



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

Navigating the WA Health Research Governance Service (RGS) as a researcher for Research Monitoring



Katherine Coltrona, Senior Policy Officer
Department of Health









CAHS & NMHS 27/8/2018

Changes to RGS Current Functionality

Tasks	New look My Tasks – merge current, overdue and archive.
User Profile	Qualifications and Expertise limited to 500 words so that only 500 words can populate into Project Details/WAHEAF.
Create a Project	Assign a CPI Delegate when creating a project.
WASM	CPI Delegate can authorise.
Application Documents	Document placeholders no longer created for AIRed docs; 'Attach' Documents only - no longer authorise requirement.
SSA Form	Notification for PI to sign SSA Form following completion.
Letters	Close button; Tooltip on Attach Documents to Letters; Letters Grid sortable.
Complaint	Finalising a Complaint – word change; unlock; remove invitations. Un-invite from a complaint. Complaint actions – unlock; finalise rows added.
Summary Tab	Project Summary relocated.
Additional Guidance	Blue text when submitting External Ethics to RGO; reference to my projects in New Project Confirmation Email.
Ethics Tab	Allow EEO (RGO NMA) to Update Project Ethics Approval Status when there is a pending RGO validation except for the status of Withdrawn.
Forms & Documents Tab	Changed to Applications & Monitoring

Tasks – New Look & Merged

UAT - My Tasks

Group	Task Type	Subject	From	Due Date	Notes	
	Invitation to Provide Quote and Authorise/Decline in Budget Form	Invitation to Provide Quote and Authorise/Decline in Budget Form	Katherine Coltrona	3/02/2017		
	Invitation to Sign Declaration	Invitation to Sign Declaration	Katherine Coltrona	8/02/2017		
	Additional Information Requested	Additional Information Requested: RGS00000000056	Katherine Coltrona	14/02/2017		
	Additional Information Requested	Additional Information Requested: RGS00000000056	Katherine Coltrona	14/02/2017		
	Invitation to Sign Declaration	Invitation to Sign Declaration	Katherine Coltrona	9/03/2017		
	Additional Information Requested	Additional Information Requested: RGS00000000056	Katherine Coltrona	8/08/2017		
	Additional Information Requested	Additional Information Requested: RGS00000002128	Katherine Coltrona	19/01/2018		
	Invitation to Join Project	RGS0000002146	Mary Davies	17/08/2018		
	Invite to HREC Meeting	Invite to HREC Meeting: CMR0000003169	Jane Dowe	5/12/2018		
	Invite to HREC Meeting	Invite to HREC Meeting: CMR0000003171	Jane Dowe	5/12/2018		

7 days over due

How to add or read a Task Note

		New User Access Request	New User Access Request : Khurram DurraniB	3/12/2017		
		New User Access Request	rgsuat+11@gmail.com	8/08/2018		
		Request for a New Site, Division and Department	Leanne HA	21/09/2017	Notes exist on this task	
		Request for CE/Delegate Authorisation	Request for CE/Delegate Authorisation: RGS0000000005	Katherine Coltrona	13/08/2017	
		Update Details Approval	Leanne Greenham	20/09/2017		

1



Edit Task Notes

Task Type: New User Access Request

From: **Due Date:** 08/08/2018

B I U

I am investigating whether this is a real person.

Words: 9/5000

Save **Cancel**

2

How to sort/filter Tasks

UAT - My Tasks

My Tasks

My Dashboards















My Projects

Create Project

Projects Search

Complaints

Complaints

Group	Task Type	Subject	From	Due Date	Notes	
(All) ▼	New User					 
	CE/Delegate Decision completed	RGS0000000054	Diana Forster	10/08/2018		
	New User Access Request	rgsuat+11@gmail.com		8/08/2018		
 	Monitoring Submission for Governance Validation	RGS0000000072	Samantha Grogan	3/08/2018		
	Invite to HREC Meeting	CMR0000003184, 08/06/2018	Diana Forster	8/06/2018		
 	CE/Delegate Decision completed for	CE/Delegate Decision completed for RGS00000002128	Katherine Coltrona	22/01/2018		

3 days over due

Archived Tasks will be hidden unless accessed through the Filter

Types of Tasks

UAT - My Tasks

Tasks Complete

Group	Task Type	Subject	From	Due Date	Notes	
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You have no tasks requiring action at this time.

HA Tasks

UAT - My Tasks

Group	Task Type	Subject	From	Due Date	Notes	
	Invitation to Sign Declaration	RGS0000002146, SSA Form	Margaret Brown	20/08/2018		
	Invitation to Sign Declaration	RGS0000002146, AR Form	Margaret Brown	20/08/2018		
	Invitation to Provide Quote and Authorise/Decline in Budget Form	RGS0000002146, Cardiology	Margaret Brown	20/08/2018		

Home Research Information Meeting

UAT - My Tasks

Group	Task Type	Subject	From	Due Date	Notes	
	Request for CE/Delegate Authorisation	RGS0000002146	Matilda Clarke	20/08/2018		

CE Tasks

Create Project

1. Add CPI Delegate name

2. Email to CPI Delegate and CPI

Declaration of Confidentiality (DoC)

Are you acting as a WA Health employee on this project?* ▼



4. I will not use the data to attempt to identify or make unauthorised contact with any individual or to provide the data to another person for those purposes.
5. I will not make any unauthorised merger of the data with any other data set, including information files provided for two or more separate projects.
6. Except in the form of conclusions drawn from the data, I will not disclose any data to any person other than another person authorised for the research project.
7. I will not publish any data provided by WA Health, or derived from that data, from which the identity of an individual is apparent or can be reasonably ascertained unless the individual has given their written consent to be identified in the publication.
8. I will comply with all obligations set out in the current *Department of Health Practice Code for the Use of Personal Health Information* for personal health data provided by the Department of Health for the purpose of the project.
9. If I become aware of any loss or misuse of the data I will immediately inform the Research Governance Officer responsible for the WA Health site.
10. At the conclusion of the research project and within the period approved for retention of the data, I will ensure the complete and confidential destruction of the data provided to me for the purpose of the project.

I have read and agree to the Declaration of Confidentiality*

CPI Delegate

Do you want to nominate a CPI Delegate at this time?* ▼

A CPI Delegate must already be a RGS Research User. If you cannot find a person, please ensure they are signed up for RGS, or contact RGS support. The CPI Delegate will only be invited to the project workspace once this form is approved.

RGS user:  

If you cannot find a person, please contact RGS Support.

I acknowledge that the person invited to join this research project is aware of the confidentiality requirements regarding this project.*

Create Project

- CPI Delegate task to join Project
- CPI Delegate has a sign up form



UAT - Project Invitation Acceptance

PRN: RGS000002146
Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Your Details

Name: Mary Davies
Membership status: Invited

Role(s) and Site(s)

Role	Site(s)
CPI Delegate	All

Membership Acceptance

Are you acting as a WA Health employee on this project?

WA HEALTH DECLARATION OF CONFIDENTIALITY
(for research personnel who are not WA Health employees)

GUIDELINES

The WA Health Declaration of Confidentiality must be completed by all research personnel (including students) who are not employees of WA Health, who will be:

- Conducting a research project within WA Health; or
- Accessing WA Health participants, their tissue or data.

The Declaration of Confidentiality must be completed by the non-WA Health employee for each research project they are involved with.

declaration

I have read and agree to the Declaration of Confidentiality

I agree that in accepting access to this research project I will be bound by confidentiality requirements regarding the project.

Documents automatically authorised

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

Ethics Approval

[Find information on Research Authorisation and Monitoring Forms](#)

Active

Forms

Forms must be authorised before they can be submitted.

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

Add	Remove	Authorise	Unauthorise	Print
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Documents

[Find recommended document templates here.](#)

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

Doc ID	Document Name	Version / Date	Status	Attached By	Date Attached	Select
6506	Human Research Ethics Application	1.0 10/08/2018	Authorised	Alex Roberts	10/08/2018	<input type="checkbox"/>

Add	Edit	View	Remove	Print
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CPI Delegate can authorise WASM

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

Ethics Approval

[Find information on Research Authorisation and Monitoring Forms](#)

Active

Forms

Forms must be authorised before they can be submitted.

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

Add	Remove	Authorise	Unauthorise	Print
-----	--------	------------------	-------------	-------

Documents

Find recommended document templates [here](#).

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

Doc ID	Document Name	Version / Date	Status	Attached By	Date Attached	Select
6506	Human Research Ethics Application	1.0 10/08/2018	Authorised	Alex Roberts	10/08/2018	<input type="checkbox"/>

Add	Edit	View	Remove	Print
-----	------	------	--------	-------

PI Delegate can authorise Budget & PI Task to sign SSA Form

Section 2 of 3 - Site Project Budget

Total Actual Costs: \$98,750.00 Total Authorised Costs: \$98,750.00 Total Funding: \$101,750.00 Shortfall (or Surplus): \$3,000.00

Royal Perth Hospital

Proposed number of participants in this site: 5 Expected project timeframe for this site: 2 year(s)

*Participant also includes a person's data, information or biological sample.

Research Department

Cardiology Authorised - Oliver Walker 13/08/2018

Major Category	Service & Support Item Provided	Cost Description	Cost per Item	Quantity	Total Cost	Cost Type	Overhead Charge?	Select
Clinical services	Overhead Charge - percentage		20.00%	1	\$15,000.00	Project specific	No	
Ethics approval	Ethics review		\$2,000.00	1	\$2,000.00	Project specific	No	
Site specific assessment	Site processing and review		\$3,000.00	1	\$3,000.00	Project specific	No	
Clinical resources	Investigator time - Principal Investigator		\$5,000.00	5	\$25,000.00	Shared	Yes	
Clinical resources	Clinical research coordinator (non-research nurse) time		\$10,000.00	5	\$50,000.00	Shared	Yes	

Supporting Department

Pharmacy Authorised - George Wright 13/08/2018

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 - complex		\$300.00	5	\$1,500.00	Project specific	No	
Pharmacy/Investigation drug related	Stock management - expiry management		\$50.00	5	\$250.00	Project specific	No	
Other	Other	Annual Service Charge	\$1,000.00	2	\$2,000.00	Project specific	No	

General Comments (mandatory in cases of shortfall)

Words: 0/5000

Buttons: << Previous, Next >>, Save, Save and Close, Cancel, **Authorise**

PI Delegate Authorisation

PI Task

UAT - My Tasks

Group	Task Type	Subject	From	Due Date	Notes
	SSA Form Completed	RGS0000002146	Alex Roberts	16/08/2018	

New RGS Functionality

Dashboard

Amendment Form

Governance Only Amendment Form

Safety Form

Progress Report

Site Final Report

Project Final Report

Researcher Dashboard

UAT - My Dashboards

Phase	PRN	Title	CPI	Project Status	Risk	
Applicati...				All selected		Tx
	RG0000002121	Test 1: National Mutual Acceptance - External Lead HREC without Specialist HREC	Katherine Coltrona	New Project	↓	
	RG0000000095	Test 3: National Mutual Acceptance - External Lead HREC without Specialist HREC	Katherine Coltrona	New Project	↓	
	RG0000002146	Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC	Jane Dowe	Pending Ethics Review	↓	
	RG0000002119	Test Project 10B: Sites_Long Name without space distort the page. Sites, Approve Project, Create Project screen, Add Member PI/AI, AR/SSA Forms etc is affected.	John Smith	Pending Ethics Review	↓	
	RG0000002113	Test 1: National Mutual Acceptance - External Lead HREC with Specialist HREC	Jane Dowe	AIRed by Ethics	→	
	RG0000000050	Can metformin be used safely in dialysis patients?	John Smith	AIRed by RGO	↓	
	RG0000000055	Research Governance Service Test Project 1.1.	Katherine Coltrona	Monitoring	↓	
	RG0000002109	Test 1: National Mutual Acceptance - Lead WA Health HREC with Specialist HREC	Jane Dowe	Monitoring	↓	

Researcher

Risk

Monitoring


Applications

Filter

Ethics Approved - require site authorisation

UAT - My Dashboards


Researcher

Phase	PRN	Title	CPI	Project Status	Risk	
Applicati...				All selected		Tx
	RG50000002146	Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC	Jane Dowe	Governance not Submitted	↓	

Aired by RGO

UAT - My Dashboards

Researcher

Phase	PRN	Title	CPI	Project Status	Risk	
Applicati...				All selected		Tx
	RG50000002146	Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC	Jane Dowe	AIRed by RGO	↓	

Monitoring Tab

Home Research Information Meeting Calendar Document Templates Contacts Help Wiki

PROJECT | Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Click on the arrows below to get step by step guidance.

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

PRN: RGS0000002146 Project status: Active Project ethics approval status: Approved
Project type: Research Short title: Test 2A 2 WA HRECs
Protocol number: 2018AZDGH#\$-1 Acronym: 2AMUAT CPI: [Jane Dowe](#)
External HREC ref: None Lead HREC: Royal Perth Hospital HREC (EC00270)
Specialist HREC: Department of Health WA Human Research Ethics Committee (EC00422)

My Role(s): CPI Delegate

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

+ Forms Find information on Research Authorisation and Monitoring Forms

+ Documents

Submit

PRN: RGS0000002146

Project status: Active

Project ethics approval status: Approved

Project type: Research

Short title: Test 2A 2 WA HRECs

Protocol number: 2018AZDGH#\$-1

Acronym: 2AMUAT

CPI: [Jane Dowe](#)

External HREC ref: None

Lead HREC: Royal Perth Hospital HREC (EC00270)

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

My Role(s): CPI Delegate

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

Forms

[Find information on Research Authorisation and Monitoring Forms](#)

Form Name



Add

Documents

Document Name

Type



Add

Submit

Add Monitoring Forms

Add Project Forms ✕

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Select Monitoring Forms

Form Name	Select
Amendment Form	<input checked="" type="checkbox"/>
Progress Report	<input type="checkbox"/>
Site Final Report	<input type="checkbox"/>
Safety Report	<input type="checkbox"/>
Project Final Report	<input type="checkbox"/>
Governance Only Amendment Form	<input type="checkbox"/>

Add Amendment Form


Add Project Forms

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Select Monitoring Forms

Message from webpage

 You are unable to create a monitoring form until at least one site has been authorised under the Administration – Governance tab.

OK

Form Name	Select
Amendment Form	<input checked="" type="radio"/>
Progress Report	<input type="radio"/>
Site Final Report	<input type="radio"/>
Safety Report	<input type="radio"/>
Project Final Report	<input type="radio"/>
Governance Only Amendment Form	<input type="radio"/>

Add Selected Form To Project Cancel


Add Project Forms

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Select Monitoring Forms

Message from webpage

 Before adding an Amendment Form, ensure that:

- Information in the Project Details tab is accurate;
- All required changes have been made in the Sites tab; and
- All required membership changes have been accepted.

Click OK to proceed or click Cancel and make the necessary changes.

OK Cancel

Form Name	Select
Amendment Form	<input checked="" type="radio"/>
Progress Report	<input type="radio"/>
Site Final Report	<input type="radio"/>
Safety Report	<input type="radio"/>
Project Final Report	<input type="radio"/>
Governance Only Amendment Form	<input type="radio"/>

Add Selected Form To Project Cancel

Forms Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form	---	---	---	---	---	---	

Documents

Add

Form can be added and edited by all PMs

Amendment Form

Next >>

Form is checked out to you for editing.

Index: **1. Form Information**
2. Declarations

1. Project Details i

1.1 PRN: RGS0000002146

1.2 External HREC ref: None

1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)

1.5 Site:*

1.6 CPI: Jane Dowe

1.7 Date of last Annual Progress Report submission: N/A i

2. Change to Project Documentation

Does the amendment involve a change to project documentation?* v

3. Change to Project Investigators i

Does the amendment involve a change to project investigators?* v

4. Addition of a Site i

Does the amendment involve the addition of a site?* v

5. Extension of Approval

Does the amendment involve an extension of approval?* v

Add Project Documents through Form

2. Change to Project Documentation

Does the amendment involve a change to project documentation?*

Please consider that changes to the project may impact on other project documents or forms within the project e.g. Budget Form, Research Agreement.

For changes to approved documentation, please submit a Summary of Changes document outlining the changes in the updated version.

Use the table below to select all documents applicable to this form. You can add additional documents via the 'Add' button.

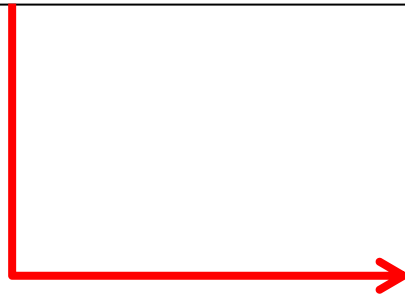
Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
--------	---------------	---------	--------	-------------	---------------	--------

2.1 Reason for change:*

Add

B I U [Cut] [Copy] [Paste] [Undo] [Redo] [Ω] [List] [List] [List] [List]

Words: 0/5000



Add Project Documents

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Monitoring Document

Document category:*

Document type:*

Document name:*

The document name entered here will appear in the final approval letter and should reflect the information in the footer of your document. Please ensure it is correct as it cannot be changed by the administrators. Do not enter the file name and avoid using underscores.

Status: Not attached

Document Details

Version number:* Version date:*

The version number and version date entered here will appear in the final approval letter. Please ensure it is correct as it cannot be changed by the administrators.

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

Upload Soft Copy (Electronic) File

Select file:*

Allowed Types: DOC, DOCX, PDF, PPT, PPTX, XLS, XLSX - Please provide a word document if possible

Select Project Documents in Form

2. Change to Project Documentation

Does the amendment involve a change to project documentation?*

Please consider that changes to the project may impact on other project documents or forms within the project e.g. Budget Form, Research Agreement.

For changes to approved documentation, please submit a Summary of Changes document outlining the changes in the updated version.

Use the table below to select all documents applicable to this form. You can add additional documents via the 'Add' button.

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
6533	Master Participant Information and Consent Form	2.0	Authorised	Mary Davies	14/08/2018	<input checked="" type="checkbox"/>
6534	Protocol	2.0	Authorised	Mary Davies	14/08/2018	<input checked="" type="checkbox"/>
6535	Summary of Changes	1.0	Authorised	Mary Davies	14/08/2018	<input checked="" type="checkbox"/>
6536	Victorian Module	1.0	Authorised	Mary Davies	14/08/2018	<input checked="" type="checkbox"/>

2.1 Reason for change:*

B I U

Master PICF changed to reflect changes to Protocol.
Protocol updated to add additional safety monitoring and data collection.
Victorian Module for Victorian Site.

Words: 23/5000

Added Form & Docs in Monitoring Tab

My Role(s): CPI Delegate

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

Forms

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form	---	---	---	---	---	---	

Add

Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Summary of Changes	Other	---	---	---	---	---	---	 
Protocol	Protocol	---	---	---	---	---	---	 
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	 

Add

Submit

Can add additional documents

Lists all PMs - select applicable one

3. Change to Project Investigators i

Does the amendment involve a change to project investigators?*

Yes

Use the table below to select all investigators applicable to this form.

Role	Name	Qualifications and Expertise Relevant to the Project i	GCP Certified	Student? i	Name and Location of Student Supervisor i	Site(s) for Which the Investigator Is Responsible	Select
		Haematologist. There is a researcher within all of us just waiting to be let loose... Being 'good' according to the Oxford English Dictionary can be aligned with a multitude of properties of which "high quality", "competent" and "skillful" are amongst those listed to name a few. We believe that the qualities required to be good researcher can be broken down into more specific core competencies. Here are the thoughts of the Mustard team, in no particular order...					
CPI	<u>Ms Jane Dowe</u> The University of Western Australia	1. <i>An analytical mind</i> "As a market researcher you are constantly analysing a variety of factors. Why does the client ultimately want to do this research? What is the appropriate methodology? When should this research take place? What are the appropriate questions to ask and how? Why did the respondent say that? What are the findings telling us? Why are they telling us that? How do I best communicate the findings? etc. On a daily basis researchers must be able to take a step back and analyse the situation presented to them. The obvious answer is not necessarily the right one" (Gareth Hodgson) "You have to be able to see the bigger picture as well as the detail. People often find it easier to do one or the	Yes	No	All		<input type="checkbox"/>











Lists all Sites - select applicable one

4. Addition of a Site i

Does the amendment involve the addition of a site?*

Site Name	Organisation Type	Jurisdiction	Region	Site Status	Select
Department of Health	Public	WA	Department of Health	Authorised	<input type="checkbox"/>
Fiona Stanley Hospital	Public	WA	South Metropolitan Health Service	Authorised	<input type="checkbox"/>
Royal Perth Hospital	Public	WA	East Metropolitan Health Service	Authorised	<input type="checkbox"/>
Sir Charles Gairdner Hospital	Public	WA	North Metropolitan Health Service	Authorised	<input type="checkbox"/>
The Alfred Hospital	Public	VIC	South Division	Pending	<input type="checkbox"/>
The Royal Melbourne Hospital	Public	VIC	South Division	Pending	<input checked="" type="checkbox"/>

4.1 Reason for change:*

B I U          

Add The Royal Melbourne Hospital as an additional site under NMA.

Words: 11/5000

i

Extension Approval & DoH Update

5. Extension of Approval

Does the amendment involve an extension of approval?*

Yes

5.1 Approval expiry date:

13/08/2023

5.2 Requested approval date:*

13/08/2023

5.3 Reason for change:*

B **I** **U**

Follow up with cor

body

6. Department of Health Data Collections - Data and/or Linkage Update

Does the amendment involve Department of Health data collections?*

Yes

Please discuss all data amendment requests with [Data Services](#) prior to completing this form. Amendment applications may require submission of new or amended documentation to reflect the changes in your data application.

Projects approved over 12 months ago may require a new [Application for Data Form](#) with all attachments. Moreover, ongoing, regular updates of data are only available if these were specified in the original application. Extraction updates should not request data past the current year.

Requests for identifiable data will require an amendment to project documentation. It should include updated version of the [Application for Data Form](#) and the [Protocol](#), with a [Summary of Changes](#) document outlining the changes.

6.1 Security Plan

6.1.1 Has the location of where the data is stored/analysed been changed?*

No

6.2 Data Details

6.2(a) The change to the project relates to:*

Extraction update

6.2(b) Select which data collections are impacted by this amendment:*

Emergency Department Data Collections

6.2.2 Provide details on the extraction and/or linkage update required:*

B **I** **U** ✂ 📄 🗑️ ⬅️ ➡️ Ω ⌵ ⌶ ⌷ ⌸

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Etiam consectetur luctus metus, id sollicitudin mi bibendum id. Donec id suscipit turpis. Morbi euismod, dolor id varius feugiat, tellus dolor finibus justo, eget dapibus magna massa condimentum ligula. Pellentesque pulvinar,

Words: 84/5000

Next >>

Save

Save and Close

Mark Complete

Cancel

Mark Complete only keeps selected information

3. Change to Project Investigators

Does the amendment involve a change to project investigators?

Yes

Role	Name	Qualifications and Expertise Relevant to the Project	GCP Certified	Student?	Name and Location of Student Supervisor	Site(s) for Which the Investigator Is Responsible
PI Delegate, RGM	<u>Ms Sarah Wilson</u> Sir Charles Gairdner Hospital		Yes	No		RGM: Sir Charles Gairdner Hospital

3.1 Reason for change:

Joined project will have access to identifiable data.

4. Addition of a Site

Does the amendment involve the addition of a site?

Yes

Site Name	Organisation Type	Jurisdiction	Region	Site Status
The Royal Melbourne Hospital	Public	VIC	South Division	Pending

4.1 Reason for change:

Add The Royal Melbourne Hospital as an additional site under NMA.

Alternative to adding a doc through a Form – Add a doc through the Monitoring Tab

My Role(s): RGM, PI Delegate

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

Forms Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form	---	---	---	---	---	---	

Documents Add

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Victorian Module	Other	---	---	---	---	---	---	
Summary of Changes	Other	---	---	---	---	---	---	
Protocol	Protocol	---	---	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	

Add

Submit

Submit Project

Safety Report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Governance Only Amendment Form 001 15/08/2018	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amended Budget Form 001 15/08/2018	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amendment Form 14/08/2018	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Associate Document With Form

Does the document relate to a previously submitted form? Yes No

Select the related form:

OK Cancel

Associate with a Form

Document Added







My Role(s): RGM

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

Forms Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Progress Report	---	---	---	---	---	---	
Amendment Form	---	---	---	---	---	---	

Documents


Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Data Application Form	Data Application Form	---	---	---	---	---	---	 
Victorian Module	Other	---	---	---	---	---	---	
Summary of Changes	Other	---	---	---	---	---	---	
Protocol	Protocol	---	---	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	

Forms and Docs can be removed if form has not been authorised or doc has not been attached to a form (you have to un attach a doc from the form prior to deletion)

My Role(s): RGM, PI Delegate

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







[-] Forms Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form	---	---	---	---	---	---	

[-] Documents Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Progress Report	---	---	---	---	---	---	
Amendment Form	---	---	---	---	---	---	

[-] Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Data Application Form	Data Application Form	---	---	---	---	---	---	 
Victorian Module	Other	---	---	---	---	---	---	
Summary of Changes	Other	---	---	---	---	---	---	
Protocol	Protocol	---	---	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	

Remove







My Role(s): RGM

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

[-] Forms Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Progress Report	---	---	---	---	---	---	
Amendment Form	---	---	---	---	---	---	

[-] Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Data Application Form	Data Application Form	---	---	---	---	---	---	 
Victorian Module	Other	---	---	---	---	---	---	
Summary of Changes	Other	---	---	---	---	---	---	
Protocol	Protocol	---	---	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	

You can also edit document details

All Monitoring Forms can be authorised by the CPI, CPI Delegate, PI or PI Delegate from any site

My Role(s): RGM, PI Delegate

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

Amendment Form

[<< Previous](#) [Edit](#) [Print](#) [Close](#)

Index: 2. Declarations ▼

7. Declarations

I declare that:

1. The information provided is true and accurate
2. All new project investigators are made aware of and comply with the ethical and governance requirements of the project; and conditions of ethics approval and site authorisation, including amendments
3. Any further changes to the project documentation, timeline, personnel or sites will be notified in writing to the reviewing HREC(s) and/or the RG Office for any site impacted by the amendment.

This form can be signed and authorised by the CPI, CPI Delegate, PI or PI Delegate.

[<< Previous](#) [Edit](#) [Close](#)

[Sign & Authorise](#)

Authorised and ready to Submit (click on the --- to see the status of a form/doc)

My Role(s): RGM, PI Delegate

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

Forms

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form	---	---	---	---	---	---	

Add

Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Data Application Form	Data Application Form	---	---	---	---	---	---	
Victorian Module	Other	---	---	---	---	---	---	
Summary of Changes	Other	---	---	---	---	---	---	
Protocol	Protocol	---	---	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	---	---	---	---	---	---	

Status

Add

Submit

Statuses Examples for a Site Final Report

View History for Site Final Report for Department of Health

Form Name	Version	Status	Locked By	Updated By	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
Site Final Report for Department of Health	1	In use	Margaret Brown	Margaret Brown				

View History for Site Final Report for Department of Health

Form Name	Version	Status	Locked By	Updated By	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
Site Final Report for Department of Health	1	Completed		Margaret Brown				

View History for Site Final Report for Department of Health

Form Name	Version	Status	Locked By	Updated By	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
Site Final Report for Department of Health	1	Authorised		Margaret Brown				

Close

Select Form & Docs to submit and click submit – docs will be auto selected if imbedded in form – can be deselected

Submit Project

Project

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Amendment Form	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Application Form	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Victorian Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Summary of Changes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Master Participant Information and Consent Form	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Cancel Submit

Successful submission onscreen message, and email to person who clicks submit. Status can be checked & green arrows shown

My Role(s): RGM, PI Delegate

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

Forms

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Amendment Form 14/08/2018	➔	➔	---	---	---	---	

Add

Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Data Application Form	Data Application Form	➔	➔	---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)	➔	➔	---	---	---	---	
Protocol	Protocol	➔	➔	---	---	---	---	
Summary of Changes	Other	➔	➔	---	---	---	---	
Victorian Module	Other	➔	➔	---	---	---	---	

Add

Submit

Submitted Form and Document Details and Statuses

Documents

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Data Application Form	Data Application Form	+	+	---	---	---	---

View History for Data Application Form

DocId	Document Name	Version / Date	Status	Attached By	Date Attached	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
6539	Data Application Form	2.0 14/08/2018	Submitted	Margaret Brown	14/08/2018	14/08/2018			

Thank you. Your monitoring submission was successful.

Forms

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Amendment Form 14/08/2018	+	+	---	---	---	---

View History for Amendment Form 14/08/2018


Form Name	Version	Status	Locked By	Updated By	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
Amendment Form 14/08/2018	1	Submitted			14/08/2018			

Close

Can't submit to RG Office an (Ethics) Amendment Form or Gov Only Amendment Form (with ethics info) until Ethics Amendment form is approved by Ethics.

	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Progress Report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amendment Form 14/08/2018						
Data Application Form						
Master Participant Information and Consent Form						
Protocol						
Summary of Changes						
Victorian Module			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Message from webpage



The Amendment Form must be approved by ethics before it can be submitted to governance.

OK

NB: Can submit an Ethics Amendment to Gov if no additional governance docs required, no need for a Gov Only Amendment

Amendment Forms and Docs validated by Ethics & email sent to person making submission. Dashboard updated.

Progress Report 14/08/2018								
Amendment Form 14/08/2018				---	---	---	---	

Documents Add

Document Name	Type	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Insurance Certificate	Insurance Certificate of Currency	---	---	---		---		
Investigator Brochure	Investigator Brochure		---	---	---	---	---	
Annual Safety Report	Other		---	---	---	---	---	
Executive Summary	Other		---	---	---	---	---	
Data Application Form	Data Application Form			---	---	---	---	
Master Participant Information and Consent Form	Participant Information Sheet and Consent Form (Master)			---	---	---	---	
Protocol	Protocol			---	---	---	---	
Summary of Changes	Other			---	---	---	---	
Victorian Module	Other			---	---	---	---	

Not valid

Valid

Forms and Documents can be AIRed either on Validation or Review – an email will be sent on Validation and Letter on Review to CPI/CPI Delegate or PI/PI Delegate

Forms

Find information on Research Authorisation and Monitoring Forms

Form Name

CAHS HREC

CAHS RGO



Amendment Form 31/07/2018



Progress Report 20/07/2018



Add

Documents

Document Name

Type

CAHS HREC

CAHS RGO



CAHS Participant Information and Consent Form

Participant Information Sheet and Consent Form (Master)



Add

Submit

Additional
Information
Required
(AIR)

Forms and Documents can be AIRed – check the status in the view history by clicking on the ? Mark. Click new version to add a new version of the Document.

View History for CAHS Participant Information and Consent Form

DocId	Document Name	Version / Date	Status	Attached By	Date Attached	Submitted Date	Validation Date	Review Completion Date	Approval Decision Date
6496	CAHS Participant Information and Consent Form	2.0 19/07/2018	AIR	Samantha Grogan	31/07/2018	31/07/2018	01/08/2018 View	01/08/2018	

Create New Version

Close

Add existing doc with new version for AIR


Add Project Document



PRN: RGS0000000072

Project title: Parent access to hospital services. Do they know how to get the services they need

Monitoring Document

Document category:* Ethics documents 

Document type:* Participant Information Sheet and Consent Form (Master)

Document name:*

The document name entered here will appear in the final approval letter and should reflect the information in the footer of your document. Please ensure it is correct as it cannot be changed by the administrators. Do not enter the file name and avoid using underscores.

Status: Not attached

Document Details



Version number: Version date: 

The version number and version date entered here will appear in the final approval letter. Please ensure it is correct as it cannot be changed by the administrators.

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

Add

Close

Governance Only Amendment Form – can only be completed by PMs associated with site

Governance Only Amendment Form 001

Form is checked out to you for editing.

Index:

1. Project Details

1.1 PRN: RGS0000002146
1.2 External HREC ref: None
1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)
1.5 RG Office:*
1.6 Site:*
1.7 CPI: Jane Dowe
1.8 Date of last Annual Progress Report submission: 14/08/2018

2. Change to Project Documentation

2.1 Does the amendment involve a change to project documentation?*

3. Change to Budget Form

3.1 Does the amendment involve a change to the Budget Form?*

4. Attach an Amendment Form

4.1 Do you need to attach an ethics approved Amendment Form for reference?*

rgsuat.health.wa.gov.au says

You do not have any associated sites for the selected RG Office. Please select a RG Office associated with your site.

Governance Only Amendment Form – update docs and ensure progress reports are up to date

Governance Only Amendment Form 001

Next >> Form is checked out to you for editing.
Index: 1. Form Information

1. Project Details

1.1 PRN: RGS0000002146
1.2 External HREC ref: None
1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)
1.5 RG Office*: East Metropolitan Health Service Research Ethics and Governance Unit
1.6 Site*: Royal Perth Hospital
1.7 CPI: Jane Dowe
1.8 Date of last Annual Progress Report submission: 14/08/2018

Overdue annual progress reports may affect the processing of amendments.

2. Change to Project Documentation

2.1 Does the amendment involve a change to project documentation? Yes

Please consider that changes to the project may impact on other project documents or forms within the project e.g. Budget Form, Research Agreement.
For changes to approved documentation, please submit a Summary of Changes document outlining the changes in the updated version.

Use the table below to select all documents applicable to this form. You can add additional documents via the 'Add' button.

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
6540	Insurance Certificate	2.0	Authorised	Margaret Brown	15/08/2018	<input type="checkbox"/>

Add Project Documents

PRN: RGS0000002146
Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Monitoring Document

Document category*: Governance documents (final)
Document type*: Insurance Certificate of Currency
Document name*: Insurance Certificate

The document name entered here will appear in the final approval letter and should reflect the information in the footer of your document. Please ensure it is correct as it cannot be changed by the administrators. Do not enter the file name and avoid using underscores.

Associated site*: Department of Health, Royal Perth Hospital
Status: Not attached

Document Details

Version number*: 2.0 Version date*: 15/08/2018
The version number and version date entered here will appear in the final approval letter. Please ensure it is correct as it cannot be changed by the administrators.

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

Upload Soft Copy (Electronic) File

Select file*: C:\Users\Kate\Desktop\RGS\ Browse...
Allowed Types: DOC, DOCX, PDF, PPT, PPTX, XLS, XLSX

Governance Only Amendment Form – update budget

body

Please ensure an updated version of the Budget Form is submitted with the amendment.

3. Change to Budget Form i

3.1 Does the amendment involve a change to the Budget Form?*











Yes No

Select the Budget Form that requires amendment:

Form Name	Sites	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Budget Form	Royal Perth Hospital	1.0	Authorised	13/08/2018	13/08/2018	13/08/2018	13/08/2018	<input checked="" type="checkbox"/>

The Budget Form must be updated via the placeholder link created on the Monitoring Tab and must be submitted together with this amendment form.

3.2 Reason for change:*

B I U          

Updated Research Department Costs

body Words: 4/5000

Governance Only Amendment Form – update budget

body

Please ensure an updated version of the Budget Form is submitted with the amendment.

3. Change to Budget Form (i)

3.1 Does the amendment involve a change to the Budget Form?*











Yes

Select the Budget Form that requires amendment:

Form Name	Sites	Version	Status	Submission Date	Validation Date	Review Completion Date	Authorisation Decision Date	Select
Budget Form	Royal Perth Hospital	1.0	Authorised	13/08/2018	13/08/2018	13/08/2018	13/08/2018	<input checked="" type="checkbox"/>

The Budget Form must be updated via the placeholder link created on the Monitoring Tab and must be submitted together with this amendment form.

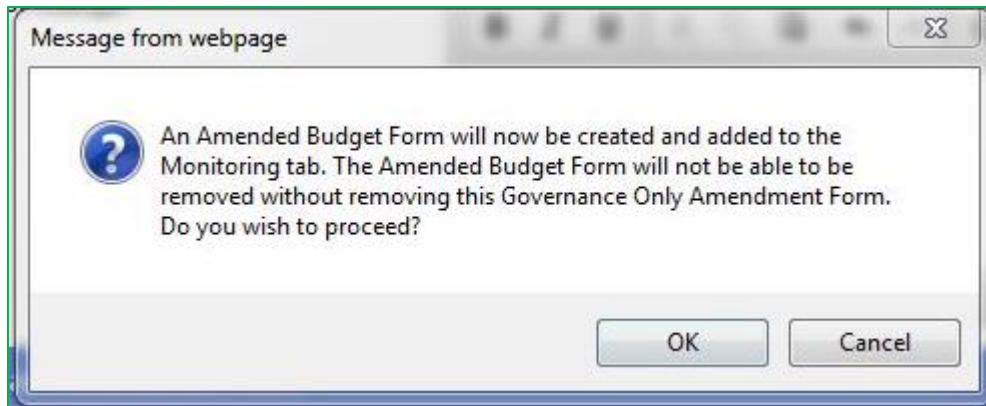
3.2 Reason for change:*

B I U          

Updated Research Department Costs

body Words: 4/5000

(i)



Sponsor can view GOA Form but can't view Budget

My Role(s): RGM, PI Delegate

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

[-] Forms

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO	
Governance Only Amendment Form 001	---	---	---	---	---	---	
Amended Budget Form 001	---	---	---	---	---	---	
Progress Report 14/08/2018	+	+	+	+	+	+	
Amendment Form 14/08/2018	+	+	---	---	---	---	

My Role(s): RGM, PI Delegate

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

Amended Budget Form 001

Next >> Print Close

Index: 1. Department(s) Selection

Can't find a department? Contact RGS Support

Section 1 of 3 - Department(s) Selection

[-] Royal Perth Hospital

Proposed number of participants in this site: 5

Expected project timeframe for this site: 2 year(s)

**Participant also includes a person's data, information or biological sample.*

Department Name	Type	Head Of Dept	Invitation Status	Invited By	HoD Delegate	Invitation Status	Invited By	Authorisation Status
Cardiology	Research Department	Oliver Walker	Accepted	Margaret Brown				Authorised
Pharmacy	Supporting Department	George Wright	Accepted	Margaret Brown				Authorised

Next >> Close

Unauthorise

Amendment Forms and Docs approved by Ethics can then be attached to Gov Only Amendment for RGOs

Use the table below to select all documents applicable to this form. You can add additional documents via the 'Add' button.

Doc ID	Document Name	Version	Status	Attached By	Date Attached	Select
6550	Participant Information and Consent Form - RPH	2.0	Authorised	Mary Davies	15/08/2018	<input type="checkbox"/>

Add

2.2 Reason for change:*

B I U
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☰
☷
i

Updated PICF

body
Words: 2/5000

3. Change to Budget Form i

3.1 Does the amendment involve a change to the Budget Form?*

No

4. Attach an Amendment Form

4.1 Do you need to attach an ethics approved Amendment Form for reference?*

Yes

Select the Amendment Form that requires attachment:

Form Name	Version	Status	Submission Date	Validation Date	Completion Date	Authorisation Decision Date	Select
Amendment Form 14/08/2018	1.0	Approved	14/08/2018	15/08/2018	15/08/2018	15/08/2018	<input checked="" type="checkbox"/>

Ethics Amendment

Nominate RGO and submit

Submit Project



Project

PRN: RGS0000002146
Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Governance Only Amendment Form 001	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amended Budget Form 001	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amendment Form 14/08/2018						
Insurance Certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Application Form			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Master Participant Information and Consent Form			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Message from webpage



You must submit both the GA and ABF together for first submission.

OK

To add comments about this submission, please go to the Comments tab.

Cancel

Submit

Safety Report

My Role(s): Sponsor

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

Safety Report

Next >>

Form is checked out to you for editing.

Index:

1. Report Information	▼
1. Report Information	
2. Declarations	

1. Project Details

- 1.1 PRN: RGS0000002146
- 1.2 External HREC ref: None
- 1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
- 1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)
- 1.5 Site*:
- 1.6 CPI: Jane Dowe
- 1.7 Sponsor organisation name:

2. Serious Breach i

- 2.1 Do you need to report on a serious breach?

3. Significant Safety Issue i

- 3.1 Do you need to report on a significant safety issue?

4. Local SUSAR or USADE i

- 4.1 Do you need to report on a local SUSAR or USADE?

5. Annual Safety Report and/or Updated Investigator Brochure (IB) i

- 5.1 Do you need to report on an Annual Safety Report and/or updated investigator brochure (IB)?

Safety Report – contains guidance who to submit to

3. Significant Safety Issue ⓘ

3.1 Do you need to report on a significant safety issue?* Yes

3.2 Significant safety issue applies to:*

- Urgent Safety Reasons
- Temporary Reasons
- Early Termination Reasons

3.3 Reasons for action:* ⓘ

This section is applicable to both ethics and governance.

A SSI is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial.

The PI must report to the:

- Sponsor – within 24 hrs of becoming aware of the event, all SAEs (as per protocol), congenital abnormality / birth defect, and any USM instigated at the site.
- as specified by the protocol all Safety Critical Adverse Events.
- RG Office – within 72 hrs of becoming aware of all SSIs.

The sponsor must report to the HREC (through the CPI), PI, and TGA:

- Any USM within 72 hrs of the measure being taken.
- An Amendment within 15 days of becoming aware of the issues.
- Temporary halt / early termination within 15 days of making a decision to halt / terminate the trial.

suscipit turpis. Morbi euismod, dolor id varius feugiat, tellus...

Pellentesque pulvinar, turpis nec convallis luctus, dolor nunc consectetur tellus, eu gravida sem neque et purus. Proin tincidunt nec urna id finibus. Nullam laoreet magna at magna aliquam, a pellentesque orci vestibulum. Pellentesque euismod nulla vitae vestibulum bibendum. Phasellus auctor facilisis nunc, vel mollis diam pellentesque vel.

body Words: 84/5000

3.4 Measures taken:* ⓘ

suscipit turpis. Morbi euismod, dolor id varius feugiat, tellus dolor finibus justo, eget dapibus magna massa condimentum ligula. Pellentesque pulvinar, turpis nec convallis luctus, dolor nunc consectetur tellus, eu gravida sem neque et purus. Proin tincidunt nec urna id finibus. Nullam laoreet magna at magna aliquam, a pellentesque orci vestibulum. Pellentesque euismod nulla vitae vestibulum bibendum. Phasellus auctor facilisis nunc, vel mollis diam pellentesque vel.

body Words: 84/5000

3.5 Further actions planned:* ⓘ

Safety Report – add documents

Add Project Documents

Monitoring Document

Are you adding a new version of an existing document?

Document category:

Document type:

Document name:

The document name entered here will appear in the final approval letter and should reflect the information in the footer of your document. Please ensure it is correct as it cannot be changed by the administrators. Do not enter the file name and avoid using underscores.

Status: Not attached

Document Details

Version number: Version date:

The version number and version date entered here will appear in the final approval letter. Please ensure it is correct as it cannot be changed by the administrators.

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

Upload Soft Copy (Electronic) File

Select file:

Allowed Types: DOC, DOCX, PDF, PPT, PPTX, XLS, XLSX

Safety Report – can submit Form and Docs to HREC & RG Office at same time – select what Docs go with Form

Submit Project

Project

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
Safety Report	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Governance Only Amendment Form 001 15/08/2018	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amended Budget Form 001 15/08/2018	---	---	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Amendment Form 14/08/2018	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator Brochure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Executive Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Annual Safety Report	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insurance Certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Data Application Form	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Master Participant Information and Consent Form	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Summary of Changes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Victorian Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Progress Report

Add Project Forms

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Select Monitoring Forms

Form Name	Select
Amendment Form	<input type="radio"/>
Progress Report	<input checked="" type="radio"/>
Site Final Report	<input type="radio"/>
Safety Report	<input type="radio"/>
Project Final Report	<input type="radio"/>
Governance Only Amendment Form	<input type="radio"/>

An active (un-submitted) Progress Report exists for this project. You must submit or remove the current Progress Report before adding a new one.

Add Selected Form To Project Cancel

My Role(s): CPI Delegate

- Edit and complete, prepopulated from Project Details.
- Update Project Details if wrong
- All PMs can complete Project section.
- 2nd Progress Report will populate from 1st Report e.g. Participants

Reminder
1 month &
1 week

Progress Report

Next >>

Form is checked out to you for editing.

Index:

1. Whole of Project
2. Project at Site
3. Declarations

1. Project Details

1.1 PRN:	RGS0000002146
1.2 External HREC ref:	None
1.3 Project title:	Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
1.4 Lead HREC:	Royal Perth Hospital HREC (EC00270)
1.5 CPI:	Jane Dowe

2. Project Summary

2.1 Approval expiry date: 13/08/2023

2.2 Project summary:

Pradaxa (dabigatran) is an anticoagulant that works by blocking the clotting protein thrombin. Pradaxa is used to prevent blood clots from forming because of a certain irregular heart rhythm (atrial fibrillation). Preventing these blood clots helps to reduce the risk of a stroke. Side effects of Pradaxa include:
•bruising and minor bleeding (such as nosebleeds and bleeding from cuts).

Progress Report – Site Report

- Can only be completed by PMs associated with site.
- CPI Delegate must complete information for sites outside WA.
- Black square indicates comments are included.

My Role(s): CPI Delegate

Progress Report

<< Previous Next >>

Form is checked out to you for editing.

Index: 2. Project at Site

7. Site Report									
Actual Start Date	Expected Participant Numbers	Actual Participant Numbers Recruited to Date	Actual Date of First Participant Recruitment	Expected Date of Last Participant Recruitment	Recruitment Status	Issues With Recruitment Since Last Report?	Site Specific Safety Issues Since Last Report?	Site Specific Amendments Since Last Report?	
Department of Health									
14/08/2018	20	20	14/08/2018	14/08/2018	Active, not recruiting	No	No	Yes	
Fiona Stanley Hospital									
14/08/2018	5	1	14/08/2018	15/08/2018	Enrolling by invitation	Yes	Yes	Yes	
Royal Perth Hospital									
14/08/2018	5	2	14/08/2018	15/08/2018	Enrolling by invitation	No	No	Yes	
Sir Charles Gairdner Hospital									
14/08/2018	5	5	14/08/2018	15/08/2018	Enrolling by invitation	No	No	Yes	
The Alfred Hospital									
14/08/2018	5	1	14/08/2018	15/08/2018	Enrolling by invitation	Yes	No	Yes	

Site Final Report to RG Office

My Role(s): RGM, PI Delegate

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

Site Final Report

Next >>

Form is checked out to you for editing.

Index: [1. Report Information](#)
[2. Declarations](#)

1. Project Summary

- 1.1 PRN: RGS0000002146
- 1.2 External HREC ref: None
- 1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
- 1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)
- 1.5 CPI: Jane Dowe
- 1.6 Approval expiry date:* 

1.7 Project summary:

Pradaxa (dabigatran) is an anticoagulant that works by blocking the clotting protein thrombin. Pradaxa is used to prevent blood clots from forming because of a certain irregular heart rhythm (atrial fibrillation). Preventing these blood clots helps to reduce the risk of a stroke. Side effects of Pradaxa include:

- bruising and minor bleeding (such as nosebleeds and bleeding from cuts),
- nausea,
- abdominal or stomach pain,
- stomach upset,
- indigestion,
- heartburn,
- diarrhea,
- skin rash, or
- itching.

Tell your doctor if you have serious side effects of Pradaxa including:

- severe heartburn,

Project Final Report to HREC


My Role(s): RGM, PI Delegate

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

Project Final Report

Next >>

Form is checked out to you for editing.

Index: 1. Report Information 

1. Project Summary

- 1.1 PRN: RGS0000002146
- 1.2 External HREC ref: None
- 1.3 Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC
- 1.4 Lead HREC: Royal Perth Hospital HREC (EC00270)
- 1.5 CPI: Jane Dowe
- 1.6 Approval expiry date:*  
- 1.7 Project summary: 

Pradaxa (dabigatran) is an anticoagulant that works by blocking the clotting protein thrombin. Pradaxa is used to prevent blood clots from forming because of a certain irregular heart rhythm (atrial fibrillation). Preventing these blood clots helps to reduce the risk of a stroke. Side effects of Pradaxa include:


Project Final Report – submit & email

Submit Project

Project

PRN: RGS0000002146

Project title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

	RPH HREC	DoH HREC	SCGOPHCG	EMHS RGO	SMHS RGO	DoH RGO
 Project Final Report	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dear Ms Margaret Brown

PRN: RGS0000002146

Project Title: Test 2A: Monitoring UAT Test - NMA - Lead WA Health HREC with WA Specialist HREC

Protocol Number: 2018AZDGH#\$-1

Your submission for the above project has been received in RGS.

This email is to confirm that the following forms and documents have been submitted:

Form or Document Name	Version	Submitted To
Project Final Report	1.0	Royal Perth Hospital HREC, Department of Health WA Human Research Ethics Committee

To view the submitted forms and documents, access the project's Monitoring tab via this [link](#).

Should you require further information, the contact details of the relevant Ethics Office or Research Governance Office can be found [here](#).

Regards,

The RGS Team

HREC and RG Office approval status for Forms

Forms

[Need help using this page?](#)

Find information on Research Authorisation and Monitoring Forms

Form Name	RPH HREC	DoH HREC	SMHS RGO	DoH RGO	
Safety Report	---	---	---	---	
Governance Only Amendment Form 003 15/08/2018	N/A	N/A	✓	---	
Governance Only Amendment Form 002 15/08/2018	N/A	N/A	---	✓	
Amendment Form 14/08/2018	✓	✓	✗	✗	
Site Final Report for Department of Health	---	---	---	✓	
Site Final Report for Fiona Stanley Hospital	---	---	✓	---	
Project Final Report	✓	✓	---	---	
Safety Report 15/08/2018	✓	✓	✓	---	
Governance Only Amendment Form 001 15/08/2018	N/A	N/A	---	✓	
Amended Budget Form 001 15/08/2018	N/A	N/A	---	✓	
Progress Report 14/08/2018	✓	✓	✓	✓	
Site Final Report for Royal Perth Hospital	---	---	---	---	
Site Final Report for Sir Charles Gairdner Hospital	---	---	---	---	
Governance Only Amendment Form 004 15/08/2018	N/A	N/A	---	---	
Governance Only Amendment Form 005 15/08/2018	N/A	N/A	---	---	