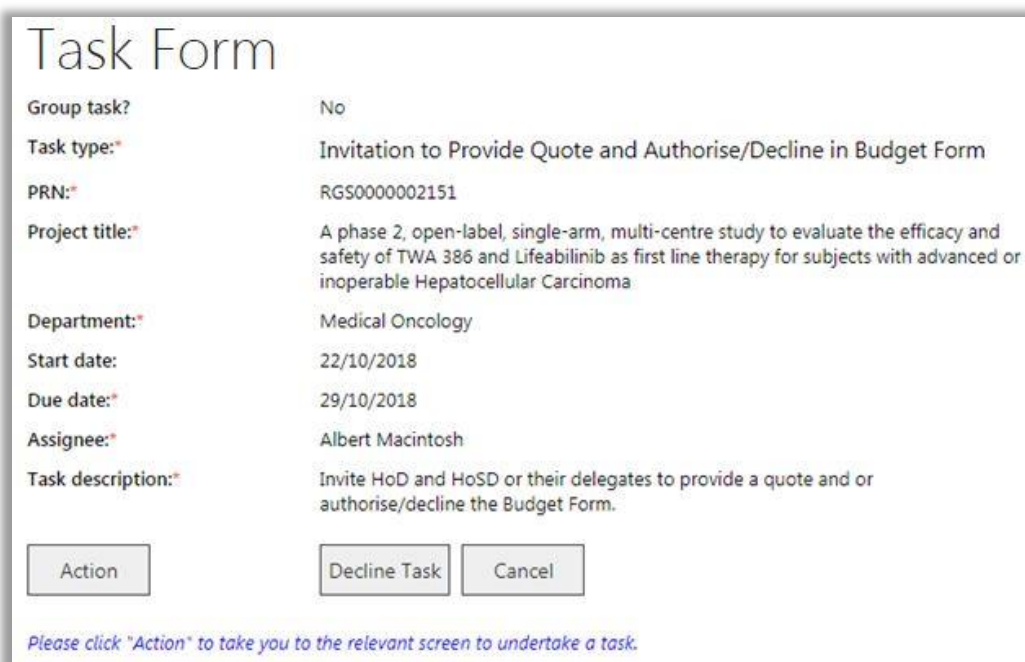
If you are not taken directly to the task, click on 'My Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: [All about Tasks](#).



2. On the My Tasks page, click on the 'Request to Quote/Authorise' link found under Tasks Type.



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.



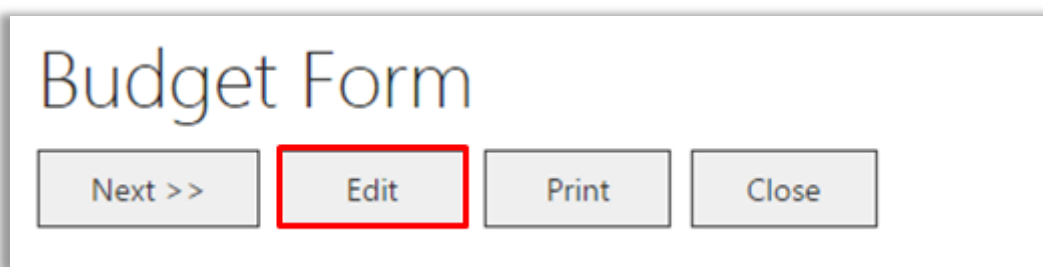
Click 'Decline the task' if you have received the task in error. You will be unable to access the project Budget Form or related documentation.

4.2 Authorise a Budget Form

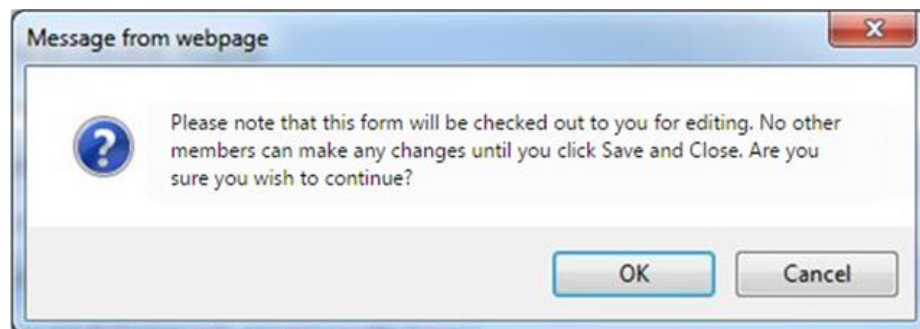
The Budget Form has 3 screens:

- 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.

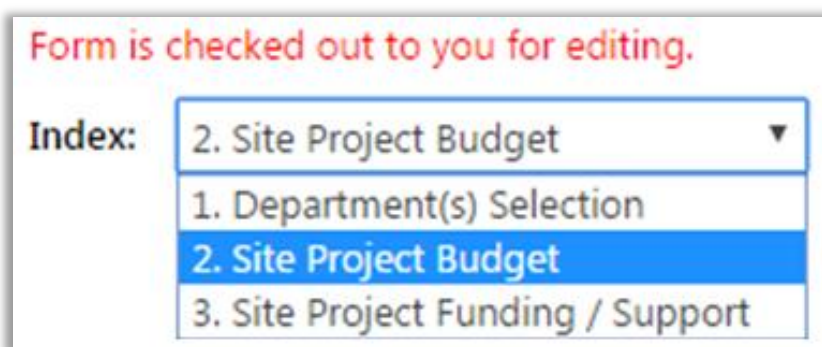
1. In the Budget Form, click 'Edit'.



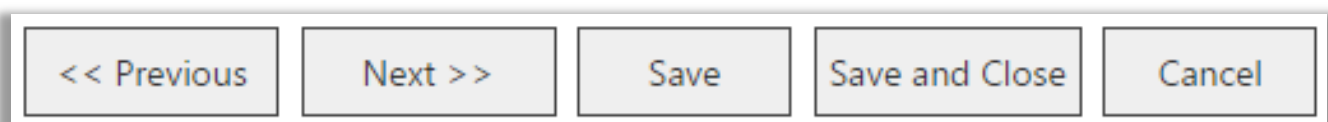
2. A confirmation message will appear. Click 'OK' to proceed.



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 Applications tab to review the project's protocol or other documents in order to determine what services are required.

Sites	Members	Project Details	Applications	Monitoring	Declarations
Comments	Letters	Publications	Summary	Timeline	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).

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

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	<input type="checkbox"/>	<input type="checkbox"/>
Biospecimen related	Biospecimen collection and pr...	20 participants x 4 tests x 4 years	\$ 25.00	360	\$9,000.00	Project specific	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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.

Section 3 of 3 - Site Project Funding / Support

Total Actual Costs: \$133,040.00 Total Authorised Costs: \$25,040.00 Total Funding: \$133,040.00 Shortfall (or Surplus): \$108,000.00

Available Funders: Novartis Pharmaceuticals Australia Pty Ltd Type of Funder: Commercial company - industry / contract research organisation \$ Funding by Sponsor or Funder: \$133,040.00 \$ In-Kind Support: Funding Status: Confirmed Remove

If the funder is not listed, ensure they have been added to the Project Details tab, Governance Information section and that the Project Details tab is authorised. You may remove funders that do not apply to this Budget Form by clicking on the 'X' in the Remove column. Refresh

Royal Perth Hospital
Proposed number of participants in this site: 40 Expected project timeframe for this site: 5 year(s)
**Participant also includes a person's data, information or biological sample.*

Research Department

Anaesthesia and Pain Medicine

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	\$21,100.00	Project specific	\$ 21,100.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Ethics approval	Ethics review	SMHS HREC	\$0.00	1	\$0.00	Project specific	\$ 0.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Site specific assessment	Site processing and review	EMHS RGO	\$2,500.00	1	\$2,500.00	Project specific	\$ 2,500.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Feasibility assessment	Preliminary assessment	PI & Clinical Trials Coordinator	\$1,000.00	1	\$1,000.00	Shared	\$ 1,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Site specific assessment	Preparation of the SSA application by the project team	Clinical Trials Coordinator	\$2,000.00	1	\$2,000.00	Shared	\$ 2,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Trial initiation	Departmental set up	all staff	\$3,000.00	1	\$3,000.00	Shared	\$ 3,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Patient accrual	Recruitment activity	PI & Research Nurse	\$200.00	40	\$8,000.00	Shared	\$ 8,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Clinical resources	Investigator time - Principal Investigator	Protocol review, safety reports etc	\$120.00	20	\$2,400.00	Shared	\$ 2,400.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Clinical resources	Clinical research coordinator (non-research nurse) time	Administration of trial	\$80.00	200	\$16,000.00	Shared	\$ 16,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Clinical resources	Outpatient time	all visits	\$200.00	240	\$48,000.00	Shared	\$ 48,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Site closeout visit	Site closeout visit	all staff	\$3,000.00	1	\$3,000.00	Shared	\$ 3,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Record archiving	Archiving of records	Clinical Trials Coordinator	\$1,000.00	1	\$1,000.00	Shared	\$ 1,000.00	Novartis Pharmaceuticals Austrz	\$ 0.00	Please select...	
Total:					\$108000.00		\$108000.00		\$0.00		

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.

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		<input type="checkbox"/>
Site specific assessment	Site processing and review	EMHS RGO	\$ 2,500.00		\$2,500.00	Project specific		<input type="checkbox"/>
Feasibility assessment	Preliminary assessment	PI & Clinical Trials Coordinator	\$ 1,000.00	1	\$1,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Site specific assessment	Preparation of the SSA applicat...	Clinical Trials Coordinator	\$ 2,000.00	1	\$2,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Trial initiation	Departmental set up	all staff	\$ 3,000.00	1	\$3,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Patient accrual	Recruitment activity	PI & Research Nurse	\$ 200.00	40	\$8,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Investigator time - Principal Inv...	Protocol review, safety reports etc	\$ 120.00	20	\$2,400.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Clinical research coordinator (n...	Administration of trial	\$ 80.00	200	\$16,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Outpatient time	all visits	\$ 200.00	240	\$48,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Site closeout visit	Site closeout visit	all staff	\$ 3,000.00	1	\$3,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Record archiving	Archiving of records	Clinical Trials Coordinator	\$ 1,000.00	1	\$1,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Add Remove **Authorise** Decline

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

Research Department

General Medicine Authorised - Jonathon Sewell 23/02/2018

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?	Select
Clinical services	Overhead Charge - percentage		10.00%	1	\$4624.00	Project specific	No	
Ethics approval	Ethics review	SCGOPHCG HREC	\$2,300.00	1	\$2,300.00	Project specific	No	
Site specific assessment	Site processing and review	SCGOPHCG RGO	\$2,300.00	1	\$2,300.00	Project specific	No	
Patient accrual	Recruitment activity	Recruitment by letter of existing patients	\$240.00	1	\$240.00	Shared	Yes	
Clinical resources	Investigator time - Principal Investigator	4 visits by each participant over 2 years	\$120.00	200	\$24,000.00	Shared	Yes	
Clinical resources	Research nurse time	4 Follow up calls each participant over 2 years	\$80.00	200	\$16,000.00	Shared	Yes	
Other	Other	Data entry	\$15.00	400	\$6,000.00	Shared	Yes	

Unlock

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'.

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	<input type="checkbox"/>	
Site specific assessment	Site processing and review	EMHS RGO	\$ 2,500.00		\$2,500.00	Project specific	<input type="checkbox"/>	
Feasibility assessment	Preliminary assessment	PI & Clinical Trials Coordinator	\$ 1,000.00	1	\$1,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Site specific assessment	Preparation of the SSA applicat...	Clinical Trials Coordinator	\$ 2,000.00	1	\$2,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Trial initiation	Departmental set up	all staff	\$ 3,000.00	1	\$3,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Patient accrual	Recruitment activity	PI & Research Nurse	\$ 200.00	40	\$8,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Investigator time – Principal Inv...	Protocol review, safety reports etc	\$ 120.00	20	\$2,400.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Clinical research coordinator (n...	Administration of trial	\$ 80.00	200	\$16,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Clinical resources	Outpatient time	all visits	\$ 200.00	240	\$48,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Site closeout visit	Site closeout visit	all staff	\$ 3,000.00	1	\$3,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Record archiving	Archiving of records	Clinical Trials Coordinator	\$ 1,000.00	1	\$1,000.00	Shared	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

Add Comment

Title: Costing Declined

Provide a reason for declining the cost provided for the department. Note that when you click 'Save', your comments will be FINAL and visible to other users. After saving, if you wish to remove the comment, you will have to unlock this department quote, select decline again and provide a new comment.

Comment:

Enter the reasons for declining here, this will be included in an email to the PI and PI Delegate

body Words: 19/5000

Save Cancel

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.

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 01
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.

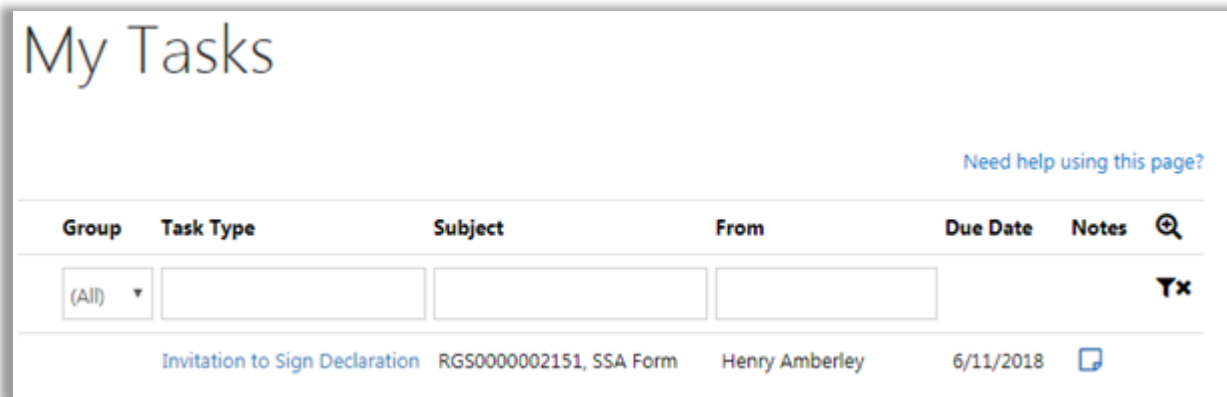
Once all authorisations have been obtained, the project can be submitted for its research governance review and site authorisation.

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>

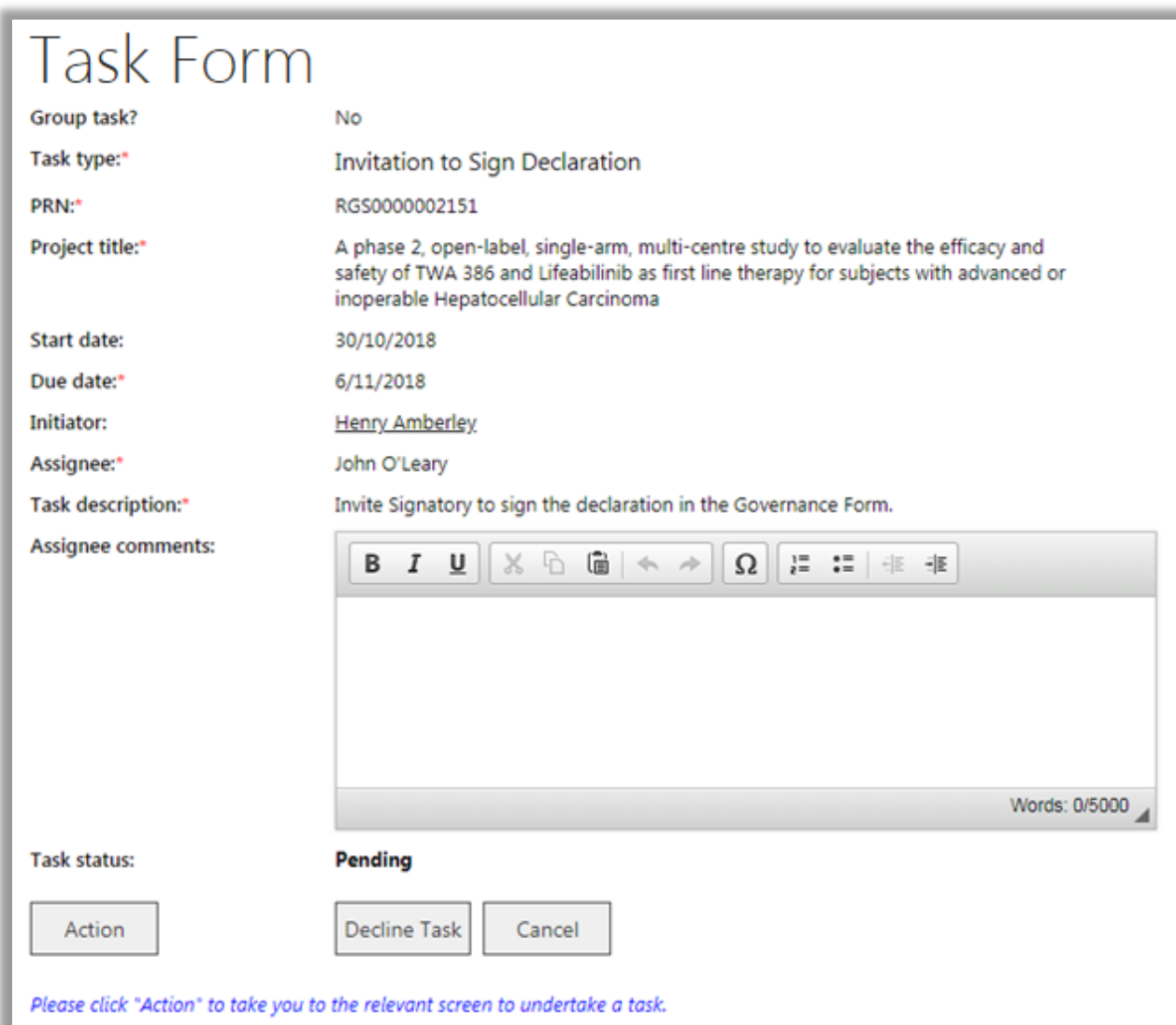
If you are not taken directly to the task, click on 'My Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: [All about Tasks](#).

The screenshot shows the RGS web application interface. At the top left is the Government of Western Australia Department of Health logo. The main header features a blue banner with the text 'Research Governance Service' and a navigation menu with links for 'Home', 'Research Information', 'Meeting Calendar', 'Document Templates', 'Contacts', and 'Help Wiki'. Below the banner, the page title is 'Home' and the main heading is 'Welcome to the Research Governance Service (RGS)'. A sidebar on the left contains a list of navigation options: 'My Tasks', 'Archived Tasks', 'My Dashboards', 'My Projects', 'Create Project', 'Projects Search', 'Publications Search', 'Profile Management', and 'Complaints'. The main content area contains a paragraph explaining that RGS supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data. It also states that the RGS is a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices, enabling the completion, submission, administration, tracking and reporting of ethics and governance applications through the ethics approval and site authorisation processes. A final paragraph notes that the RGS must be used to process all ethics and governance applications involving WA public health organisations. To the right of the text is a photograph of a smiling woman holding a baby, with other healthcare professionals in the background.

2. On the My Tasks page, click on the 'Invitation to Sign Declaration' link found under Task Type.



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.



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

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 the Applications tab to review the project's documentation. From the Applications 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 Applications tab.

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
Timeline	History			

2. The SSA will open as a single page; you can scroll to the bottom of the page to the Declarations or use the Index to go straight to the Declarations section.

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: RGS000000000

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

1.1.2 Short title:

3. At the Declarations section you can 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 i

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	<input type="checkbox"/>
Jonathon Sewell	Divisional Director - Sir Charles Gairdner Hospital	Sign		Invited	Henry Amberley	<input type="checkbox"/>

[<< 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

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 Authorisation tab in the project workspace, click on 'My Tasks' on the menu situated on the left-hand side of the screen. Refer to the Help Wiki: [All about Tasks](#).



Government of Western Australia
Department of Health

Research Governance Service

Home Research Information Meeting Calendar Document Templates Contacts Help Wiki

Home

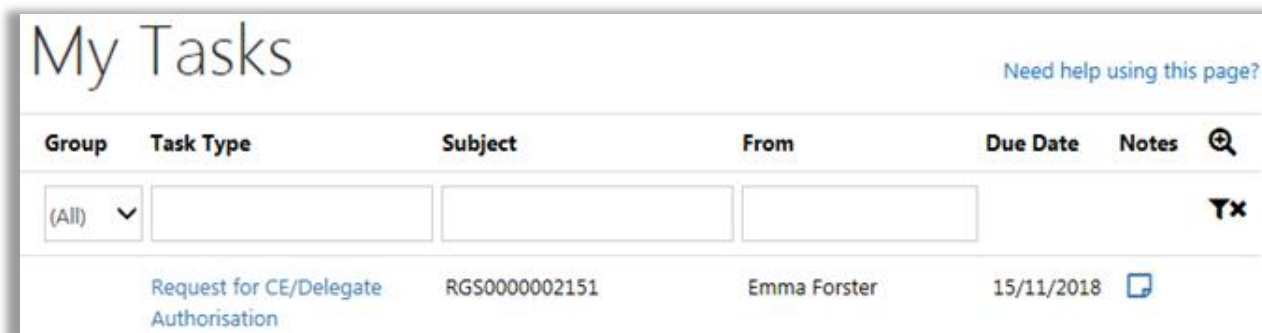
Welcome to the Research Governance Service (RGS)

RGS supports the research governance framework for all human research conducted within WA Health or accessing WA Health participants, their tissue or data.

The RGS is a centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices. Enabling the completion, submission, administration, tracking and reporting of ethics and governance applications through the ethics approval and site authorisation processes.

The RGS must be used to process all ethics and governance applications involving WA public health organisations.

Click on My Tasks is located on the left hand menu, click on the 'Request for CE/Delegate Authorisation' link found under Tasks Type.



My Tasks

Need help using this page?

Group	Task Type	Subject	From	Due Date	Notes
(All) ▼					TX
	Request for CE/Delegate Authorisation	RGS0000002151	Emma Forster	15/11/2018	

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.

6.2 Review RGO Recommendation

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

The screenshot shows the 'Authorisation' tab with a navigation menu at the top: Validation, Authorisation, Comments, Ethics, Governance, Files & Documents, and Fees. The main content area is titled 'Applications' and contains a tree view with the following structure:

- Applications
 - Ethics Approval
 - Site Authorisation
 - Sir Charles Gairdner Osborne Park Health Care Group Research Governance Office
 - Sir Charles Gairdner Hospital

A note below the tree view states: *Note: The site status must be updated in the Administration - Governance tab to reflect any decisions made.*

Below the note are two tables:

RGO Review

ID	Overall Review Assessment	Status	Review Completion Date	Reviewing RGO	Time Elapsed (in days)
6254	AIR	Completed	07/11/2018	Emma Forster	2
6257	Recommended	Completed	07/11/2018	Emma Forster	1

CE/Delegate Authorisation

ID	RGO Recommendation Decision	CE / Delegate Authorisation Decision	Status	Authorisation Decision Date	CE / Delegate	Invited By	Time Elapsed (in days)
6257	Recommended	Invited	Pending		Jonathon Sewell	Emma Forster	1

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

The screenshot shows a window titled 'Provide Site Authorisation'. The form contains the following elements:

- A header field: 'Recommendation for Site/Organisation'.
- A text area containing: 'The governance review for this project has been completed for this site.'
- A dropdown menu for 'RGO recommendation decision:' with 'Recommended' selected.
- A rich text editor for 'Comments:' with a toolbar and a 'Words: 0/5000' indicator.
- A rich text editor for 'Site specific conditions for authorisation (if any):' with a toolbar and a 'Words: 0/5000' indicator.

- RGO Recommendation Decision** – this will provide the RGO's recommendation regarding authorisation.
- Comments** – this field may contain comments from the RGO regarding their recommendation decision.
- 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.

The screenshot shows the 'Forms and Documents' section of a web application. It contains two tables and a text editor.

Forms Table:

Form Name	Version	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Current Status	Review Assessment
Site Specific Assessment (SSA) Form	1.0	01/11/2018	06/11/2018	08/11/2018		RGO recommended	RGO recommended
Budget Form	1.0	01/11/2018	06/11/2018	08/11/2018		RGO recommended	RGO recommended

Documents Table:

Doc ID	Document Name	Version	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Current Status	Review Assessment
8593	CTRA draft	0	01/11/2018	06/11/2018	08/11/2018		Noted	Noted
8601	CTRA Novartis Pharmaceuticals Australia Pty Ltd and SCGOPHCG	1	07/11/2018	07/11/2018	08/11/2018		RGO recommended	RGO recommended
8594	Ace Insurance Certificate	1	01/11/2018	06/11/2018	08/11/2018		RGO recommended	Authorised

Below the tables is a text editor with a toolbar containing icons for Bold (B), Italic (I), Underline (U), Cut (X), Copy, Paste, Undo, Redo, Bulleted List, Numbered List, Decrease Indent, and Increase Indent. The text area contains the placeholder text 'CE / delegate review comments'. A word count indicator at the bottom right shows 'Words: 0/5000'.

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. If the document name is in black text a copy of it has not been uploaded into RGS and you should receive a hardcopy. You can view the whole project workspace by clicking on the SSA Form to open it.

The screenshot shows the 'Site Specific Assessment (SSA) Form' for 'Sir Charles Gairdner Hospital'. At the top, there is a navigation menu with buttons for Sites, Members, Project Details, Applications, Monitoring, Declarations, Comments, Letters, Publications, and Summary. Below the menu are buttons for Timeline, History, and Administration.

The main heading is 'Site Specific Assessment (SSA) Form' followed by 'Sir Charles Gairdner Hospital'. There are three buttons: 'Next >>', 'Print', and 'Close'.

An 'Index:' dropdown menu is open, showing a list of sections:

- 1. Project Details
- 2. Broad Research Area, NHMRC Group and Field of Research
- 3(1). Investigators (for sites covered by this form) - Sir Charles Gairdner 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

On the left side of the index, there are labels for sections: '1. Project Details', '1.1 Project', '1.1.0 PRN:', '1.1.1 Project title:', '1.1.2 Short title:', and '1.1.3 Acronym:'. The '1.1.1 Project title:' label is partially obscured by the text 'A phas safety inoper'.

At the top of the SSA Form click on 'Applications' 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

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 any other forms and documents either:
 - Retain as '**RGO recommended**' if you are not comfortable giving approval at this time
 - Select '**Authorised**' – if you approve this form or document.
 - Select '**Not Authorised**' – 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 just leave the forms as documents as they are and select 'AIR' against the CE/Delegate Authorisation Decision.

Add a comment in the comments section to notify the RGO of the reason for your decision. The RGO will use this information in correspondence with the PI.

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

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

To authorise a project, change the status of all forms in the Review Assessment to 'Authorised'. Documents can be marked as Authorised or Noted (an individual document can be marked as Not Authorised 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: Please select...

Site specific conditions for authorisation (if any):

- AIR
- Authorised
- Not authorised
- Early termination
- Temporary halt
- Closed

Words: 0/5000

Name	Position	Signature	Date
Jonathon Sewell	Head of Department		

Save Sign & Finish Close Cancel

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

ID	RGO Recommendation Decision	CE / Delegate Authorisation Decision	Status	Authorisation Decision Date	CE / Delegate By	Invited By	Time Elapsed (in days)
6257	Recommended	Authorised	Completed	08/11/2018	Jonathon Sewell	Emma Forster	1

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 April 2018

Dr April Clark
Fiona Stanley Hospital
Robin Warren Drive
Murdoch WA 6150

Dear Dr Clark

PRN:	RGS0000000054
Project Title:	A Randomized, Multicenter, Open-Label, Phase 3 Study of Acalabrutinib (ACP-196) Versus Investigator's Choice of Either <u>Idelalisib</u> Plus <u>Rituximab</u> or <u>Bendamustine</u> Plus <u>Rituximab</u> in Subjects with Relapsed or Refractory Chronic <u>Lymphocytic Leukemia</u>
Protocol Number:	ACE-CL-309

Thank you for submitting the above research project for governance review. I am pleased to advise you that Fiona Stanley Hospital has granted authorisation for this research project to be conducted at the following participating site(s):

Fiona Stanley Hospital

In addition to those approved by the Human Research Ethics Committee (HREC), the authorised site specific documents include:

Document	Version	Version Date
Ace Insurance Certificate		20/12/2017
Indemnity Form		15/03/2018

Site authorisation of this project is valid from 06 April 2018 subject to continued ethical approval from the Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee and compliance with the 'Conditions of Site Authorisation for a Research Project' (Appendix A). To find the original letter and any possible attachments, click [here](#) when logged into [RGS](#).

Should you have any queries about Fiona Stanley Hospital's consideration of your project, please contact the Research Governance Office at SMHS.REG@health.wa.gov.au or on 6151 1180. The Research Governance Office's Standard Operating Procedures are available from the Research Governance Office.

I wish you every success in your research.

Yours sincerely

Dr John O'Leary
Executive Director

6.5 Not Authorise a Project for a Site

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.

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

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

8594 [Ace Insurance Certificate](#) 1 01/11/2018 06/11/2018 08/11/2018 RGO recommended Not Authorised

CE / delegate review comments

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This project will not be conducted at this site as there is currently insufficient resources available

body Words: 16/5000

Authorisation by CE / Delegate

CE / delegate authorisation decision: Not authorised

Site specific conditions for authorisation (if any):

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Words: 0/5000

Name	Position	Signature	Date
Jonathon Sewell	Head of Department		

Save Sign & Finish Close Cancel

The project status will be displayed on the Summary tab in the project workspace. The RGO will

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

be notified of your decision and create a Not Authorised letter for you to sign.