Hello and welcome

Welcome to all new users of the Research Governance Service (RGS). Since the RGS went 'live' to the public on **5 December 2016** we have had over 1100 users sign up with a multitude of roles in the system. Thank you to all the hard work that the WA Health RGS Admins, research ethics and governance staff have contributed to making the RGS function.

The development of the RGS has been a long road. The impetus for its development was to enable WA Health to join the National Mutual Acceptance (NMA) program that allows for multi-centre approval by a Certified Australian public health Human Research Ethics Committee (HREC). There are currently 5 jurisdictions signed up to the NMA; however WA Health was not eligible because there was not a whole of health IT system that governed the administration of research projects.

The development of the RGS first started in 2012 with a series of meetings with researchers, HREC members, ethics and research governance staff. The main theme from all parties was the need for an application that was available to all, a one stop shop, which serviced the needs of both researchers and administrators. Another vital component of the system was reducing duplicate data entry, security and the ability to maintain confidentiality. From these meetings, high level requirements were developed on how to capture and hold all the information required by all parties for the life of a research project. The ever changing landscape of research ethics and governance also meant that future proofing the system was also a key component in its development.

The complexity in developing the system meant that it was necessary to split it into stages with **Stage 1** being launched in December 2016 and **Stage 2** upgrading the RGS progressively over the next 18 months. These changes will expand the RGS functionality and the administration of the research projects through monitoring and attaching links to publications. The first of these upgrades will allow WA Health to sign up to the NMA and will allow for HREC approval from outside of WA Health. This will have a big impact both on the RGS and how research will be approved at WA Health sites.

RGS today

The RGS has over 280 research projects that are either progressing through their ethics and/or research governance review towards ethics approval and site authorisation, or have already commenced recruiting participants. RGS is available 24/7 anywhere a user has access to the internet. Users are accessing it from all over Australia, Europe, Asia and US.

As with any new IT system there are glitches that are only discovered with use of the system, that no amount of testing is able to pick up. The development team have been quick to respond to fix problems as they arise, release enhancements, as well as continuing to develop the Stage 2 release. Any issues should be reported to RGS.Support@health.wa.gov.au

Help Wiki

Now that the RGS is in production there have been stumbling blocks that a number of users have come across. The Help Wiki is available and is a great help to navigate through the RGS. It is located on the right hand side of the horizon menu in RGS.

| Home | Research Information ▽ | Meeting Calendar | Document Templates | Contacts | Help Wiki |

Once in the Help Wiki there is an expanding menu on the left hand side of the screen that allows you to narrow your search to what part of the process you need help with.

For other common stumbling blocks/questions refer to FAQs.

Ethics Forms

The RGS has been built to accept two ethics forms, the WA Health Ethics Application Form (WAHEAF) which researchers can use for research projects that are conducted within WA Health; and the WA Specific Module (WASM) which accompanies the Human Research Ethics Application (HREA). The HREA should be used for multi-centre projects when the project involved sites external to WA Health. Researchers conducting research at multiple sites within WA Health have the option of using either the WAHEAF or the WASM (with the HREA). If there is the possibility of a site being involved that is not within WA Health then the recommendation is to use the WASM and HREA.

HREA and RGS

The new HREA was not built into RGS as the information required was not available when the RGS was built, so it will have to be added as a document. If the HREA is being used, the form that has to be completed in the RGS is the WASM. For more information on this refer to Help Wiki: Add, fill out and authorise an ethics form.

Adding the HREA is done through Documents. The document type for the form is 'Human Research Ethics Application (HREA)'. It is important to put the right document type when using the HREA because the RGS checks if you are using the WASM as the ethics form, and that you are also submitting the required document type.

HREA is replacing the NEAF

The HREA is replacing the National Ethics Application Form (NEAF). Researchers can no longer create a NEAF and the platform that existing NEAFs reside on will be retired on 30 June 2017 and no longer be available. The HREA is the form that is used for multi-centre research that includes sites outside of WA Health. If you have already completed a NEAF it can be added as the HREA document type in RGS until 30 June 2017.

Budget Form

The Budget Form works differently from all other forms as it is technically complex, allowing for multiple authorisations for separate departments in parallel. In the back end it is divided into different tables which allow for each department to edit and authorise their sections (departments) independently. Therefore it doesn't have a mark complete button before you invite people to quote or authorise their sections, because in reality the form is actually complete after they have provided their quotes/authorisation. It will stay in progress until it is finally authorised by the Principal Investigator. The Budget Form has 3 sections.

The following process should be followed to complete the Budget Form:

1. **Section 1** – PI/PI Delegate adds the Research Department and Supporting Departments to the budget. The HoDs will have the status of 'pending'.
2. **Section 2** - PI/PI Delegate enters their costs for the Research Department (& third party agency if required).
3. **Section 1** - PI/PI Delegate invites the Head/Delegate of Supporting Departments to provide their quotes by selecting the department and clicking 'Invite'.
4. **Section 2** - Supporting Departments enter their costs and authorise these costs.
5. **Section 3** - PI/PI Delegate enters the funding for both the Research (& third party Agency if required) and Supporting Departments.
6. **Section 1** - PI/PI Delegate invites the Head of Research Departments to authorise the Research Department, which is their way of authorising the whole budget (instead of signing the SSA Form as in the past). If the Head of the Research Department is part of the Project Team, their next Senior Line Manager (e.g. Divisional Director) must be invited to authorise the Research Department section.
7. **Section 2** - Head of the Research Department authorises the Research Department section.

Once all the above is complete:

- all costs at the top of the Budget Form should become authorised and the correct balance between costs versus funding should be displayed
- the PI can now authorise the Budget Form. They should click edit and go to **Section 3** and click the authorise button (this is like the PI signing the Budget Form)
- the form is then ready for viewing by those signing the SSA Form (Business Manager, Divisional Director etc.)
- once the SSA Form and the Budget Form are both authorised then they can be submitted to the RG Office.

Remember in governance (submission to the RG Office) the system is built so you can submit governance forms and documents at any time, they don't need to be in a package like ethics. This is to speed up the governance review. The only forms/documents that have to be submitted together are the SSA Form and the Budget Form. Therefore you could submit an insurance document or draft Clinical Trial Research Agreement for review before you have completed the SSA/Budget Forms. This is in line with the NHMRC's good governance practice process to reduce KPI related to governance review. When submitting documents in this manner you have to associate the document with a form in the system (for tracking) but you don't have to submit that form at the same time as the document.

RGS Support

After reviewing the Help Wiki, if you need additional help with using RGS, please email RGS.Support@health.wa.gov.au please leave your phone number if you wish to speak to someone and they will endeavour to call you as soon as possible.

Business Support

If your enquiry is more related to ethics and governance processes, policy or contractual enquires (not related to RGS), contact details for WA Health Ethics and Governance Offices, policy and contractual personnel can be found at Contacts.