WA Health is joining the NMA from 31 August 2017

Commencing 31 August 2017, WA Health will participate in the National Mutual Acceptance of ethical and scientific review for multi-centre human research projects conducted in public health organisations (NMA) scheme following the signing of a Memorandum of Understanding with the NMA member jurisdictions – the Australian Capital Territory, New South Wales, Queensland, South Australia and Victoria on 18 July 2017.

What is NMA?

The NMA ensures all multi-centre research projects being conducted at public health organisations within the participating jurisdictions must be ethically and scientifically reviewed only once by a NHMRC Certified Lead HREC participating in the NMA. The exception is those research projects that require additional specialist review. WA Health sites must accept the ethical and scientific review undertaken by a NHMRC Certified Lead HREC participating in the NMA as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

Which WA Health HRECs can be Lead (reviewing) HRECs under NMA?

There are only 3 certified HRECs within WA Health that can Lead HRECs under NMA:
1. Child and Adolescent Health Service HREC (EC00268)
2. Sir Charles Gairdner and Osborne Park Health Care Group HREC (EC00271)
3. South Metropolitan Health Service HREC (EC00265).

Which ethics application forms are used?

The Human Research Ethics Application (HREA) must be used for all NMA applications. For ethics submissions to:

• WA HRECs – complete the NHMRC HREA and upload it as a pdf to RGS.

• ACT, NSW, QLD, SA or VIC HRECs – complete the HREA in Online Forms.

Which jurisdictional-specific information must accompany the ethics application?

If the sites from these jurisdictions are involved in the project, these supporting documents must be submitted to the reviewing HREC (irrespective of the committee's location).

• *NSW Privacy Form* if project includes 'adult persons who are unable to give consent'
• *Victorian Specific Module* (VSM)

• *Western Australian Specific Module* (WASM) refer to Multi-centre Research on how to complete and submit the WASM to both WA Health and non-WA Health HRECs.

Where can I find guidelines?

The *WA Health NMA Guidelines August 2017* provides guidance on how the scheme works within WA Health and additional NMA guidance documents (version July 2017) are located on the RGS Multi-centre Research page. August 2017 versions will be available soon.

How do non-WA CPIs complete the WASM in RGS?

CPIs that are submitting an application to a reviewing HREC outside of WA for a project involving WA sites, must always complete the WASM in RGS, as it is tied to the HREA.

If the ethical review is performed in ACT, NSW, QLD, SA or VIC, the non-WA CPI must register with RGS and 'Create a New Project'. Once the project is created the CPI (or CPI Delegate) must complete the Sites, Members, Declarations (as applicable) and Project Details tabs before creating and completing a WASM in the Forms & Documents tab. Refer to Quick Start for Researchers & Hospital Administrators for quick step-by-step guidance regarding this process.

Do not 'submit' the completed WASM at this point (as the reviewing HREC may require changes). Print the WASM as a pdf to your PC and uploaded it as a supporting document to the HREA in Online Forms.

Research governance for sites in WA

The PI (and site Project Members) must use the RGS to create, complete and submit the relevant governance forms to the WA Health RG Office affiliated with the WA Health site:

•   WA Health Site Specific Assessment (SSA) Form and Budget Form
•   WA Health Access Request Form
•   WA Health Declaration of Confidentiality
•   WA Health Research Conflict of Interest Form.

If the ethical approval is performed outside WA, the non-WA CPI should use RGS to submit the approved WASM (in the 'active' section of Forms & Documents tab) along with the uploaded approved HREA (pdf) and supporting documents to the relevant WA RG Office. This can occur independently of the PI creating and submitting the SSA or Access Request forms.

Research governance for sites in ACT, NSW, QLD, SA or VIC

The CPI must use Online Forms to create a SSA form for each participating site in ACT, NSW, QLD, SA or VIC.

If the ethical review is performed in WA, the CPI (WA) should use Online Forms to create a Minimal Dataset Form (MDF), upload copy of HREA and supporting documents, create SSA(s) and transfer each SSA to the site Principal Investigator.

If the ethical review is performed in ACT, NSW, QLD, SA or VIC, the Online Forms process to create the SSAs and transfer them to the PIs remains as per usual practice.

No NMA retrospective approval - what does that mean for my project?

NMA is not retrospective; projects that already have ethics approval must remain under their approving HREC and apply the conditions of approval that were applied by the reviewing HREC. However, in accordance with the *Standard Principles for Operation,* additional sites from newly joined jurisdictions may be added to projects approved under the NMA process, by way of amendments.

If your project is already going through the ethical review process with a WA Health HREC and it is being conducted across Australia, then it should continue to approval with that HREC.

If the project is changing to the NMA scheme and has already been created in RGS but not yet submitted to a WA Health HREC, there may be changes that need to be made. If the CPI is outside WA, the CPI for the project will need to be changed, refer to Help Wiki 'Change the CPI'. The Internal & External HREC in section 1 of Project Details may have to be changed, refer to Help Wiki Complete Project Header for National Mutual Acceptance (NMA). In section 2 of Project Details, question 3 the 'Type of ethical review' should be updated to 'National Mutual Acceptance single ethical review'.

What happens to projects that are only being conducted in WA?

If your project is only being conducted in WA it can still be submitted to any accredited WA Health HREC. It will be processed using the WA Health Single Ethical Review scheme as per current processes. The NMA scheme will not apply.

Will the National Ethics Application Form (NEAF) be accepted?

The NEAF will no longer be accepted by WA Health's HRECs (except in special circumstances if it has originated from 'Online Forms', check with the WA Health HREC for acceptability). Online Forms are changing from the NEAF to HREA on 31 August 2017.

Clinical Trial Research Agreements updated!

The March 2017 updated **Medicines Australia** and **Medical Technology Association of Australia** clinical trial research agreements (with WA standard amendments in the schedules) are now available from RGS Document Templates.

Clinical Trial National Statistics

The members of the Clinical Trials Jurisdictional Working Group (CTJWG) have produced an interim *Second Activity Report on Clinical Trials in Australian Public Health Institutions 2015-16* which captures the majority of new clinical trials approved in public health organisations in five jurisdictions in Australia. It includes the time taken for each of the two approvals needed for every clinical trial in Australia - ethics and research governance.

What's new with RGS?

The RGS was recently updated on **30 June 2017**. This is the first part of Stage 2 staggered releases with enhancements based on user feedback and ongoing development of modules to support NMA and monitoring. The following enhancements were made:

•   Allow projects to nominate an external HREC for NMA and to upload approved ethics forms and documents from an external HREC to a WA RG Office.
•   Improve the Budget Form display and allow for Head of Supporting Department Delegate, ability to un-invite a Hospital Administrator, remove funders not specific to the site budget, print at any time and improvements for RGS Admins management of third party agencies.
•   Allow a PI to be a CPI Delegate.
•   Add additional messages and tooltips to guide users.

All of these changes have been put into the Help Wiki and the user training manuals that are available on the Help Wiki pages.

Budget Form updated

The Help Wiki [Add, fill out and authorise a Budget Form](#) has been updated with the new look of the Budget Form which now opens in its own window so that if you have a wide PC screen you can see all the cost and funding columns without requiring a scroll bar.

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 technical aspects of the Budget Form do not allow for it to be authorised in the Forms & Documents tab.

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.

*Note the Research Department is the department where you are conducting the research e.g. Nephrology Department.

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.

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.

Lost Tasks

The task menu is divided into three sections current tasks, overdue tasks and archived tasks. The Help Wiki - All about Tasks has instructions on how tasks work. One problem users are facing is that they can't find the email that first told them there is a task for them or they can't find their task once they have logged into RGS. Any task that has not been actioned or finished will be in either the Current Tasks (less than 3 days old) or Overdue Tasks. When you receive a task you have to click 'Action' to go through the process of completing the task.

There seems to be some confusion on what the 'Finish' button does. The 'Finish' button only takes the task from Current or Overdue and places it into Archived. If you have clicked 'Finish' on a task but still need to access the task you will find it in the Archived section.

If you have clicked 'Finish' without first clicking 'Action' or you need to go back to the task first, go to Archived Tasks. Next expand the Task Type and then click on the task you want.

When the task opens you will only have the option of view.


When you click View it will open the task or take you to the project workspace related to the task.

Future enhancements to be released in September!

Another Stage 2 release will occur at the end of August. One of the enhancements will include changing the Project workspace chevron to green as you complete each stage. It will also contain additional guidance that is revealed when you click on the chevron, as per example below:
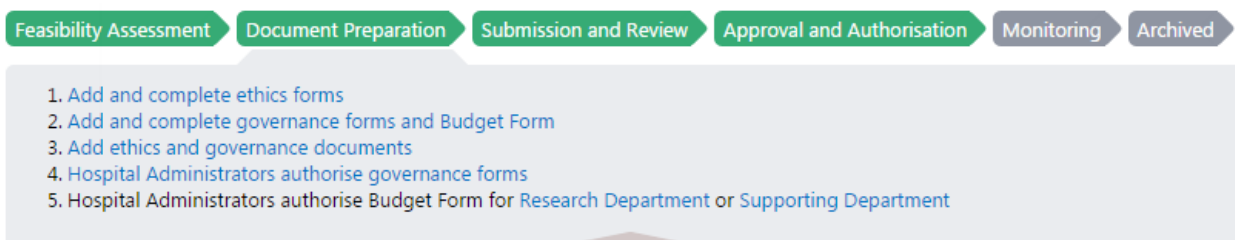
Help Wiki

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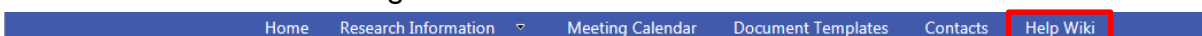
Once in the Help Wiki there is an expanding menu on the left hand side of the screen that allows you to narrow your search to what part of the process you need help with.

For other common stumbling blocks/questions refer to FAQs.

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.