



Research Governance Service (RGS)

GUIDE FOR RESEARCHERS

This guide to WA Health's [Research Governance Service \(RGS\)](#) is written with first time and infrequent research users in mind. It will take you step-by-step through your ethics and governance submissions providing tips to help navigate the less intuitive aspects of the RGS.

This guide is written to be used as you sit at your computer and work through your RGS submissions following the online prompts and instructions. It assumes:

- The minimum level of computer literacy and familiarity with navigating online web spaces expected of WA Health employees.
- A solid understanding of how to conduct research and what is involved in obtaining research ethics and governance approvals.

If you are new to research and/or completing ethics and governance submissions, you must seek appropriate training and/or supervision within your Health Service and read the *WA Health Research Governance Policy (2012)*. You can find links to this policy and relevant guidelines (and a lot of other useful information about conducting research within WA Health) on the RGS home page under 'Research Information' next to the 'Home' button on the blue menu bar.

First, go to the RGS home page: <https://rgs.health.wa.gov.au/Pages/Home.aspx>

STEP 1: Sign up as an RGS User

Click '**Sign Up**' on the home page and follow the prompts, noting the tips below.

- If you are a WA Health employee consider using your WA Health log in password, especially if you will be an infrequent user of RGS. No one needs *another* password!
- Select: 'Research User'

EMHS Research Hub

Email: EMHS.REG@health.wa.gov.au

Web: www.emhs.health.wa.gov.au/research



- If you do not know what being ‘*Good Clinical Practice (GCP) certified*’ means, then you aren’t and should tick ‘no’. Answering ‘no’ will not restrict your access to RGS.
- If you work for WA Health tick ‘yes’ to ‘*Are you a Public Health employee?*’. Otherwise, tick ‘no’.
- You will be asked to provide a *primary* email (typically your main work email) and a second *alternate* email (such as a Hotmail or Gmail account).
 - Your primary email will be your RGS User Name.
 - The alternate email allows you to access the system when you cannot access your primary email (e.g. at home or travelling) (See Step 2: Sign In).
- If you are a **WA Health employee** you must know where you sit in the organisational structure to find your department.
 - If you do not know this, ask your Head of Department or Business Manager.
 - If your department does not appear to exist please call your Research Governance Office
<https://rgs.health.wa.gov.au/Pages/Contacts.aspx#WA-Health-RGOs>
 and ask them to investigate and, if necessary, create the department. *This is important because a correctly situated department is needed when you complete the site authorisation and create the project budget.*
- If you are **not a WA Health employee** you will have to provide a WA Health Employee as a referee. This person must be able to confirm you have a bone fide reason for using RGS. The referee should provide you with the information necessary for you to complete this section, including their full organisation details – region, organisation, division and department.
- Your request will be reviewed by an RGS administrator. They check for errors (e.g. in email addresses) and confirm you are legit. This should take no more than 1 hour (often a matter of minutes) and you will receive an email when this is done.
- You are now searchable in RGS as a ‘research user’. This means colleagues with whom you are collaborating on projects can invite you into specific projects.
- You can also now sign in and create your own project space (See Step 4: Create a Project Workspace) to get started on an application.

STEP 2: Sign In

Click '**Sign In**' to log into RGS.

Within a few seconds a numeric code will be sent to your primary email or via SMS.

Type in the code (or copy/paste from the email) and click **'Verify'**.

- If you don't receive an email/SMS with your code, click 'Send/Receive All Folders' in Outlook and check your 'junk' or 'spam' folder.
- If you still do not have an email, you can click **'Resend'**. You can also have the new code sent to either your primary or alternate email address.

STEP 3: Complete your RGS Profile

As a new RGS user, it's a good idea to go to your profile (**'Profile Management'** on the left hand menu) and complete the information, following the tips below. The information in your profile will be automatically migrated into the forms for all future projects so this will save time in the long run. Otherwise go to [Step 4: Create a Project Workspace](#).

- Select your **area/s of research speciality**.
- Enter your **qualifications and expertise**.
- Consider uploading a **photo**.
- Consider publishing your information on the **Investigator Speciality List**. If you agree to this, your Title, First Name, Surname, Organisation, Phone (Business), Photo and Area of Research Speciality will be displayed on the [public](#) RGS webpage. This list will allow external stakeholders to contact you to collaborate in future research projects.

You can also **update** your details at any time. For example, you can:

- Update your contact details, including your primary and alternative email addresses.
- Update your qualifications or employee, such as when you change position.
- Switch to being a "public health employee" if you take on a position within WA Health.
- If you are a student, enter your institution and course.
- Keep a record of research-related training you have attended.
- Upload a copy of your CV, which is then viewable by the HREC reviewing your research project/s.

STEP 4: Create a Project Workspace

Now, you're ready to create a workspace for your project.

New workspaces must be created by the project's *Coordinating Principle Investigator (CPI)*. This is the "Chief" or "Lead" researcher on the project and the person responsible for submitting the ethics application. The CPI cannot delegate this task.

If you are the CPI, click '**Create Project**' and enter the required information, noting the mandatory fields (*) and *hovering your mouse over the  icon if the question/required information is unclear* (Note: mandatory fields (*) and information  icons are present in all RGS sections and forms).

- First select if your project will be conducted:
 - Within WA Health only
 - Within WA only (including non-WA Health sites) or
 - Across Australia
- Next **Add Project Site(s)** following the prompts to add the sites. You can add all the sites at this stage or just the 'lead' site (the CPI's site), adding the other sites later.
- Enter the **title**, exactly as per the protocol. *Use plain text – do not bold or fully capitalise as this will be migrated through all subsequent forms and letters.*
- Only add a **short title** if one is really necessary (i.e. if the title is very long). Otherwise leave blank. Similarly, only add an **acronym** if there really is one.
- Add 3 **keywords** for use when people search for projects.
- **Type of ethical review:** Select either:
 - **WA Health single ethical review** – The project will be conducted at one or more WA Health sites under the authority of a WA Health HREC.
 - **National Mutual Acceptance (NMA) single ethical review** – The project will be conducted at one or more Australian sites under the approval of an NMA-certified HREC (i.e. in most cases an interstate certified HREC). *See below for more information about these projects.*
- Select the **administering Research Governance Office**. This is the office that will review the governance application for the single or lead site (e.g. if the single/lead site is RPH, the administering office is the EMHS RG Office). *A list of WA Health Research Governance Officers (RGOs) and the sites they cover is under 'Contacts' in the main blue menu bar on the RGS page.*
- If you are not a WA Health employee, or not acting as one for this particular project, you will be asked to sign a **Declaration of Confidentiality** before pressing **submit**.

The request **will** be reviewed by the nominated RGO as soon as possible.

- The RGO might contact you if they have any questions about the project. You will receive an email when the project space has been created.
- You can also contact the RGO by going to **'Contacts'** in the main blue menu bar on the RGS homepage. *Don't be shy about calling the RGO and asking for the space to be created if you need to get going on your application.*

National Mutual Acceptance (NMA) projects (N/A if your project is WA only – Go to [Step 5](#))

If you are using the NMA scheme for your project (i.e. a national lead NMA-certified HREC will provide ethical approval for WA Health site/s) there are a couple of things you need to know when creating the project workspace:

- The workspace must be created by the national CPI. In most cases this person will be outside of WA and may need to sign up as an RGS User ([Step 1](#)). The CPI Delegate may also be the national or lead site coordinator and will likely also have to sign up as an RGS user. *It is essential that the local WA Health team takes responsibility for assisting the national team to create the workspace and prompt them to take the necessary steps efficiently.*
- You can add all public organisation sites from across Australia. 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 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. So, it is most efficient to add the WA Health site/s at this stage and add the remaining sites later ([Step 6: Add and Manage Sites](#)).
- The **type of ethical review** is 'National Mutual Acceptance single ethical review'.
- The **administering Research Governance Office** is the office that will review the governance application for the WA site. *A list of WA Health Research Governance Officers (RGOs) and the sites they cover is under 'Contacts' in the main blue menu bar on the RGS page.*

STEP 5: Orient to the Project Workspace

Click **'My Projects'** on menu on the left-hand side of the RGS home page. This menu lists Active, Closed and Archived projects and your role in them.

Click on the *Project Reference Number (PRN)* to access the project workspace.

The **project header** is always visible, displaying the project's key information and a visual representation of the **project lifecycle** with each milestone step changing from **grey** to **green** as the project progresses.

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

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

PRN: RGS0000001231 Project status: Active Project ethics approval status: Pending
Project type: Research Short title: Anchor Registry
Protocol number: CD03469 Acronym: CPI: [Anthony Freeman](#)
External HREC ref: HREC/18/CRGH/65 Lead HREC: Sydney Local Health District Human Research Ethics Committee - Concord Repatriation General Hospital (EC00118)
My Role(s): RGS Admin, RGO

Below the header are the **project tabs** that include adding or removing sites, inviting and allocating roles to project members and preparing and submitting your applications.

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

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

To submit your ethics and governance submissions, you'll be working across the first four tabs:

- Sites
- Members
- Project Details
- Applications

STEP 6: Add and Manage Sites

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
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The first thing to do is go to the **'Sites'** tab and (if necessary) add any additional sites (if you only nominated a single site when creating the workspace).

Click **'Add Project Site(s)'** and follow the prompts.

- You can add multiple additional sites in one go.

- Once back on the main 'Site' page be sure to click 'Save' before moving on.
- The CPI, CPI Delegate, PI, PI Delegate can all deactivate/reactivate a project site throughout the project's life.
- If you cannot find a site in the drop-down menu, click the '**RGS Support**' link and email the site's *official name* in full, the address and phone number. RGS Support will create the site.

STEP 7: Add and Manage *Project Members*

Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
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Access to the workspace is by invitation, initially from the CPI who has overall responsibility for the conduct of the project.

It is important to first **understand the specific project roles**, their function in RGS and how they relate to the responsibilities over the life of a research project.

- The key roles are *Coordinating Principal Investigator (CPI) & CPI Delegate* for completing and submitting the ethics application and site *Principal Investigator (PI) & PI Delegate* for completing and submitting their respective site governance submission.
- There can only be one CPI for the project and one PI for each site.
- The CPI can appoint one CPI Delegate. This position can be changed to another person at any time. The CPI Delegate can fulfil most of the CPI responsibilities in the RGS with the exception of 'authorising' the *ethics application* form just prior to submission.
- Similarly, each PI can appoint one PI Delegate who can complete most of the *site governance submission* with the exception of 'authorising' the governance application prior to submission.
- CPI and PI delegates are optional and are most relevant for larger sponsored projects involving paid study coordinators who take on the delegate roles.
- The CPI can also be the PI for their site. If the project is single site, it is likely they *will* be the same person. All sites *must be allocated a PI* who is an employee of the site.
- The CPI Delegate can also be a PI Delegate (for a single or multiple sites).
- An *Associate Investigator (AI)* is any other investigator at a site who is not the PI but is a named investigator on the project.

- *Research Group Member (RGM)* is the default role given to anyone invited to the project without a specific role. Typically, RGMs will be research assistants or study coordinators who do not have a specific CPI or PI Delegate role at any given time. They can be re-allocated to one of the delegate roles at any time.
- Finally, RGS allows a *Sponsor* representative to be invited into a workspace to assist with the ethics and governance submissions. These are representatives of the sponsoring organisation which may be a pharmaceutical/technology company, a Contract Research Organisation (CRO), collaborative research group, a higher education institution or a research institute. The Sponsor can assist with the completion of the ethics application forms and supporting documents *but is not able to view the site Budget Form*.

Adding members

It is a good idea to get everyone involved in the project added to the workspace early on.

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 the ethics form.

To invite a member to the project, click '**Add Member**' and follow the prompts, searching for the member in the RGS User database.

- If a user's name cannot be found they may *not be a RGS User*. Click '**Invite an Anonymous User**' and follow the prompts. This will send the person an email asking them to sign up to RGS. *Or, you can contact them offline and email them this manual with the sign up instructions in Step 1.*
- Some roles are restricted to one person (e.g. there can only be one PI per site). If you need to invite a new member and then re-assign roles, first invite the new member in one of the 'generic' roles (RGM or AI) and then re-assign the roles once they have accepted their initial invitation.
- Once invited, the user will receive an email invitation to the project. The invited users must accept the invitation by following the link in the email or by going to their '**Tasks**'.

Changing member roles

Roles can be added or removed by a CPI, CPI Delegate, PI or PI Delegate. Any individual member can remove themselves.

- To edit a member's role in the project, select the member and then click '**Edit Member**' and follow the prompts. This is easy to do and the member will receive an email informing them of the changed role.

- 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.
- If a CPI, PI or AI is removed from the project the reviewing HREC and relevant site/s should be notified using an Amendment Form.

Changing the CPI

Only the current CPI or an RGS Administrator can change the CPI.

- To remove a CPI, a replacement must have been nominated and invited to the project in a generic role (e.g. RGM).
- The current CPI can then select him/her self in the members list, click 'Edit Member', select the CPI role and click 'Remove Role'. Follow the prompts to complete and simultaneously add the new CPI from the project members list. *You will not be able to remove your CPI role without adding a replacement.*
- If the change has occurred after HREC approval and/or site authorisation, an Amendment Form must be submitted to the reviewing HREC and all RG Offices associated with the project sites.

You can now start your ethics and governance applications.

STEP 8: Complete *Project Details*



Before completing your ethics and governance Applications, first complete the '**Project Details**' tab. This has four sections:

1. Project Header
2. Ethics Information
3. Governance Information
4. Investigator Contact Information

You will be asked to enter key information about the project. This scaffolds out the requirements of the project, determining which sections of the ethics and governance forms are relevant (or not) to your project.

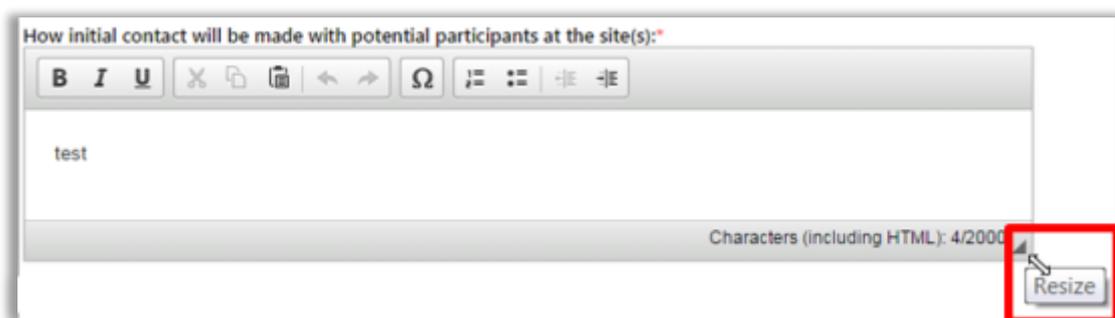
It is worth investing some time getting this information right because the information you enter will be migrated into the forms when you create them next in Step 9: Applications. It also ensures the important aspects of your project are searchable

and reportable and will also migrate into monitoring forms once the project is up and running, saving time later.

Navigation and data entry tips

These navigation tips are valid throughout RGS, including when completing the forms ([Step 9](#)) but the first time you will need them is when completing Project Details:

- You can move between the four sections using the pulldown *Index* to the right of the screen under the grey tabs.
- To complete a section first click 'Edit'. Once in edit mode you can complete the section. You can also 'Next' through the sections completing them one after the other.
- Each section has mandatory fields (*) and you can hover your mouse over the  icon if the question/required information is unclear.
- For text heavy sections of more than a few paragraphs, you can drag the border of a text box to extend its length.



- Get in the habit of clicking 'Save' every few minutes, or prior to moving to the next section. Click 'Save and Close' when exiting a section.
- When a section is complete, first click 'Mark Complete'. This changes the status of the section to 'Completed' to inform other Project Members that this section is now final and ready for authorisation. 'Completed' sections can still be edited, by first clicking 'Unlock'.
- All Project Members (including Sponsors) can edit, mark complete and unlock all four sections. However, only certain members are allowed to complete the final step and 'authorise' (or, if necessary, 'unauthorise') specific sections. This is to ensure the 'Project Details' information is correct prior to populating the forms.
 - Only the CPI/CPI Delegate can 'authorise' [Section 2. Ethics Information](#)
 - Only a PI/PI Delegate can 'authorise' [Section 3. Governance Information](#)
- Once completed, each section can be 'authorised' by the members above.

The content

If you have any questions about the content of the Project Details sections, it is highly advisable to contact the relevant HREC or Research Governance Office. It's a good opportunity to have a chat to the HREC Coordinator to discuss your project and find out when the next HREC meeting and deadline is, and/or to discuss the site governance requirements with the local Research Governance Coordinator (RGO).

1. Project Header - tips

- The information in this section should be self-explanatory and you have entered most of it when you created the project space.
- Select the Lead HREC from the menu.
- Most projects do *not* need Additional HREC '(Specialist)' review. The *only* projects that do are those that will require access to the WA Health data collections via the Data Linkage Branch. Otherwise, leave this blank.
- National Mutual Acceptance (NMA) projects:
 - If your project is being ethically reviewed under the NMA Scheme (i.e. by a 'certified' lead HREC) you need to set up the Project Header to reflect this.
 - First indicate if the NMA certified HREC is *outside of WA Health*. If you select 'No' you can then select the Lead HREC from the drop down menu of WA Health certified HRECs.
 - If you select 'Yes', you will be asked to first select the state that the HREC is in and then select the HREC name from the drop down menu. Finally, enter the External HREC Reference number *if known*.

2. Ethics Information - tips

- You will be asked to complete an outline of the key ethical information for the project (e.g. defining the participant population and recruitment method). This information will populate the ethics application form, so complete this section accurately and to a high standard. Think of this as the start of completing your ethics application form. Note the mandatory fields (*) and hover your mouse over the  icon if the question/required information is unclear.

3. Governance Information – tips

- This section is straightforward, but the information is important because it helps to set up the governance form. The most important parts are to clarify any involvement of *external parties* (Universities or commercial organisations) with whom agreements might be necessary and to *identify all funders*.

- All funders (both monetary and in-kind) must be added to question 7 before the governance forms are created and completed because the available funders will be populated into the Budget Form attached to the governance form. *If you cannot find a funder from the drop down menus, contact the RGS Support.*

ALL research has costs and absorbs human and material resources. These costs must be covered one way or another. Some projects have specific monetary grants or are funded by commercial organisations. Some are entirely supported 'in-kind' by the researcher's department or are 'self-funded'. Many rely on a combination of monetary funding, 'in-kind' support and 'self-funding'. Regardless, all monetary costs and human, material and time-related resources associated with conducting the project must be listed in the budget and covered by some form of funding or support.

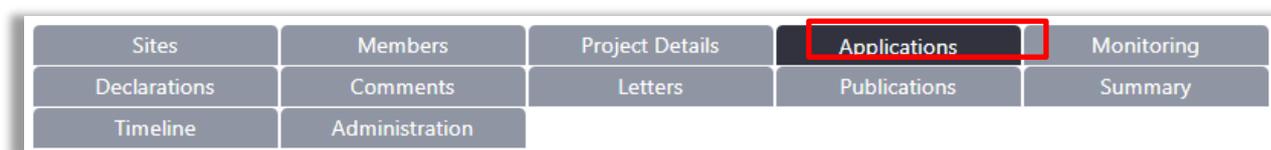
- For monetary funding: Select all funding organisation from the pull down menus.
 - For monetary funding the funder is where the funding or grant is coming from (e.g. the sponsor or NHMRC), not who the administrating organisation or contract research organisation is.
 - There may be several funders providing monetary funding in a project.
 - The administrating organisation or contract research organisation details can be added to question 7.1 for invoicing.
- For in-kind funders:
 - The funder organisation is the one that is providing the in-kind support, such as the WA Health institution that pays project member's salaries if they are not covered by specific project-related monetary funding (e.g. *Royal Perth Hospital*).
 - Essentially all investigator-initiated projects, and many that are grant funded, will still rely on some degree of in-kind support from the WA Health institution/s at which the research will be conducted. So, it is generally necessary to add the CPI and PI/s sites (e.g. *Fiona Stanley Hospital*) as a funder.
 - All non-commercial projects will have their HREC and/or site governance review fees covered in-kind by their respective Area Health Service. For example if the research department is at RPH, the *East Metropolitan Health Service Executive* will cover the review fees and so must be listed as a funder.

4. Investigator Contact Information – tips

- Just complete the '*Qualifications and Expertise Relevant to the Project*' field for each of the project members listed. Note: This information can be updated by the member *in their RGS profile* (under: 'Qualifications and expertise'), negating the need to enter it for each project they are involved in.

When all four '**Project Details**' sections are 'authorised' you can go to the '**Applications**' tab (formerly '**Forms & Documents**') to complete the ethics and governance forms and upload supporting documents.

STEP 9: Complete Applications



Sites	Members	Project Details	Applications	Monitoring
Declarations	Comments	Letters	Publications	Summary
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The Applications tab is divided into two sections:

- Ethics Approval
- Site Authorisation

Orientation

Within each of these sections there are 'Active' and 'Submitted' sub-sections. While working on a new application (either ethics or site authorisation) your forms and documents will be 'Active' and when submitted, they move under 'submitted'. You can use the '+' and '-' signs to minimise sections you are not working on and focus on the section you are.

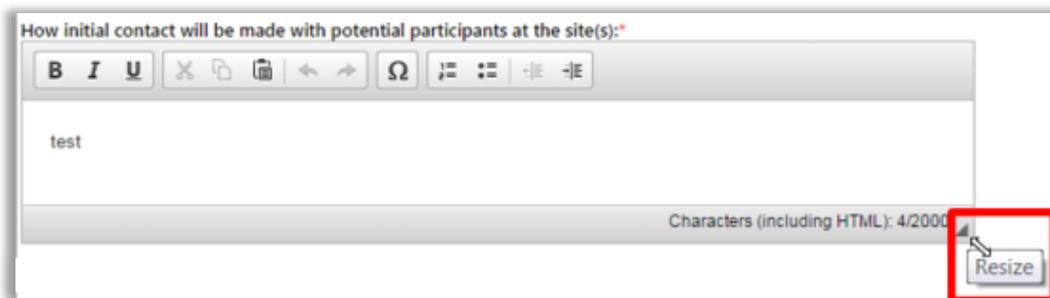
Adding and completing an ethics form

- Under 'Applications' – 'Ethics Approval' – 'Active' you will see a 'Forms' grid. Click 'Add Form' and select one of the two ethics forms available in the RGS:
 - *WA Health Ethics Application Form (WAHEAF) **OR***
 - *Western Australian Specific Module (WASM)*
- For all local projects to be completed only within WA Health (including at multiple WA Health sites) select the WAHEAF.
- For National Mutual Acceptance (NMA) projects select the WASM:
 - For NMA projects, the WASM must be completed in the RGS and the Human Research Ethics Application (HREA) uploaded as a supporting document. You cannot use the WAHEAF for NMA projects *even if the NMA certified HREC is a local WA Health HREC.*
 - The HREA must be completed externally and uploaded to the RGS as a supporting document.
 - For NMA, if an External HREC (outside of WA Health) is the Lead HREC you must complete the WASM in RGS, print it and submit it along with your ethics application to the external HREC outside of RGS.

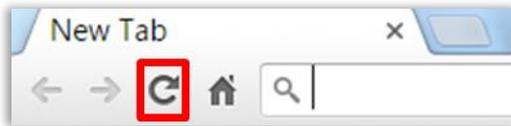
- When the External Lead HREC has approved the ethics application, the CPI or CPI Delegate, must upload the approved HREA and supporting documents (including the ethics approval letter) and submit them with the approved WASM to the WA Health Governance Office.
- Version 1.0 of the selected ethics form will appear under the 'Ethics Approval' – 'Active' section of the Applications tab. Its status is 'Pending' and it is ready for completion.

Completing the WAHEAF

- Version 1.0 of the WAHEAF is automatically populated with information previously entered in 'Project Details'.
- You just need to complete the remaining fields by clicking on the name of the form and, once in the form, clicking 'Edit'.
- The form works just like 'Project Details'. Use the **Form Index** to navigate through the 7 sections, clicking 'Save' regularly and as you 'Next' through the sections. Be sure to click 'Save & Close' if you want to exit and come back to the form later.
- Update the relevant fields, paying particular attention to mandatory fields (*) and hovering your pointer over the information icon ⓘ for more information.
- As with 'Project Details' you can paste information in from other sources but might need to partially reformat the information (*Note: if you are pasting text with links to 'Endnotes' or 'Footnotes' for citations; the text should first be pasted into a word document to break the link/code with the 'Endnotes' or 'Footnotes' and then pasted into RGS. The Endnotes can then be added to the RGS field separately*).
- You can also drag the border of text heavy boxes to extend their length.



- **Click on Your Web Browser's Refresh button to fetch the Latest Information.** If changes are made to the Sites tab, Members tab or Project Details tab while you are preparing the WAHEAF, the updated information needs to be migrated into the WAHEAF. Click the web browser's 'Refresh' button (typically F5 on your keyboard) to fetch the latest information and to refresh the current form. Below is an example, if Google Chrome is used:



- When the form is completed, any project member can click 'Mark Complete' at the end of Section 6 (below 6.7 Dissemination of Results). On the main 'Applications' page the form's status will change from 'Pending' to 'Completed'. This is to inform all project members that the form has been finalised and is ready for authorisation.
- To 'authorise' the WAHEAF:
 - (1) All listed PIs must go to Section 7. Declarations and sign next to their name.
 - (2) Then the CPI can then go to the main 'Applications' page, click the 'Select' box next to the WAHEAF and click the 'Authorise' button (*Note: The 'authorise' button will not be 'live' and available to the CPI until all PIs have signed the declaration page*).
 - (3) The WASM has no required signatures and requires authorisation only by the CPI. **Only the CPI can complete this final step of authorising an ethics form prior to submission to the HREC.**
- Once the WAHEAF is authorised, the CPI and CPI Delegate can now submit the form to the HREC.
- Before submitting to the HREC, upload your **supporting documents** into the 'Documents' grid below the 'Forms' grid. This simply involves clicking 'Add' and following the prompts to upload the document from your computer.
- Typical documents to add for ethical review:
 1. Protocol (**mandatory**)
 2. Participant Information and Consent Form (PICF)
 3. Recruitment documents (e.g. letters, posters, advertisements)
 4. Questionnaires, surveys, interview outlines
 5. Other participant documents (e.g. identification card, diaries)
- Once your documents are uploaded, you will need to click 'Select' for each document and 'authorise'.
- When you have an 'authorised' form and 'authorised' documents, click **'Submit to Ethics'** and follow the prompts to submit to the HREC. Be sure to select the form and all the documents you want to submit so they go to the HREC in one go.
- You will receive an automatic email indicating your submission has been received by the HREC Executive Officer. See [Step 10: Validation of Submissions](#) for what happens next.