

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.

1.3 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 \underline{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: <u>Sign up as RGS User (for WA Health Employees)</u>.

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: <u>Roles in RGS</u>.

🗹 RGS User
Research User
Hospital Administrator
Committee Member
Research Governance Officer
Ethics Executive Officer

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 <u>email</u> 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 inkind.

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

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 'S 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: | <u>https://rgs.health.wa.gov.au/Pages/task-form.aspx?fm=V&tud=9325</u>

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: <u>All about Tasks</u>.



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 Provide Quote and Authorise/De	cline in Budget Form	(1)		
RGS0000002133 Pharmacy - Request to Quote/Authorise	Pending	Henry Amberley	22/02/2018	1/03/2018

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.

C	A1-
Group task?	No
Task type:"	Invitation to Provide Quote and Authorise/Decline in Budget Form
PRN:"	RGS000002133
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

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'.

Budget	Form			
Next >>	Edit	Print	Close	

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'.

Form is	checked out to you for editing.
Index:	2. Site Project Budget
	1. Department(s) Selection
	2. Site Project Budget
	3. Site Project Funding / Support

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.

<< Previous Next >>	Save	Save and Close	Cancel
---------------------	------	----------------	--------

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: <u>Fill out and authorise a Budget Form (for a supporting department)</u>

Supporting Department									
PathWest									0
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 🔻		
General Comments (man B I U (X ि बि	Biospecime collection and processing (central labs) – performed by pathology staff personnel Biospecimen collection and processing (central labs) – performed by research nurse Biospecimen storage Biospecimen storage Biospecimen torage					Add	Remove	Authorise	Decline
	return/destruction							V	/ords: 0/5000

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'.

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. 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.

General Comments (mandatory in cases of shortfall)
Identify the department then you can add any comment you need to related to the costings, funding or items regarding your departments support of the budget.
body

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.

Supporting Department								
- Pharmacy								0
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 •		
						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.

Anior Catagoni								
viajoi Calegory	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 paticipants x 4 tests x 4 years	\$25.00	360	\$9,000.00	Project specific	No	

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 It
Trial initiation	Departmental set up	Set up fee	s
Site closeout visit	Site closeout visit	Close out fee	s
Pharmacy/Investigation drug related	Stock management – drug stoc 🔻	Annual Administration fee	s
Pharmacy/Investigation drug related	Stock management – expiry m: *	Annual storage fee	S
Pharmacy/Investigation drug related	Drug preparation and dispensir *	Dispensing Fee	S
Pharmacy/Investigation drug related	Drug preparation and dispensir 🔻	Remote monitoring fee - \$100 per instance	S
<			

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.

itle:	Costin	ng Decl	ined	ŧ														
rovide a reason isible to other us nd provide a ne	for declinin sers. After si w comment	ig the ci aving, ij t	ost p f you	provided fo u wish to r	or the remov	depa e the	rtmer comr	nt. Noi nent, j	e that ou wi	when I hav	you i e to u	lick : nlock	Save', j this de	your co Ipartm	mmer ent qu	nts will ote, se	be Fil lect de	NAL an ecline a
Comment:"	В	I	U.	X %	6	4	14	Ω	12	::	-12	1						
	Ent	ter the r	reas	ons for de	eclinin	ng he	re, thi	s will	be inc	luded	in an	ema	i to th	e Pl ar	nd Pí		1	
	Ent Del	ter the r	reas	ons for d	eclinin	ng he	re, thi	s will	be inc	luded	in an	ema	il to th	e PI ar	nd PI			
	Ent Del	ter the r legate	reas	ons for d	eclinir	ng he	re, thi	s will	be inc	luded	in an	éma	il to th	e Pl ar Wor	d PI	5000	4	

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 Pl/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 <u>Select the departments section</u> within the <u>Help Wiki: Add, fill out and authorise a Budget Form</u>.

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.



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: <u>All about Tasks</u>.



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 Provide Quote and Authorise/Decline i	n Budget Form (1)						
RGS000002133 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.

Group task?	No
Task type:"	Invitation to Provide Quote and Authorise/Decline in Budget Form
PRN:"	RGS000002133
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

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'.

Budget	Form			
Next >>	Edit	Print	Close	

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

2	Please note that this form will be checked out to you for editing. No other members can make any changes until you click Save and Close. Are you
-	sure you wish to continue?

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

Form is	checked out to you for editing.	
Index:	2. Site Project Budget	,
	1. Department(s) Selection	
	2. Site Project Budget	
	3. Site Project Funding / Support	

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 Foi	rm				

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	t per Item 🕧	Quantity 🕕	Total Cost 🕧	Cost Type 🕧	Overhead Charge?	
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 Coodinator	\$	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 🔻	V	
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 🔻		0
Clinical resources	Outpatient time *	all visits	\$	200.00	240	\$48,000.00	Shared •		
Site closeout visit	Site closeout visit *	all staff	s	3,000.00	1	\$3,000.00	Shared •	Ø	C
Record archiving	Archiving of records *	Clinical Trials Coordinator	\$	1,000.00	1	\$1,000.00	Shared •		

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 🔻		6
Biospecimen related	Biospecimen collection and pr	20 paticipants x 4 tests x 4 years	\$ 25.00	360	\$9,000.00	Project specific *		•

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 Co	osts:	▲ Total At \$133,040.00	uthorised Costs	8		\$25,040.00	■ Total Funding	s S	133,040.00	Short Short	fall (or Surplus):	\$108,000.00	1
Available Funders		Type of Funde	r					\$ Funding by Sponsor or	Funder		\$ In-Kind Support	Funding Status	Remove
Novartis Pharmace	uticals Australia Pty Ltd	Commercial o	ompany - indust	ry / con	tract research o	rganisation		\$133,040.00				Confirmed *	×
If the funder is not li	isted, ensure they have bee	n added to the Project Details tab, G	overnance Inforn	nation s	ection and that t	the Project Detai	ls tab is authorised. Y	ou may remove funders that do not a	pply to this E	Budget Form	by clicking on the 'X' in the R	emove column.	Refresh 🚺
🖃 Royal Pert	h Hospital												
Proposed number	of participants in this sit	n: 40									Expected project tim	eframe for this site: 5 year(s)
*Participant also inclu	ides a person's data, informa	ion or biological sample.											
E Arrestarch Dep	arunent												
- Anaestnes	a and Pain Medicine												U
Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Qty	Total Cost	Cost Type	\$ Funding by Sponsor or Funder ①	Sponsor Funder Name 🕧	\$ In-H Supp	Kind ort 🕧	In-Kind Funder Name 🕧	Fund Description 🕧	
Clinical services	Overhead Charge		25.00%	1	\$21,100.00	Project specific	\$ 21,100.00	Novartis Pharmaceuticals Austra ¥	\$	0.00	Please select *		
Ethics approval	Ethics review	SMHS HREC	\$0.00	1	\$0.00	Project specific	\$ 0.00	Novartis Pharmaceuticals Austra *	\$	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 Austra *	\$	0.00	Please select *		
Feasibility assessment	Preliminary assessment	PI & Clinical Trials Coodinator	\$1,000.00	1	\$1,000.00	Shared	\$ 1,000.00	Novartis Pharmaceuticals Austra *	\$	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 Austra ¥	\$	0.00	Please select *		
Trial initiation	Departmental set up	all staff	\$3,000.00	1	\$3,000.00	Shared	\$ 3,000.00	Novartis Pharmaceuticals Austra *	\$	0.00	Please select *		
Patient accrual	Recruitment activity	PI & Research Nurse	\$200.00	40	\$8,000.00	Shared	\$ 8,000.00	Novartis Pharmaceuticals Austra *	\$	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 Austra *	\$	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 Austra ¥	\$	0.00	Please select *		
Clinical resources	Outpatient time	all visits	\$200.00	240	\$48,000.00	Shared	\$ 48,000.00	Novartis Pharmaceuticals Austra *	\$	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 Austra 🔻	\$	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 Austra 🔻	\$	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.

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 9	6	\$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 Coodinator	\$ 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		0
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		

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

General Medicine						Authorised	1 - Jonathon Sewell 2:	3/02/2018
Major Category	Service & Support Item Provided 🕕	Cost Description	Cost per Item 🕧	Quantity 🕧	Total Cost 🕧	Cost Type 🕧	Overhead Charge? 🕧	Selec
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	

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?	Selec
Clinical services	Overhead Charge - percentage		25.00 9	6	\$21100.00	Project specific		
Ethics approval	Ethics review	SMHS HREC	\$ 0.00		\$0.00	Project specific		
lite specific assessment	Site processing and review	EMHS RGO	\$ 2,500.00		\$2,500.00	Project specific		
easibility assessment	Preliminary assessment *	PI & Clinical Trials Coodinator	\$ 1,000.00	1	\$1,000.00	Shared		
ite specific assessment	Preparation of the SSA applicat *	Clinical Trials Coordinator	\$ 2,000.00	1	\$2,000.00	Shared		
rial initiation	Departmental set up	all staff	\$ 3,000.00	1	\$3,000.00	Shared		
atient accrual	Recruitment activity *	PI & Research Nurse	\$ 200.00	40	\$8,000.00	Shared		۵
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		
iite closeout visit	Site closeout visit *	all staff	\$ 3,000.00	1	\$3,000.00	Shared		
lecord archiving	Archiving of records *	Clinical Trials Coordinator	\$ 1,000.00	1	\$1,000.00	Shared		

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

itte:	Costing Declined		
Provide a reason f risible to other use and provide a new	or declining the cost provided for the department. I rs. After saving, if you wish to remove the commer comment.	Note that when you click 'Save', your comments nt, you will have to unlock this department quote	will be FINAL and , select decline aga
Comment:"		Ω = = =	
	Enter the reserve for declining here, this u		
	Delegate	will be included in an email to the PI and PI	
	Delegate	will be included in an email to the PI and PI	
	Delegate	will be included in an email to the PI and PI	
	Delegate	will be included in an email to the PI and PI	
	Delegate	will be included in an email to the PI and PI Words: 19/50	00 _
	Delegate body	will be included in an email to the PI and PI Words: 19/50	00 _

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.



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: <u>All about Tasks</u>.



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
⁴ 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:*	RG5000000012
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 G G (→ Ω) = := = # # Words: 0/5000 ∡
Task status:	Pending
Action	Decline Task Cancel
Please click "Action" to take you to	o 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 >> Prin	t Close	Index: 1. Project Details		×					
1. Project Details		2. Broad Researc 3(1). Investigator	h Area, NHMRC Group and Fie s (for sites covered by this for	eld of Research m) - Royal Perth Hospital					
1.1 Project		4. Credentialing a 5. Participants	and Training						
1.1.0 PRN:	RGS	6-11. Questions 12. Indemnity an	d Insurance						
1.1.1 Project title:	A rar with	ndomised 13. Research Agr controllec 14. Intellectual Pr	eements roperty amical and Padiation Safety						
1.1.2 Short title:	oster	parthritis 16. Resource and 17. Funds Manag	Budget Information ement Details						
		18. Declarations							

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: <u>All about Tasks.</u>

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.

 I certify that I h within this Dep I certify that the site(s). My signature in in the Budget F 	ave read the research project details of artment and at the site(s). ere are suitable and adequate facilities adicates that I support this research pr form associated with this form.	covered by this for s, resources and roject being carri	orm and that funding for t ed out using	t the research i the research pr 3 such resource	s appropriate to be cor oject to be conducted a s and funding, as docu	nducted at the mented
Name	Position	Signature	Date	Invitation Status	Invited By	Select
lbert Macintosh	Business Manager - Sir Charles Gairdner Hospital	Sign]	Accepted	Henry Amberley	
	Divisional Director - Sir Charles	Sign		Invited	Henry Amberley	

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: <u>All about Tasks</u>.



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
4 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.

Validation	Ê.	Authorisation	Comme	ents	Ethics	Governance	Files &	& Docui	ments	Fees
Application	ns									
+ Ethics A	Appro	val								
-	.pp.o									
🖃 Site Aut	thoris	ation								
🛨 Sir C	Charle	s Gairdner Osborn	e Park Heal	th Care	e Group Rese	arch Governance Of	ffice			
+ Child	d and	Adolescent Health	n Service Re	search	Governance	Office				
🖃 Sout	th Me	tropolitan Health S	service Rese	earch E	thics and Go	vernance Unit				
- Fi	iona	Stanlov Hospital								
	iona .	stanley nospital								
N	Vote: T	he site status must b	e updated in	the Adr	ministration - (Governance tab to refl	ect any de	cisions m	ade.	
N	Vote: T	<i>he site status must b</i> eview	e updated in	the Adr	ministration - (Governance tab to refl	ect any de	cisions m	ade.	
N RI	Note: T RGO Re ID	the site status must be eview Overall Review Ass	e updated in essment	the Adr	ministration - (s	Governance tab to refle Review Completion	ect any de n Date	cisions m Review	ade. ing RGO	Time
N R I	Note: T RGO Re ID	he site status must b eview Overall Review Ass	e updated in essment	the Adr Status	ministration - (s	Governance tab to refli Review Completion	ect any de n Date	cisions m Review	ade. ing RGO	Time Elapsed (in days
N Ri I	Vote: T RGO Re ID 2133	he site status must be eview Overall Review Ass AIR	e updated in essment	the Adr Status Comp	ministration - (s	Governance tab to refl Review Completion 05/04/2018	ect any de n Date	cisions m Review <u>Tegan</u>	ade. ing RGO <u>Williams</u>	Time Elapsed (in days
N Ri I 2 2	Vote: 7 RGO Re ID 2133 2134	AIR Recommended	e updated in essment	the Adr Status Comp	ministration - (s oleted oleted	Governance tab to refl Review Completion 05/04/2018 05/04/2018	ect any de n Date	cisions m Review <u>Tegan</u> <u>Tegan</u>	ade. ing RGO <u>Williams</u> <u>Williams</u>	Time Elapsed (in days 2 1
N R I 2 2 2 2	Vote: 7 RGO Re ID 2133 2134	he site status must be eview Overall Review Asso AIR Recommended egate Authorisation	e updated in essment	the Adr Status Comp Comp	ministration - (s oleted oleted	Governance tab to refl Review Completion 05/04/2018 05/04/2018	ect any de n Date	cisions m Review <u>Tegan</u> <u>Tegan</u>	ade. ing RGO <u>Williams</u> <u>Williams</u>	Time Elapsed (in days 2 1
N Ri 2 2 2 1	Vote: T RGO Re ID 2133 2134 CE/Del	AIR Recommendation Recommendation Decision	e updated in essment CE / Deleg Authorisa Decision	the Adr Status Comp Comp gate tion	ministration - (s oleted oleted Status	Governance tab to refl Review Completion 05/04/2018 05/04/2018 Authorisat Decision I	ect any de n Date tion C Date D	cisions m Review <u>Tegan</u> <u>Tegan</u> E / elegate	ode, ing RGO <u>Williams</u> <u>Williams</u>	Time Elapsed (in days 2 1 Time Elapsed (in days

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

The governance review for this pr	oject has been completed for this site.	
RGO recommendation decision:	Recommended	
Comments:	BIU X∩ © ← → Ω ⊑ ≔ ≢ ≢	
	Words: 0/5000	
Site specific conditions for authorisation (if any):		

- **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: <u>Request additional information</u>, <u>Authorise a project for a site</u> and <u>Not Authorise a project for a site</u> to change the 'Review Assessment' for each form and document.

orms								Please select
Form	Name 🕧	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	AIR Authorised Not Authorised
Site S Asses	pecific sment (SSA) Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	RGO recommended Under review
Budg	et Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	RGO recommended
Docur	te							
Jocui	lients							
Doc ID	Document Name	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	Review Assessment 🧃
Doc ID 4455	Document Name	Version 0	Submission Date 05/04/2018	Validation Date 05/04/2018	Review Decision Date 05/04/2018	Authorisation Decision Date	Current Status RGO recommended	Review Assessment
Doc ID 4455 4454	Document Name	Version 0 0	Submission Date 05/04/2018 04/04/2018	Validation Date 05/04/2018 04/04/2018	Review Decision Date 05/04/2018 05/04/2018	Authorisation Decision Date	Current Status RGO recommended RGO recommended	Review Assessment (RGO recommended RGO recommended

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.

Sites	Members	Pro	oject Details	Forms & Documents	Declarations
Comments	Letters	Pi	ublications	Summary	Timeline
Reports	History				
Site Specific Royal Perth Hospit	c Assessme al	ent ((SSA) F	orm	
Next >> Print	Close	Index:	1. Project Details	ĩ	•
			1. Project Details		
1. Project Details			2. Broad Researce	h Area, NHMRC Group and Fie	ld of Research
1 1 Project			4. Credentialing	and Training	ny noyai Peruri iospitai
1.1.0 PRN:	RGS	00000000	6-11. Questions 12. Indemnity an	d Insurance	
1.1.1 Project title:	A rai	ndomised	13. Research Age	eements	
	with	controllec nded-relea	15. Biosafety. Ch	ropeny emical and Radiation Safety	
	oste	oarthritis	16. Resource and	d Budget Information	
1 1 2 Short title			17. Funds Manag	gement Details	
1.1.2 50010 0000			18. Declarations		

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: <u>Navigate the project workspace</u> 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: <u>Request additional information</u>, <u>Authorise a project for a site</u> and <u>Not Authorise a project</u> <u>for a site</u>.

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.

CE / delegate authorisation decision: Site specific conditions for authorisation (if any):	Please select AIR Authorised Not authorised		0
Namo		Constina	Words: 0/5000
vame Iohn O'Leary	Head of Department	Signature	Date
		Save Sign & Finish	Close Cancel

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/D	elegate Authorisation				
ID	RGO Recommendation Decision	CE / Delegate Authorisation Decision	Status	Authorisation Decision Date	CE / Delegate
9	Recommended	AIR	Completed		<u>Jonathon</u> Sewell
10	Recommended	Not Authorised	Completed	09/10/2016	<u>Jonathon</u> 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.

Form I	Name 🕧	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	Review Assessment	i
Site Sp Assess	pecific ment (SSA) Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	Authorised	~
Budge	t Form	1.0	05/04/2018	05/04/2018	05/04/2018		RGO recommended	Authorised	
Docum	ients								
Doc ID	Document Name	Version	Submission Date	Validation Date	Review Decision Date	Authorisation Decision Date	Current Status	Review Assessment	đ
4455	GSK CTRA final	0	05/0 <mark>4</mark> /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 / de	legate review com	iments	BIU		Ω (* *)				
									1

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

decision:	Authorised	\sim		0
Site specific conditions for authorisation (if any):				0
Name	Position 🕕	Signature	Date	
Name	Position 🕖	Signature	Date	

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

10	Overall Review Ass	essment Stat	tus	Review Completion Date	e Reviev	ving RGO	Time Elapse (in day
2133	AIR	Cor	npleted	05/04/2018	Tegan	Williams	2
2134	Recommended	Cor	npleted	05/04/2018	Tegan	Williams	1
CE/De	legate Authorisation		120-025-02	A	CE /	Invited	Time
ID	RGO Recommendation	CE / Delegate Authorisation	Status	Decision Date	Delegate	Ву	Elap

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.

0.0			
Dr April Clark			
Fiona Stanley Hosp	bital		
Robin Warren Drive	9		
Murdoch WA 6150			
Dear Dr Clark			
PRN:	RG\$000000054		
	A Randomized, Multicenter, Open-Label, Phase	3 Study of Acalabrutinib (ACP-196) Ve	ersus Investigator's
Project Title:	Choice of Either Idelalisib Plus Rituximab or Be	ndamustine Plus <mark>Rituximab</mark> in Subjects	s with Relapsed or
	Refractory Chronic Lymphocytic Leukemia		
Protocol Number:	ACE-CL-309		
nciude.			
Document		Version	Version Date
Document Ace Insurance Certi	ificate	Version	Version Date 20/12/2017
Document Ace Insurance Certi Indemnity Form	ificate	Version	Version Date 20/12/2017 15/03/2018
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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.

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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

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

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.