Research Governance Service (RGS)

Researcher User Guide

Part A: Create a New Project

Version 4.0

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Contents

1. Role of the Research User

This role should be selected if you are intending to be a member of a research project team **(Project Member)** involved in an application processed through the RGS. Your specific role within each project may differ. You can be a Coordinating Principal Investigator (CPI), CPI Delegate, Principal Investigator (PI), PI Delegate, Associate Investigator (AI), Research Group Member (RGM) or Sponsor role which gives you different levels of access/security within the project. You can have multiple roles in a project. For further information on these role go to Help Wiki Roles in RGS

2. Research User Access

2.1 Sign Up as Research User

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

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

2.2 Update an Existing User to a Research User

The RGS Administrator can update the roles of RGS Users. Users that require a Research User role assigned to them after signing up to RGS, must contact RGS Support to request Research User access.

3. Create a New Project Workspace

All new research projects are allocated their own unique workspace to ensure security of information and an audit log of those accessing the project. The creation of this workspace must be approved by an Administrating Research Governance (RG) Office to ensure:

- the validity of the research project i.e. it is a research project conducted within WA Health or accessing WA Health's participants, their tissue or data
- duplicate workspaces are not created for the same project, as project workspaces cannot be merged following creation.

To request the creation of a new project workspace the CPI (i.e. the person submitting the ethics application to the Human Research Ethics Committee (HREC)) must complete and submit a 'Create Project' form. This must be done by the CPI as their name will populate across the project. If you are not the CPI you must not complete the form.

The application is typically processed within 1-2 working days however, actual processing time may vary depending on a range of factors.

### National Mutual Acceptance (NMA)

For the NMA scheme a new project workspace must be created by the CPI irrespective of whether the Lead HREC is from WA Health or an external jurisdiction participating in the NMA. This will allow for the CPI or CPI Delegate to either:

1. Submit their ethics application to a WA Health Lead HREC and/or Specialist HREC; or
2. If submitting to a Lead HREC outside of WA Health:
   - Complete the WA Specific Module, print and submit it to the external HREC.
   - Upload the approved ethics forms, documents and approval letter to a WA Health RG Office.

1. Click on 'Create Project' to launch the form. It is situated on the left-hand side of the RGS screen.

2. A warning message will launch outlining the role of the CPI and the processing of new project requests. If you are the CPI click 'OK' to proceed or 'Cancel' to return to the homepage. The CPI is the person who submits the project to the Lead and/or Specialist HREC for scientific and ethical review and is responsible for the ongoing communication with the reviewing HREC.
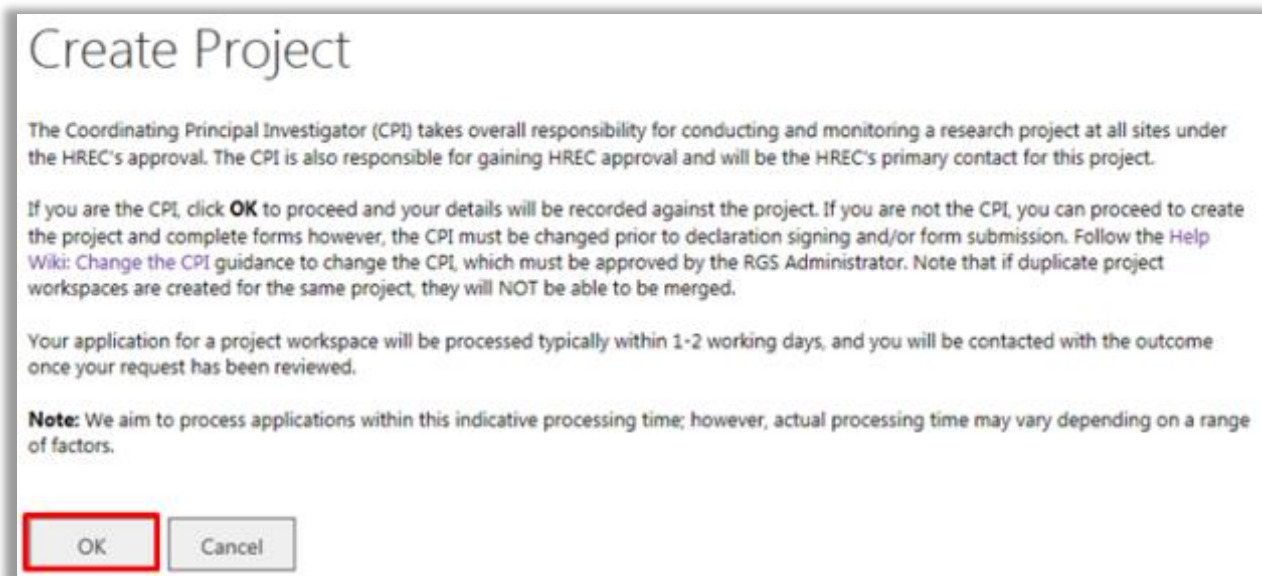
3. The 'Create Project' screen will launch. All mandatory fields have a red asterisk (*) next to them.

Sites for This Project Section

Select the 'Jurisdiction where the project will be conducted within Australia':

- Within WA Health only
- Intra-jurisdictional (within WA only)
- Inter-jurisdictional (across Australia).

Your answer should reflect all sites where the project is being conducted irrespective of whether the project is reviewed by HRECs outside of WA Health.

The NMA scheme applies to the ethical review of multi-centre research projects conducted across jurisdictions, if the project will be reviewed under NMA, **select 'Inter-jurisdictional'**.

4. Click 'Add Project Site(s)' to launch the Select Site(s) screen.

Only add sites that are covered by Lead or Additional (Specialist) HREC's ethical review as this will be used to populate the Sites tab and WA Health Ethics Application Form. At this time, the Human Research Ethics Application (HREA) cannot be pre-populated.

Based on your answer to 'Jurisdiction where the project will be conducted within Australia' you will be asked to select jurisdiction, organisation type and/or region. The organisation types are:

- Public – select the Region and then the site(s)
- Private - select the site(s)
- Research Institutes / Universities – select the site(s).

There are only a small number of private organisation and research institute that WA Health HREC provide ethical approval for, please check with the HREC Office before adding any of these sites.

Select a site by clicking on the site to transfer it from 'Available Sites' to 'Selected Sites', and vice versa. When all the sites have been selected, click 'Add Project Site(s)' to save any changes made, or 'Cancel' to discard them. To remove a site from the Create Project screen, select the site and click 'Remove'.

If you cannot find a site, click 'Request for a new site' located on the left-hand side of the Create Project screen. You can continue to progress with the form as long as you have nominated at least one site. Additional sites can be added later in the project's Sites tab.
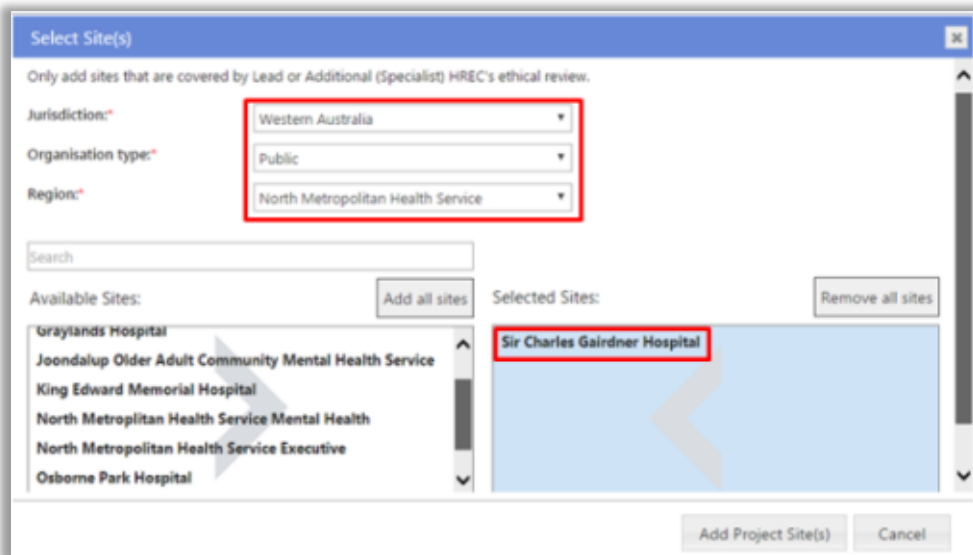
User tip: The Department of Health website has further information about the structure and Health Service Providers (HSPs) and the hospitals and health services linked to the HSPs.

For NMA, only add public organisation sites from jurisdictions participating in the NMA.
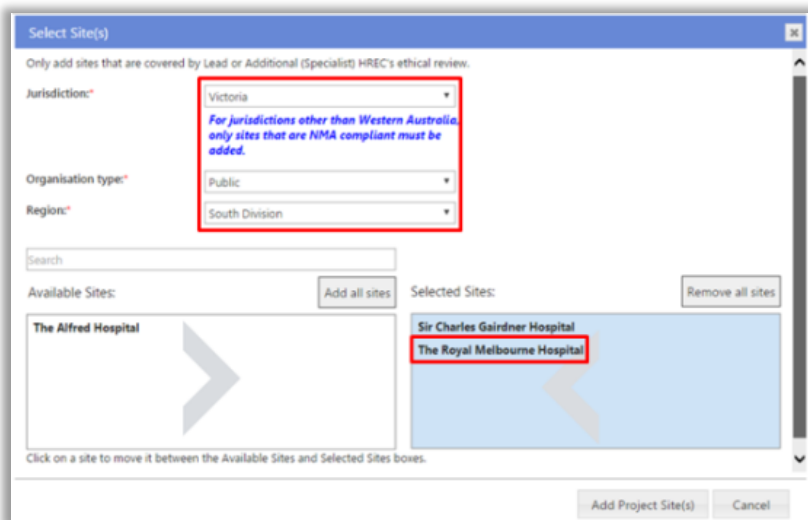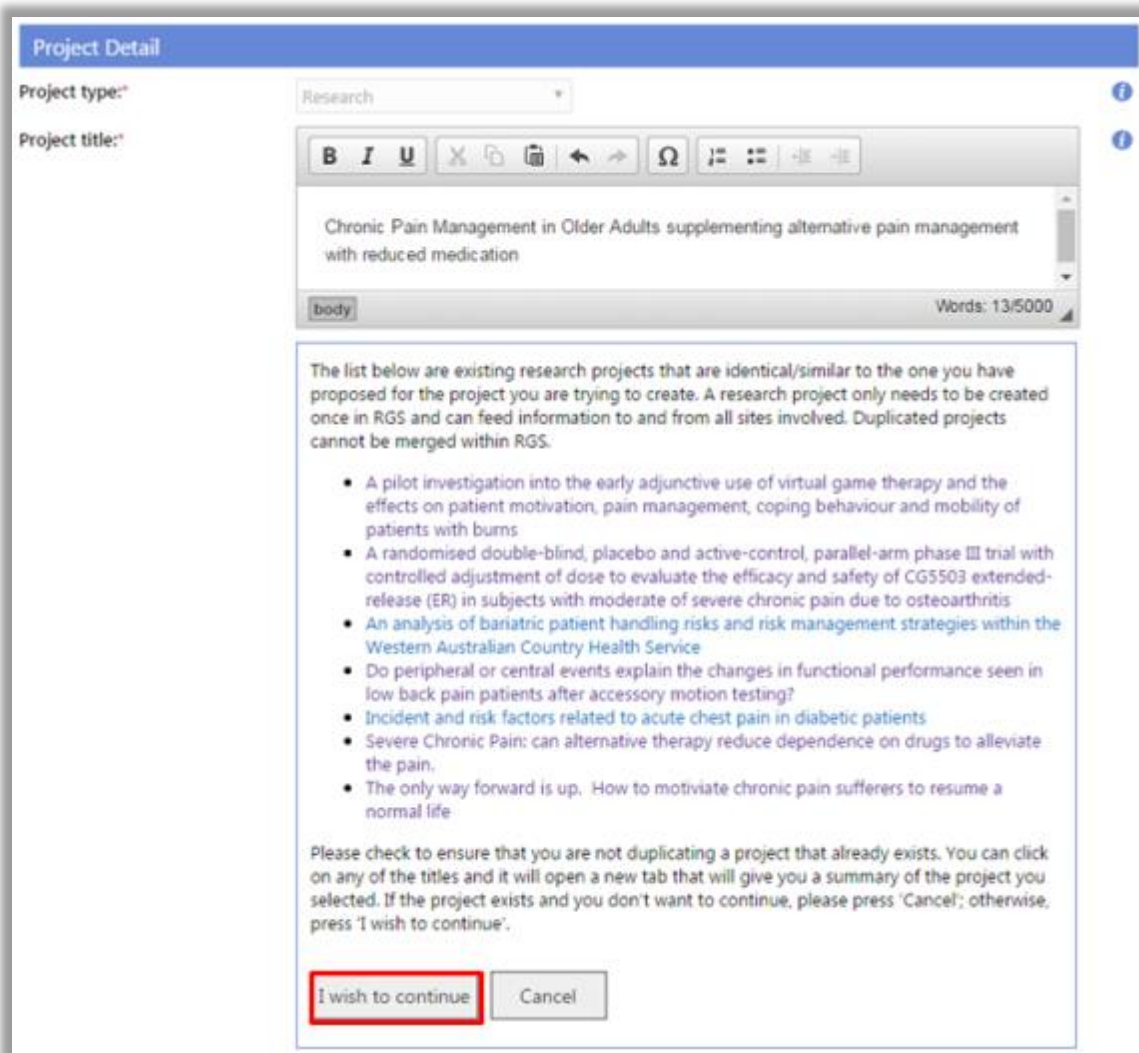
Project Detail

5. Complete the following:

- **Project type:** this is currently locked to Research projects only. If your project is deemed by the reviewing HREC as 'Quality Improvement' or 'Authorised Prescriber', this can be amended in Project Details – Project Header.
- **Project title:** this should be the same as the title of the research protocol. Do not bold as this is populated throughout the system.
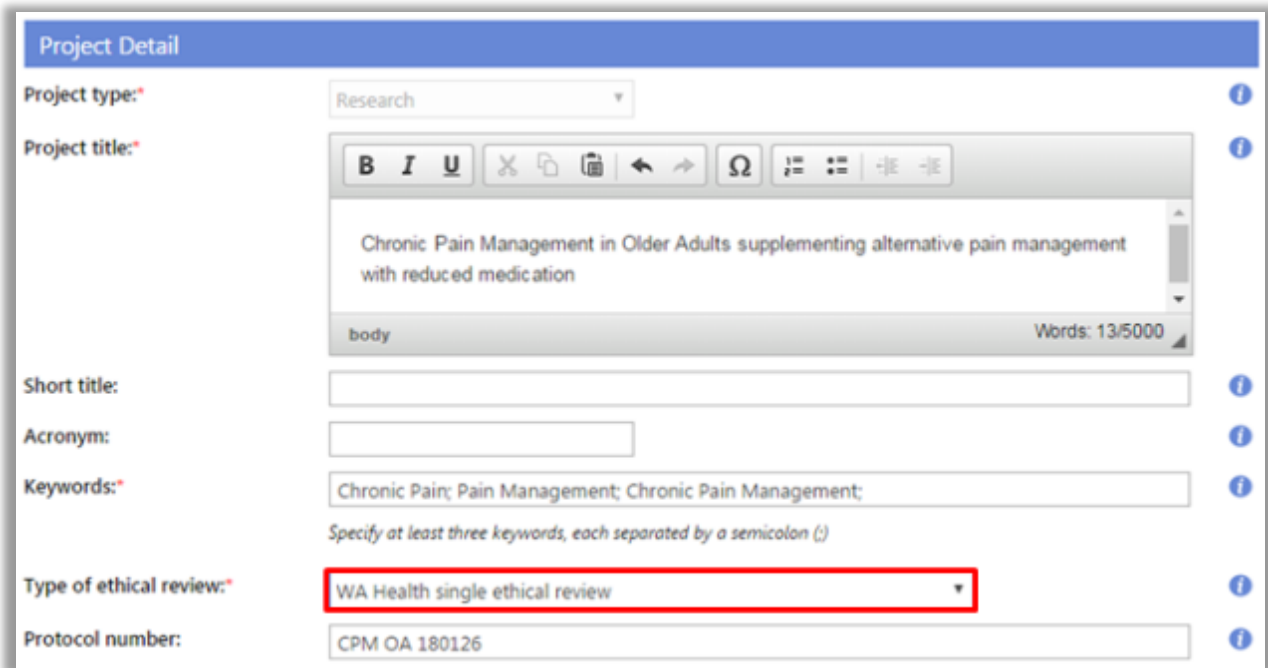
When you type the Project title, existing projects that are identical/similar will be shown to ensure a duplicate project workspace is not created for an existing project. Once created a project workspace and their associated forms and documents cannot be merged with another project. You can click on any of the titles and it will open a new tab that will give you a summary of the project you selected. If the project exists and you don't want to continue, please press 'Cancel'; otherwise, press 'I wish to continue'.

- **Short title:** is the lay title that explains the project with a minimum of medical terminology and is usually included on the Participant Information Sheet and Consent Form.
- **Acronym:** This is the acronym by which the project is referred to, it is not mandatory.
- **Keywords:** this should be a minimum of three (3) keywords and should be separated by a semi-colon (;). These keywords enable users to accurately search for the project.
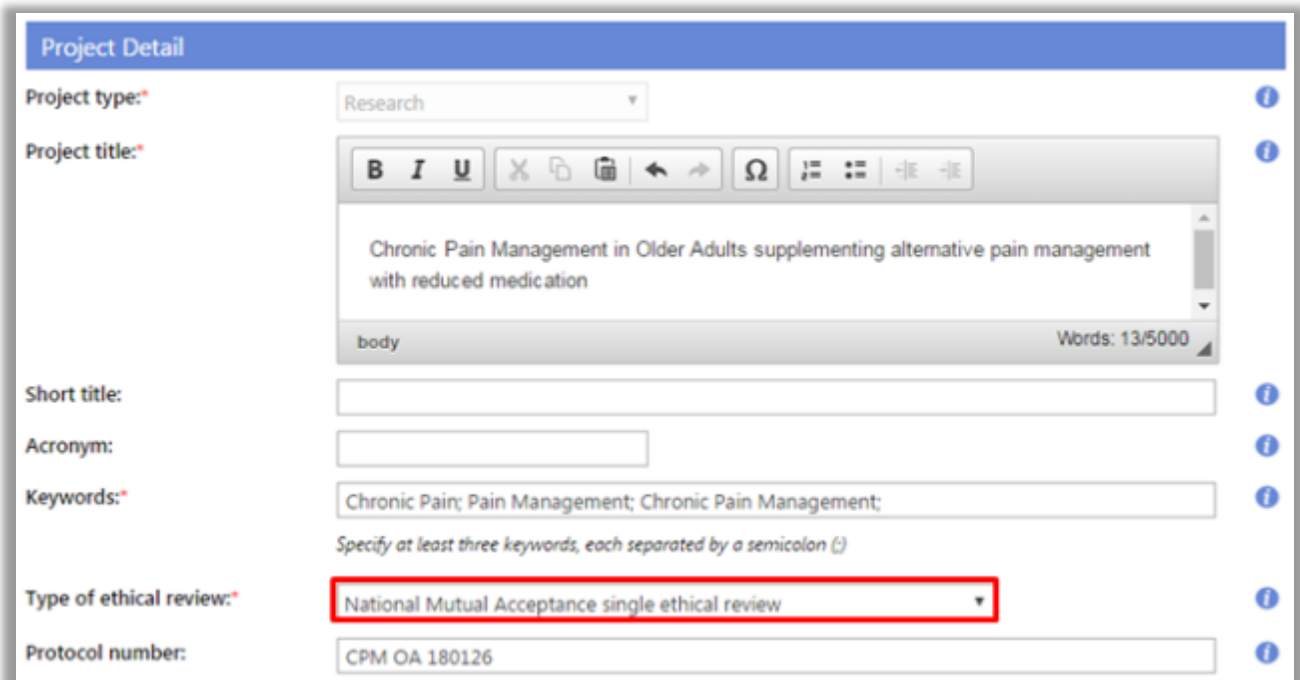- **Type of ethical review:** Select either:

i. **WA Health single ethical review** - The research project is conducted at one or more WA Health sites under the authority of a WA Health HREC (This authority may include an additional ethical review by a specialist WA Health HREC).

ii. **National Mutual Acceptance (NMA) single ethical review** - The research project is conducted at one or more Australian sites under the authority of a NMA certified HREC. (This authority may include an additional ethical review by a specialist NMA HREC).

- **Protocol number:** is the number listed on a Protocol. If there is no protocol number associated with this project, you can put not applicable (NA). If required, protocol templates are available for clinical trials and non-clinical trials on the RGS Document Templates page. To meet Good Clinical Practice Guidelines, the protocol should contain, but not be restricted to, the information contained within the applicable protocol template.

Administering Research Governance Office

6. The jurisdiction is currently locked to Western Australia. Select the name of the Administering RG Office to nominate the office to process the form. To ensure minimal delays it is suggested that it goes to the RG Office responsible for a site where you intend to conduct the project.

Declaration of Confidentiality (DoC)

7. All Project Members who are not WA Health employees are required to sign a WA Health Declaration of Confidentiality for each project they are involved with. **In addition, if you are a WA Health employee and you are undertaking this project in a non-WA Health employee capacity you must complete the DoC.**

Select whether you are a WA Health employee. If the answer is 'No', read the declaration, click 'I have read and agree to the Declaration of Confidentiality' before submitting the form.

CPI Delegate

8. You can nominate a CPI Delegate when requesting the project workspace. The person you nominate has to be a current RGS user. You can type in the person's name and click the Check Name icon 👤 or to search for the person click the Browse icon. 📖When you have selected the person tick the box regarding the confidentiality requirements.

9. Click 'Submit' to send the Create Project form to the nominated Administering RG Office for review, or 'Cancel' to discard your changes. If all field validation rules have been met, a confirmation screen will be shown.

10. Applications are typically processed within 1-2 working days by the RG Office and you will receive an email approving or declining your request.

4. Navigate the Project Workspace

Once a project is created in RGS it will have its own workspace. The workspace holds all the information related to the project. Access to the project by Project Members and Hospital Administrators is controlled by an invitation process. Access to the project by HRECs and RG Offices is controlled by the submission of forms or documents related to the review process.

To access a project workspace click on 'My Projects' on the left-hand side of the RGS screen. The My Project screen will show all your Active, Closed and Archived projects and your role in them. You can search for projects by their PRN, Project Title and your Role. Click on the Project Reference Number (PRN) to access the project workspace.

4.1 Project Header

The project header is visible wherever you are in the project workspace. It contains:

- **Project title:** this is in a blue band at the top.
- **Project lifecycle:** this section changes from grey to **green** as the project progresses.
- **PRN (Project Reference Number)**: this number is automatically assigned to the project and is used in all ethics and governance correspondence (it replaces the previous manually issued HREC reference numbers).
- **Project status:** this shows the current status of the project i.e. active, closed, archived.

- **Project ethics approval status:** is the current ethical approval status based on the Lead HREC's review i.e. pending, AIR, Approved, Not Approved.
- **Project type:** this currently defaults to research.
- **Short title:** this is a shortened version of the project title, if applicable.
- **Protocol number:** this is the number identifier assigned to the protocol.
- **Acronym:** this is the acronym for the project title, if applicable.
- **CPI:** this is the user that has taken on this role and created the project.
- **External HREC ref:** this is an external HREC identifier for projects that have been approved by a non-WA Health HREC once WA Health joins the NMA scheme.
- **Lead HREC:** this is the Lead HREC that has given approval for the research project.

Certain parts of the project header are editable in the Project Details tab. Refer to Help Wiki: Fill out and authorise Project Details.

Project lifecycle

The project lifecycle arrows can give you step by step guidance, click on the arrows to see the topics under that section. Clicking on the topic hyperlinks will open a new tab/window with the Help Wiki page for that topic.

4.2   Project Tabs

The Project tabs launch different screens that provide information and allow you to manage your project. When you open a new project the default tab is the Project Summary.

To submit an ethics and governance application you should complete and/or progress through the tabs in the following order:

- Sites
- Members
- Project Details
- Applications
- Declarations (as applicable).

The Project tabs have the following functionalities:

- **Sites:** allows Project Members to view sites associated with the project. The CPI, CPI Delegate, PI, PI Delegate can add or activate/deactivate a site. Refer to Manage Sites.

- **Members:** allows Project Members to view members associated with the project. The CPI, CPI Delegate, PI, PI Delegate can add existing Research Users to the project or remove or update roles of Project Members. Refer to Manage Project Members.
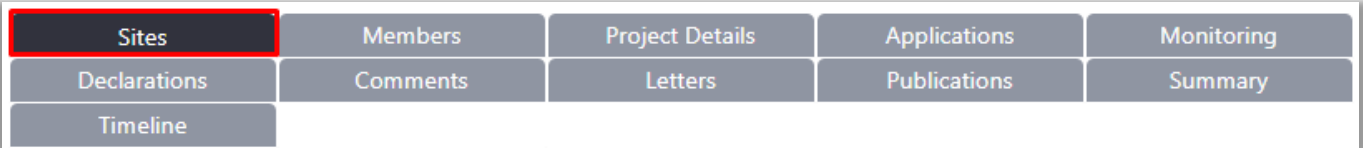
- **Project Details:** allows Project Members to view and edit common fields that are used in both the ethic and governance forms so that information is entered once and populated in these forms. The CPI, CPI Delegate, PI, PI Delegate must authorise/unauthorise different sections of Project Details prior to the completions of forms. Refer to Help Wiki**:** Fill out and authorise Project Details.

- **Applications**: allows Project Members to view, add and edit forms or documents related to your project depending on their role (e.g. Sponsor role has restricted access to governance forms). The CPI, CPI Delegate, PI, PI Delegate have varying restrictions on whether they can authorise/unauthorise ethics and governance forms and documents. Refer to Help Wiki: Add and fill out a Form (for project members) and Upload supporting documents.

- **Monitoring:** once the project has approval and site authorisation this tab allows Project Members to view, add and edit monitoring forms (e.g. amendments forms, progress, safety and final reports) and their accompanying documents.

- **Declarations**: allows Project Members to view and complete Research Conflict of Interest forms. Refer to Help Wiki: View or add a Declaration. It also contains a list of all non-WA Health employees that have signed a Declaration of Confidentiality.

- **Comments:** allows Project Members to add comments against an ethics or governance application, viewable by other Project Members. Refer to Help Wiki: Add a Comment.

- **Letters:** allows Project Members to view all letters related to a project's review and approval sent by either the HREC or RG Office. Refer to Help Wiki: View Letters.

- **Publications:** this will be developed in Stage 2.

- **Summary**: allows Project Members to view a summary of the project and its progress through the review and approval/authorisation process. It is the landing tab when users enter the project workspace.

- **Timeline**: allows Project Members to view the research governance timeline, providing KPIs related to the ethics approval and site authorisation processes. Refer to Help Wiki: Track a project through the review process.

5. Manage Project Sites

Prior to completing the Project Details and Applications tabs, Project Members should ensure all sites involved with the project are displaying in the Sites tab. The Sites screen will display any sites that have either been added initially through the Create Project form, or subsequently added or activated/deactivated by the CPI, CPI Delegate, PI, or PI Delegate.

5.1 Add a Project Site

The CPI, CPI Delegate, PI, PI Delegate can add a project site throughout the project's life. When a site is added to a project after ethics approval has occurred, the CPI, CPI Delegate, PI, or PI Delegate will be prompted to submit an Amendment to the HREC.

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

1. Click on the Sites tab and the screen will launch. Ensure the nominated **'Jurisdiction where the project will be conducted within Australia'** is still valid. The list of available sites you can add to the project will be determined by this selection.


OR

2. If you change the 'Jurisdiction where the project will be conducted within Australia' you will receive a warning to remove or deactivate the sites that are no longer relevant before you can change this field. Click 'OK'.

3. Click 'Add Project Site(s)'. The Select Sites Select screen will launch. **Only add sites that are covered by Lead or Additional (Specialist) HREC's ethical review.** Based on your answer to 'Jurisdiction where the project will be conducted within Australia' you will be asked to select jurisdiction, organisation type and/or region. The organisation types are:

- Public – select the Region and then the site(s)
- Private - select the site(s)
- Research Institutes / Universities – select the site(s).

4. Select a site by clicking on the site to transfer it from 'Available Sites' to 'Selected Sites', and vice versa. You have the ability to add or remove all sites within a Region. To do this either click 'Add all sites' or click 'Remove all sites'. When all the sites have been selected click 'Add Project Site(s)' to save any changes made, or 'Cancel' to discard them.
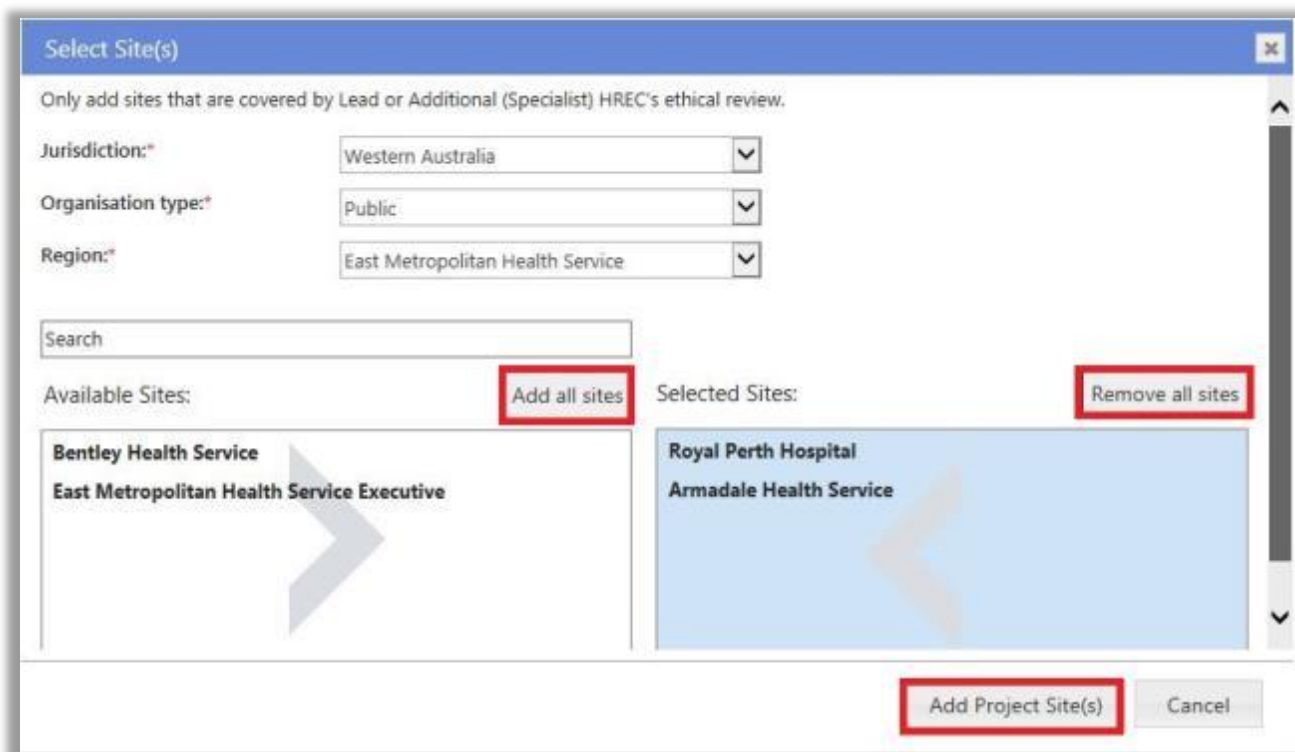
5. After adding sites, the sites will be displayed in the Sites tab with the status of 'Not Saved'; at this time any site added in error (that has not been saved) can be removed. Select the site and click 'Remove'.

6. Click 'Save' to save the site(s). The selected site's status will show as 'Active' on the sites screen. Once saved, a site can only be removed from a project by deactivating it. WA sites will default to the top of the screen. Click on the column headers to sort the table by columns.

5.2   Request Creation of Site, Division, Department

If you cannot find a site in the drop-down menu, email RGS Support to request a site be added.

Sites/Organisations are currently only created if they are a WA Health site or where a WA Health HREC is providing approval for a research project. With the signing of the National Mutual Acceptance public health site for participating states have been added, these are ACT, NSW, QLD, SA and VIC. The only other organisations that are created is where a WA Health HREC has agreed to conduct the review for that organisation some of these are Lion's Eye and Telethon Kids Institute.

If the site is to be named in the ethics application as a site where the research is being conducted this is done on the Project Details tab under '2. Ethics Information'. Section 2 has a field 'Other site names' which is a free text field where these sites can be added.

5.3   Activate/Deactivate a Project Site

The CPI, CPI Delegate, a project site throughout the project's life. Once a site is added to a project it can only be removed by deactivating it.

If a site is deactivated prior to a submission to a RG Office the forms and documents associated with the site and all the information for the site will be LOST. Any project member associated just with that site will also be made inactive (the sites associated with the project member can be edited in the Members tab)
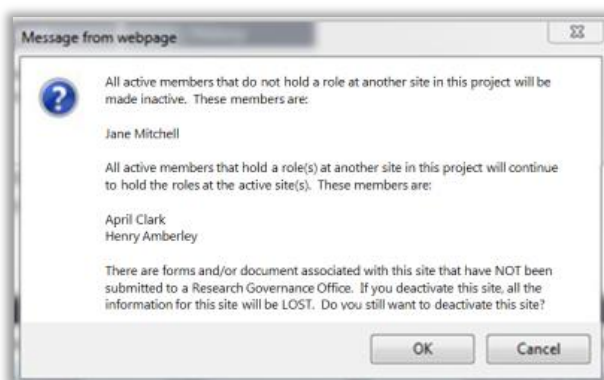
If a site is deactivated following a submission to a RG Office the forms and documents will be kept. If a site has received site authorisation it should be closed rather than deactivated. Contact the Research Governance Office for information on this process.

When a site is deactivated, Project Members for the site remain as members of the project but are no longer linked to the inactive site for that project. If the site is the only site associated to the Project Member, the **Project Member will also become 'Inactive'** in the Members tab.

1. To deactivate a site, select a site's name found in the 'Selected Sites' grid in the Sites tab, and click 'Deactivate'.
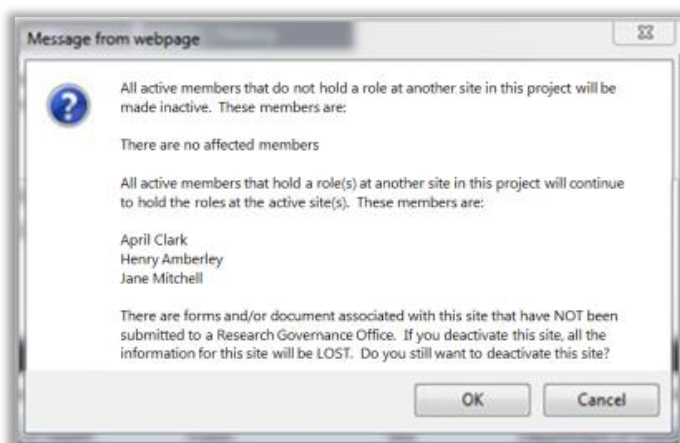
Site Name	Organisation Type	Jurisdiction	Region	Active/Inactive	Site Status	Select
Fiona Stanley Hospital	Public	WA	South Metropolitan Health Service	Active	Pending	☐
Fremantle Hospital Health Service	Public	WA	South Metropolitan Health Service	Active	Pending	☐
Royal Perth Hospital	Public	WA	East Metropolitan Health Service	Active	Pending	☑
Sir Charles Gairdner Hospital	Public	WA	North Metropolitan Health Service	Active	Pending	☐

Add Project Site(s)   Remove   Deactivate Site

An automated message will appear, if any project members are still associated with the site it will inform you of this. To prevent the project member becoming inactive click 'Cancel' and then

Message from webpage

All active members that do not hold a role at another site in this project will be made inactive. These members are:

Jane Mitchell

All active members that hold a role(s) at another site in this project will continue to hold the roles at the active site(s). These members are:

April Clark
Henry Amberley

There are forms and/or document associated with this site that have NOT been submitted to a Research Governance Office. If you deactivate this site, all the information for this site will be LOST. Do you still want to deactivate this site?

OK   Cancel

go to the Members tab and edit the project member to remove them from the site and add them to another.

If there are no project members associated with the site, the automated message will inform you of this. Click 'Ok' to save your changes, or 'Cancel' to discard them. The sites status will now be inactive.

Message from webpage

All active members that do not hold a role at another site in this project will be made inactive. These members are:

There are no affected members

All active members that hold a role(s) at another site in this project will continue to hold the roles at the active site(s). These members are:

April Clark
Henry Amberley
Jane Mitchell

There are forms and/or document associated with this site that have NOT been submitted to a Research Governance Office. If you deactivate this site, all the information for this site will be LOST. Do you still want to deactivate this site?

OK   Cancel

When you click 'OK' the sites will now be inactive.

2. To re-activate a site, select a site's name found in the 'Selected Sites' grid in the Sites tab, and click 'Activate Site'. The sites will now be active.

Site Name	Organisation Type	Jurisdiction	Region	Active/Inactive	Site Status	Select
Fiona Stanley Hospital	Public	WA	South Metropolitan Health Service	Active	Pending	☐
Fremantle Hospital Health Service	Public	WA	South Metropolitan Health Service	Active	Pending	☐
Royal Perth Hospital	Public	WA	East Metropolitan Health Service	Inactive	Pending	☑
Sir Charles Gairdner Hospital	Public	WA	North Metropolitan Health Service	Active	Pending	☐

Add Project Site(s)	Remove	Activate Site

3. Remember to nominate at least one active site, if not you will get a warning.

Site Name	Organisation Type	Jurisdiction	Region	Status	Select
Aboriginal Health	Private	WA	Child and Adolescent Health Service	Inactive	☐
Centre for Clinical Interventions	Private	WA	NMAHS Mental Health	Inactive	☐
Perth Children's Hospital	Public	WA	Child and Adolescent Health Service	Inactive	☐

Add Project Site(s)	Remove	Activate/Deactivate Site

Can't find site? Request for a new site >>

Save	Cancel	Please select at least one active project site.

6. Manage Project Members

Prior to completing the Project Details and Forms & Documents tabs, the Project Members should ensure all investigators involved with the project are displaying in the Members tab, as their details are populated into the Project Details tab and subsequently into the ethics and governance forms. The Members screen will display the CPI added initially through the Create Project form and any additional active or inactivate Project Members.

Project Members:

- Who have access to identifiable personal health information/data from WA Health must be invited to the project on RGS.
- May have more than one role in the project (e.g. they will be the CPI for all project sites, and also a PI for one or more sites). Click on the '+' to expand the view of the project member's roles.
- Can only have one role for a site at a time (except when a CPI is also the PI for a site or the member is also a CPI Delegate or PI Delegate).
- Can remove themselves from the project, but by doing so, they are revoking their access rights to the project.

The table below shows the multiple roles a person can have within a project.

Green is allowed, amber has restrictions (usually based on sites) and red is not allowed.

The CPI, CPI Delegate, PI or PI Delegate can add/invite or activate/remove Project Members, as well as edit their roles within the project (refer to Help Wiki: [Roles in RGS](#) for definitions of roles).

After the creation of a project workspace the CPI can add a CPI Delegate to the project to take on most of the CPI responsibilities, except for authorising and signing ethics forms.

The following rules apply to Project Members:

1. **CPI & CPI Delegate:**
   - There can only be one CPI and CPI Delegate per project at any given time.
   - Only a CPI and CPI Delegate can add PIs.
   - The CPI should also be added as a PI for the site(s) they will be PI for.
   - The CPI and CPI Delegate are responsible for authorising the 'Project Details' sections 1,2 and 4 and the ethics forms. The WA Health Ethics Application Form (WAHEAF) can only be authorised by the CPI.

2. **PI & PI Delegate:**
   - Each site must have a PI assigned to it.
   - The PI and PI Delegate can be assigned to one or more sites, but there can only be one PI and PI Delegate per site.
   - The PI and PI Delegate are responsible for authorising the 'Project Details Governance Information' section and site specific governance forms.

3. **CPI & PI Delegates:**
   - Delegates are optional.
   - The CPI can assign the CPI Delegate and the PI Delegate.
   - The PI can assign their own Delegate. A PI cannot assign a Delegate for another PI.
   - The CPI can be the PI Delegate.
   - The CPI Delegate can be the PI Delegate.
   - The PI can be the CPI Delegate and a PI Delegate for another site.
   - The AI can be a CPI Delegate and a PI Delegate.
   - .The Sponsor cannot be a delegate.
   - RGM can be PI Delegate for the same site.

4. **Associate Investigator (AI):** The AI has the same access rights as Research Group Members (RGM). The AI is included on all forms as an investigator on the project.

5. **Research Group Member (RGM):**
   - Can also be a CPI and/or PI Delegate
   - Can't be a RGM at a site where they have another role (except the role of PI Delegate for the site).
   - RGM can edit, and complete 'Project Details' and any form (ethic and site specific governance for sites they are allocated to) in the project workspace. They can also add documents.

6. **Sponsor:** cannot take on another role and cannot be a delegate.

6.1 Add a Project Member

1. In the project's workspace, click on the Members tab.
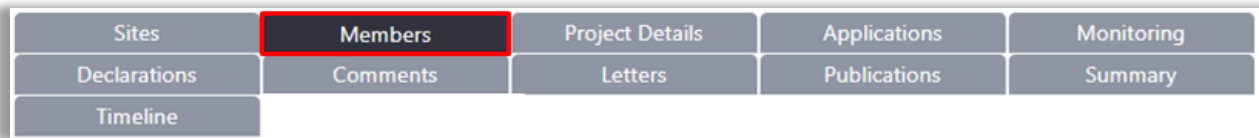
2. To add a new project member, click 'Add Member'. The 'Add Project Member' screen will launch.
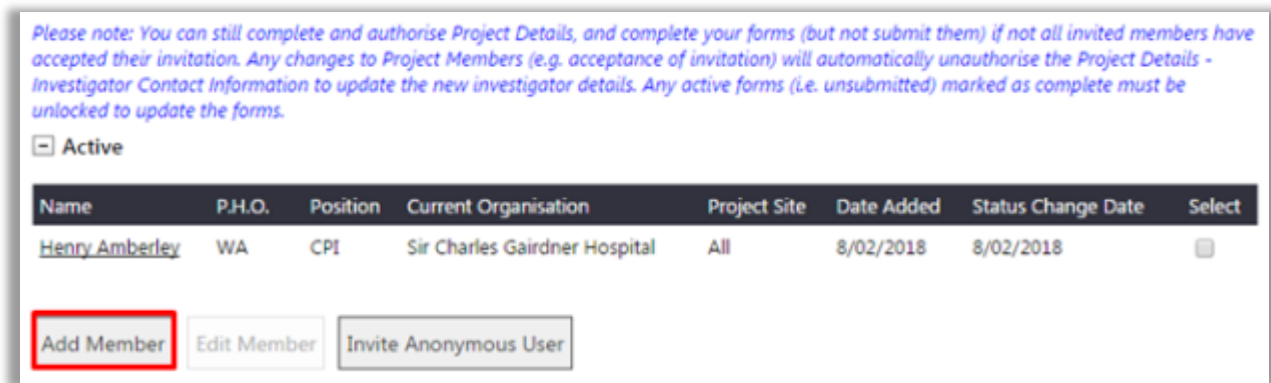
3. In the 'Search For Research User' section, enter the name of the RGS User you wish to add to your project. Only one user may be added at a time.
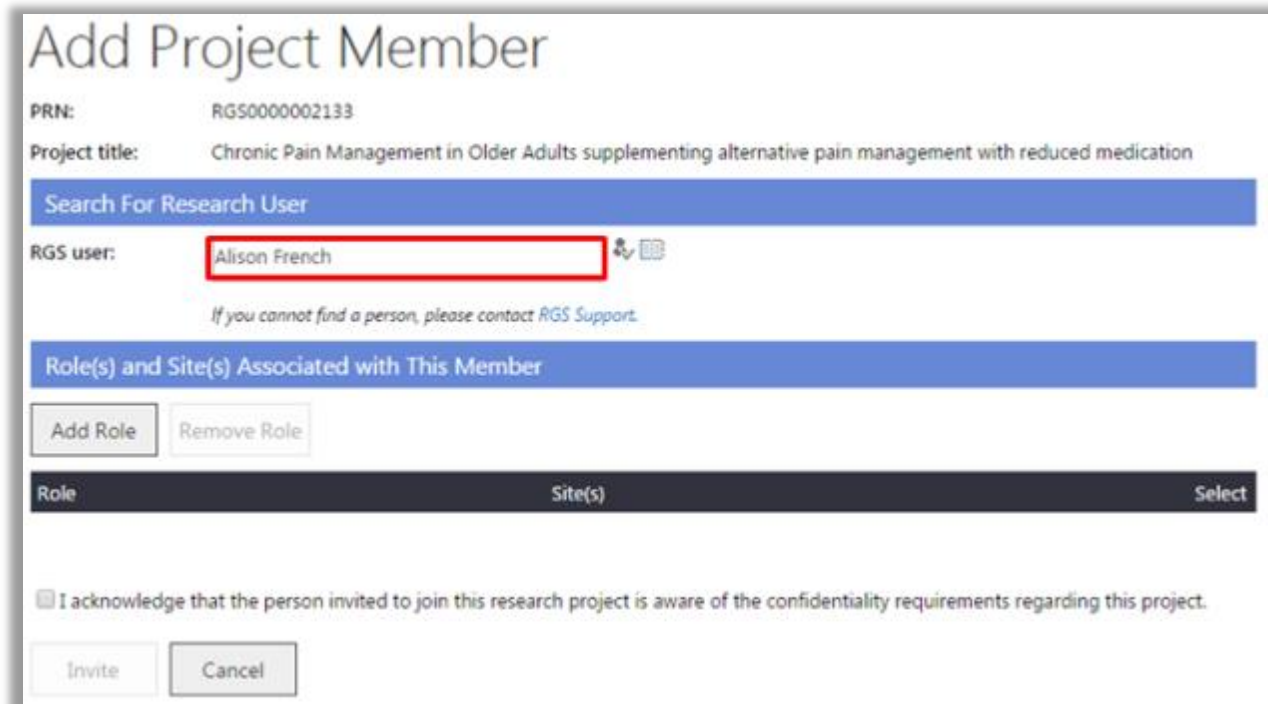
4. When you have typed in the user's name, click on the person icon to confirm. If the user is a RGS User, the name will show as a link.
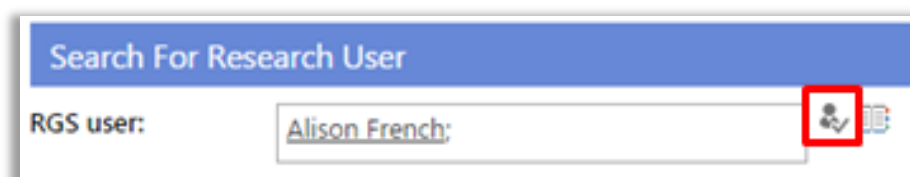
Alternately, use the address book to locate a user. Click the 'Address Book' icon. The Address Book screen will launch. Type the user's first name into the search and click the search icon, select the name and click 'OK'. Alternatively you can scroll through the names until you find the user and then select them and click 'OK'.

If a user's name cannot be found they may not be a RGS User. Click Cancel and return to the Members Screen to Invite an Anonymous User (refer to Help Wiki: Invite an Anonymous User to sign up in RGS) or alternatively contact RGS Support to see if they are a RGS User.

4. When the RGS User is found, click 'Add Role' to proceed. The 'Add Role' screen will launch.

5. Select the Project Member's role in this project, from the list of available roles. Only one role may be added at a time. If you do not assign a role to a Project Member, the default role is Research Group Member (RGM).

6. After choosing the role, based on the Project Members role (Refer to Help Wiki: Roles in RGS) the screen may or may not list the sites that need to be associated with that role. For example:

- **CPI Delegate:** no site selection is required as the CPI Delegate has delegated responsibility for all sites.
- **PI:** select the site(s) the project member is a PI for. The CPI should also be made a PI for the site(s) they are PI for. Only a CPI or CPI Delegate can add a PI.
- **PI Delegate**: select the PI who the PI Delegate is associated with, no site selection is required as the PI Delegate will be associated with the PIs sites.
- **AI:** select the site(s) the project member is an AI for.
- **RGM:** select the site(s) the project member is a RGM for.
- **Sponsor:** select the site(s) the project member is a Sponsor for. Sponsors will have restricted access rights to the project e.g. they are unable to view the Budget Form. **It is important that sponsors are only given this role in the project.**

'Select' the site(s) associated with the Project Member's role and click 'Add'.

7. To remove a role that has been added, select the role and click 'Remove Role'.

8. After adding the role(s) for the Project Member, select that you 'acknowledge that the person invited to join this research project is aware of the confidentiality requirements regarding this project' (it is your role to ensure this has occurred). Click 'Invite' to send a project invitation to the Project Member, or 'Cancel' to discard the changes. At least one role must be present to successfully invite a Project Member.

9. If you attempt to add a user that is already a member of the project, you will be notified with this error message.

10. Once invited the person's name will appear in the invited section of the Members tab.

6.2   Un-invite a Project Member

You can un-invite a person you have previously invited if they have not accepted the invitation. Tick the box under Select across from their name and click the Un-invite button.

The person you have uninvited will receive an email to inform them that their invitation has been withdrawn and the task generated from the initial invite will be removed from their task list.

6.3 Accept or Decline a Project Invitation

Once invited, the user will receive an email invitation to the project. The invited users may either access the invitation through the Tasks page or the email invitation.

1. If you have received an invitation to join a project, sign in to RGS and open the task in the Tasks page (Current or Overdue). Click on the link and this will launch the Task Form.

My Tasks				
Task Name	**Task Outcome**	**Initiator**	**Created**	**Due Date**
◢ Task Type : Invitation to Join Project (1)				
Invitation to Join Project: RGS0000002133	Pending	Henry Amberley	8/02/2018	15/02/2018

Alternatively, if you are already logged into RGS click on the link found in the invitation email you received. This will launch the Task Form.

Dear Dr William Gardner,

I would like to invite you to participate as a Project Member (PM) for the following project:

PRN: RGS0000002133
Project Title: Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication
Protocol Number: CPM OA 180126

Please use the link below to action the task associated with this project. This will take you to a membership page which will show your membership role and provide you with the option to Accept or Decline this invitation.

RGS Task: https://rgs.health.wa.gov.au/Pages/task-form.aspx?fm=V&tid=1674

If you accept, you will then have access to this project's documentation and tasks based on your role.

If you decline the invitation, you will not have access to this project.

Regards,
Henry Amberley

2. In the Task Form, click 'Action'. You can also click 'Cancel' to return to the task later. If you have completed the task and it has not moved click 'Archived Task'.

Task Form	
Group task?	No
Task type:*	Invitation to Join Project
PRN:*	RGS0000002133
Project title:*	Chronic Pain Management in Older Adults supplementing alternative pain management with reduced medication
Start date:	8/02/2018
Due date:*	15/02/2018
Initiator:	Henry Amberley
Assignee:*	William Gardner
Task description:*	Invite RGS Research User to become a member of a project.
Assignee comments:	

Task status: **Pending**

[Action] [Cancel] [Archive Task]

Please click "Action" to take you to the relevant screen to undertake a task. Do not click "Archive Task" unless you have actually carried out the task e.g. authorised a form.

3. The Project Invitation Acceptance screen will launch. Select Yes or No to '**Are you a WA Health employee?**' (this should be relevant to your employment capacity whilst working on this project). If No is selected, you will be required to tick the '**I have read and agree to the Declaration of Confidentiality**'. In addition you must tick the '**I agree that in accepting access to this research project I will be bound by confidentiality requirements regarding the project**' before you can click 'Accept'. If you have been invited in error, click 'Decline' to decline the invitation.

4. You will then receive a successful acceptance notification and you will be listed as an 'Active' Project Member.

Or a successful decline notification:

The Project Members can see accepted/declined invitations under the Members tab. Until the user accepts the invitation, their details will appear under the Invited group. If they decline the invitation, the user's details will move to the Declined group. However, this does not prevent them being re-invited at a later time.

6.5 Invite an Anonymous User to the Project

If you are trying to invite a RGS User to become a Project Member and you cannot find their name, it may be because they are not a current RGS User (i.e. they have not been given access to RGS). These people are known as Anonymous Users. An Anonymous User must sign up to RGS first as a RGS User and Research User, before they can be invited to join a project.

An email template is available in the Members tab to invite the Anonymous User to sign up to RGS.

1. To invite a person to sign up to RGS, click 'Invite Anonymous User'.

2. An email for 'Research Governance Service (RGS) Invitation' will launch. The email contains the project details and a link to the Sign Up page within RGS. Enter the email address of the recipient, edit the content of the email as appropriate and click 'Send Email', or 'Cancel' to discard the changes.

6.6   Edit a Project Member's Role

1. A Project Member can have roles added or removed by a CPI, CPI Delegate, PI or PI Delegate. To edit a Project Member's role in the Members tab, select the member and then click 'Edit Member'. The Edit Project Member screen will launch.

Add Project Member Role

2. In the Edit Project Member screen, to add a role, click 'Add Role' The Add Role screen will launch.

Select the 'Role in this project' for the Project Member. Depending on the role chosen, select the site(s) for which the user is associated with (refer to Help Wiki: Add a Project Member). Click 'Add' to save the changes made, or 'Cancel' to discard them. Click 'Save' to return to the Members tab.

The Project Member will receive an email notification advising them of the change in role.

Remove Project Member Role

3. To remove a role, select the role, and then click 'Remove Role'. A confirmation notification will appear, click 'OK' to proceed or 'Cancel' to discard your changes. Click 'Save' to return to the Members tab. To change the CPI, refer to the Help Wiki: Change the CPI for the next steps. Note that changing the CPI will require approval from the RGS Administrator.

6.7   Change the CPI

Note that only the RGS Administrator and the CPI can change the CPI. When removing the current CPI, RGS requires you to nominate a new CPI.

1. To remove a CPI's role in the Members tab, select the member and then click 'Edit Member'. The Edit Project Member screen will launch.

2. Select the CPI role and click 'Remove Role'.

3. A confirmation message will appear. Click 'OK' to proceed, or 'Cancel' to discard the change.

4. The Select New CPI screen will launch. You will be required to select a 'New CPI' from the list of active Project Members. The comment field is mandatory and you must provide a comment, such as a reason for the change, and then click 'OK'.

5. After removing the CPI role, ensure that the user has other role(s) left under 'Current Membership'.

Otherwise, you will be prompted with this error message.

6. Click 'Save' to save the changes made, or click 'Cancel' to discard them. The project membership change will initially appear within the 'CPI Change Pending' grid. The request to change the project's CPI will now be sent to the RGS Administrator as a task for approval.

Once approved, the new CPI will be shown under the 'Active' grid.

If the change has occurred after Ethics approval or site authorisation an Amendment form must be submitted to the reviewing HREC and all RG Offices associated with the project sites.
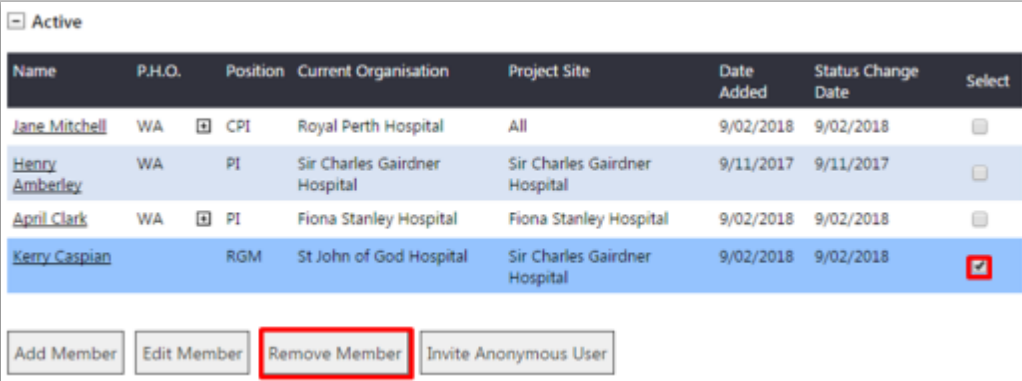
If a RGS Administrator has initiated the change of CPI, the changes made will automatically be processed and will not need to be sent for approval.

6.8   Remove an Active Project Member

A CPI, CPI Delegate, PI or PI Delegate can remove Project Members. All Project Members can remove themselves.

Project Members can only be removed if their role in the project is 'AI', 'RGM' or 'Sponsor'. This means, the CPI Delegate, PI, and PI Delegate roles first need to be changed to the RGM role before being removed. Once the Project Member is listed as an RGM they can be removed. If a CPI, PI or AI is removed from the project the reviewing HREC and relevant site should be notified using an Amendment Form.

1. To remove an active Project Member on the 'Members' screen, select the member to be removed, within the 'Active' grid. Click 'Remove Member'.

2. A confirmation message will appear to confirm that the Project Member's membership is being revoked. You may enter a comment regarding the reason for removing the project

member. Click 'OK' to save the changes made, or 'Cancel' to discard them.
3. Once removed from the project, the person's name will now appear within the 'Inactive' grid with the status as 'Inactive'. To keep the Project Member's status as active, click 'Cancel'. You may reactivate the user at a later stage.

6.9   Activate an Inactive Project Member

1. If you need to activate an Inactive Project Member you will need to email RGS.Support

7. Sign a Declaration of Confidentiality

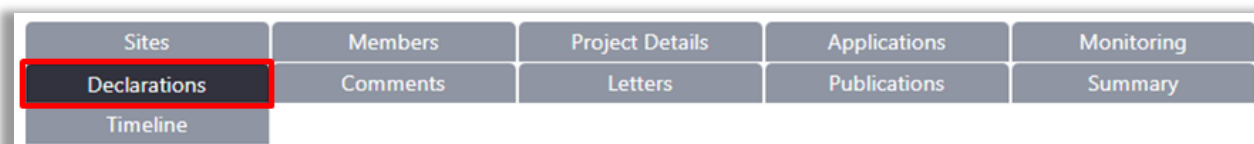## When to sign the Declaration of Confidentiality (DOC)

1. If you are a non-WA Health Employee, you will be requested to sign a Declaration of Confidentiality at these key actions within RGS:

- When requesting a project workspace creation as a CPI - refer to Help Wiki: Create new project for the detailed steps.
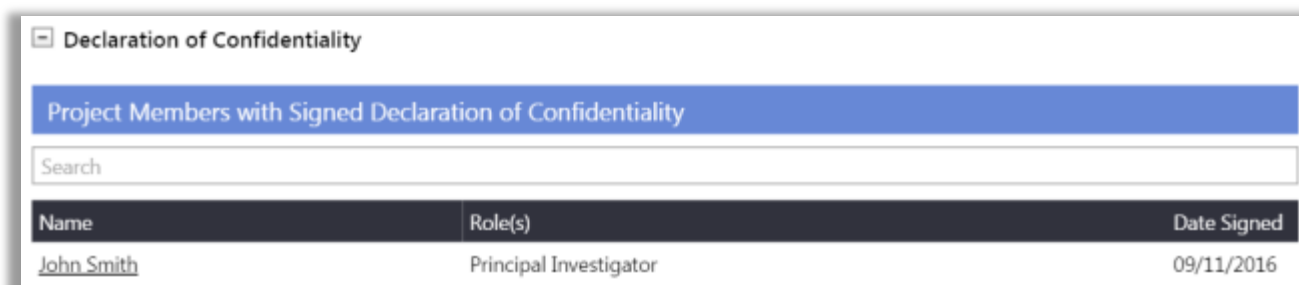- When accepting an invitation to join a project - refer to Help Wiki: Accept or decline a project invitation for the detailed steps.

In these scenarios, you will be asked to confirm whether you are a WA Health employee or not, by answering **'Are you a WA Health employee?'** If you answer 'No', you will be required to tick '**I have read and agree to the Declaration of Confidentiality**' before you are able to submit the form.

Viewing the signed DOCs in a project

1. To view all Project Members who have signed the DOC, click on the 'Declarations' tab in the project's workspace.

2. The Declaration of Confidentiality section will show the list of Project Members who have signed the DOC.

8. Search for a Project in RGS

All RGS Users can use 'Projects Search' to find any project within RGS based on the entered search criteria. Access to the projects through 'Projects Search' will be based on the user's roles in the system and whether they are a member of a project. Research Users who wish to be part of a project should contact the CPI to request an invitation to join the project.

1. Click on 'Projects Search' found on the left navigation pane.

2. On the Projects Search screen, enter your desired search criteria and click 'Search'. Clicking 'Reset' will erase any values previously entered in the search. Click on the tooltips on the screen to know more about a particular search field.

3. Once the 'Search' button is clicked, the search results are shown. You may filter the search results by entering values in the 'Refine your results' field and click 'Apply Filter'. Clicking 'Clear Filter' will erase any values previously entered in the filter, and will show the complete search results again.

4. If you are a member or the project or have the appropriate access rights, you can click on the link embedded onto a PRN. This will direct you to the project's workspace. Click on the column title to sort by column headers.

5. If you are not a member of the project or do not have the appropriate access rights, this error message will be shown:

Sorry, you do not have sufficient permissions to perform this action.

6. Contact RGS Support if you have any enquiries about a specific project.