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### What's new in RGS? – \*April 2018 changes\*

Stage 2 (Release 2B) changes will be deployed to RGS on **April 2018**. Look out for the updated Help Wiki pages & user manuals in the coming weeks!

The April enhancements are a combination of the ongoing development of the RGS by the Project Team, and user feedback captured at the user experience workshops, Business User Group meetings and from requests for assistance to RGS.

A list of all Stage 2B changes will be available after deployment at [\\*What's new in RGS?\\*](#). **In addition, the following features have been added to RGS:**

#### 1. Saving Issue

Earlier this year some users had issues with saving their data if they were working on a form for longer than 30 minutes as the SharePoint server was timing out after this time, despite the user clicking save. This issue has been resolved but if any users continue to lose their data please report the issue to [RGS.Support@health.wa.gov.au](mailto:RGS.Support@health.wa.gov.au).

### Past enhancements – 2017 & 2018

Stage 1 of RGS was launched in December 2016 with the knowledge that it would continue to be updated with multiple Stage 2 releases to refine the system and capture the monitoring component of research projects. Release 1A (March) and Release 1B (September) were deployed in 2017. Stage 2 (Release 2A) was deployed on the 19 January 2018.

If you do not use the system frequently, a list of all Stage 2 changes are available from [\\*What's new in RGS?\\*](#)

## Downloading Documents with Internet Explorer

The restriction on downloading documents when using Internet Explorer on WA Health Hospital or Department of Health computers has now been resolved. If you do have a problem please contact your help desk.

## Help Wiki – Help, User Guides and Videos

The Help Wiki has now separate pages for Help, User Guides and Videos. These have all been recently updated with the changes from the January 2018 release.

The [Help](#) contains links to ‘Popular Actions’ and the on-line guidance pages.

[User Guides](#) contains the RGS User Guides (formally known as Training Manuals).

[User Videos](#) contains a series of training videos which will be uploaded as they are developed in the next 6 months. The first ones are available by clicking on the link below:

[Videos](#) 1 & 2 cover System Requirements and the RGS Public Pages

[Videos](#) 3 - 8 cover the process to create a research budget and complete the RGS Budget Form

## User Experience Feedback

In February 2018, the Department of Health and Health Support Services (HSS) contacted RGS Business User Group (BUG) Members to ask users to provide feedback on a new RGS Dashboard under development. Feedback will inform the development of this screen to be released in June 2018.

Recent feedback from RGS users include:

- “I’m enjoying the RGS system now that I sort of get how it works. I LOVE the auto-populating function. It beats typing things over and over.”
- “The RGS Support resource at [rgs.support@health.wa.gov.au](mailto:rgs.support@health.wa.gov.au) is invaluable. I really appreciate the time to step me through things”.

## Ethics and Governance Review Fees

The fees for the review of research projects apply to all new projects submitting a budget and are captured within the “Research Department” for each site. The cost of these reviews are either paid by the sponsor or absorbed by the site as in-kind support. If you need further clarification on these costs please contact the appropriate Ethics or Research Governance Office. Contact details can be found on the RGS public pages.

Research Ethics and Governance Office	Ethics Review Fees	Governance Review Fees
SMHS	\$3,500	\$3,500
EMHS	\$3,500	\$3,500
SCGOPHG	\$3,500	\$3,500
WNHS	\$2,500	\$3,500
NMHS MH	\$2,000	\$3,000
CAHS ethics + governance	\$2,750	\$2,750
CAHS governance only	NMA	\$3,500
DOH		
WACHS	\$3,500	\$3,500

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This and past newsletters are also available [online](#).

## Report on Business User Group activity

The latest meeting of the Business User Group (BUG) for RGS was held on 15 March 2018.

The members had given feedback prior to the meeting on suggested enhancements and this was collated and presented to the members with timeframes for implementation.

A presentation was given on the upgrade to the Task menu and the new Dashboard. Both of these are still in the development stage with user experience workshops still to be conducted at a number of hospitals.

A first look at the reporting available from RGS was demonstrated. All Health Service Providers (HSP) have been requested to nominate who will have access to these reports.

A presentation of the data migration was given and the data custodians at each site will be contacted for further information.

There will also be a restructure of permissions for Ethics and Research Governance staff to allow them to assist researchers at the start of their projects. If you require assistance please contact [RGS Support](#).

To identify who your BUG members are to provide feedback to the RGS Project team, contact your Research Ethics and Governance Office. Alternatively you can provide feedback through [RGS.Support@health.wa.gov.au](mailto:RGS.Support@health.wa.gov.au)

## Collaboration with other researchers

If investigators are wishing to collaborate on research projects they can either search on the [Investigator Speciality List](#) on the RGS Public Pages or use [Project Search within RGS](#) and then click on the Coordinating Principal Investigator (CPI) name to find their contact details.

## Move to Perth Children's Hospital

The Child and Adolescent Health Service is closing Princess Margaret Hospital and opening the new **Perth Children's Hospital** in 2018. The staff are currently working towards a move date in June 2018 and research projects at PMH will transition to the new hospital. If you have any existing or upcoming research projects that you think may be affected by this move, please do not hesitate to contact the CAHS Research Governance office on Ph: 9340 8405 or via email: [PCH.ResearchTransition@health.wa.gov.au](mailto:PCH.ResearchTransition@health.wa.gov.au)

## Events and Announcements

Events and Announcements can be found at the bottom of the RGS Home page. . The Events section list conferences and training opportunities that may be of interest to researchers.

The Announcement section has any news relevant to RGS and research as well as a link to the RGS newsletter.

## What's happening nationally

### National Mutual Acceptance FAQs

#### Retrospective inclusion of WA public health system approved research projects under the NMA process

Recently there have been 2 multi-jurisdictional projects that were approved by a WA public health system Human Research Ethics Committee (HRECs) prior to WA participating in the National Mutual Acceptance (NMA) scheme, that the project team has tried to move under the ethical approval of an Eastern States NMA certified HREC via the way of an amendment.

In accordance with National Mutual Acceptance Standard Principles for Operation August 2017, Principle 02, Number 3:

*3. There will not be retrospective inclusion of approved research projects under the NMA process. However, additional sites from newly joined jurisdictions may be added to projects approved under the NMA process, by way of amendments.*

This statement is interpreted as thus:

As WA did not join the NMA process until 31 August 2017, this means that there will not be retrospective inclusion of WA previously approved projects prior to 31 August 2017 under the NMA process (they will continue to operate outside NMA under the monitoring of the original reviewing WA HREC).

A WA site can only be added as an additional site after 31 August 2017 to a project previously approved by a NMA certified HREC through an amendment process if there had not been a previous approval by a WA Health HREC to conduct the project at that WA site.

#### WA Specific Module

The WA Specific Module (WASM) must accompany the Human Research Ethics Application (HREA) when a NMA certified reviewing HREC is reviewing a multi-centre research project involving a WA site and must be noted on the ethics approval letter. This is also the case when a WA site is added to a project previously approved by a NMA certified HREC through an amendment process (if there had not been a previous approval by a WA Health HREC).

The only approved version of the WASM that should be considered by the reviewing HREC, is the one completed within the [Research Governance Service \(RGS\)](https://rqs.health.wa.gov.au/Pages/Research-Ethics.aspx) IT system (an example of the [WASM](https://rqs.health.wa.gov.au/Pages/Research-Ethics.aspx) is available at <https://rqs.health.wa.gov.au/Pages/Research-Ethics.aspx>). This means the CPI must create a project within RGS to complete the form. The previous word document (version 2.2. November 2016) available from google searches has been superseded by the RGS version and is not to be used as it has been amended. ***If NMA HRECS use this old version for their review, site authorisation will not be granted by the WA sites.***

#### Where can I find further information on NMA?

The [WA Health NMA Guidelines December 2017](#) provides guidance on how the scheme works within WA Health and additional NMA guidance documents (August 2017) are located towards the middle of the [RGS Multi-centre Research page](#).

#### 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 WA may be added to projects approved under the NMA process, by way of amendments. Follow the process in the [WA Health NMA Guidelines December 2017](#) to add your site to a NMA approved project.

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:

- [Members tab](#) - If the CPI is outside WA, the CPI for the project will need to be changed, refer to Help Wiki [‘Change the CPI’](#).
- [Section 2 of Project Details](#) - question 3 the ‘Type of ethical review’ should be updated to ‘National Mutual Acceptance single ethical review’.
- [Section 1 of Project Details](#) - The Internal & External HREC may have to be changed, refer to Help Wiki [Complete Project Header for National Mutual Acceptance \(NMA\)](#).

### **Australian clinical trials handbook revised**

The revised [Australian clinical trial handbook](#) is now available on the Therapeutic Goods Administration (TGA) website.

The Handbook has been updated to reflect current practice. They have also consolidated information from the following previous clinical trials guidance documents:

- [Access to unapproved therapeutic goods – Clinical trials in Australia](#)
- [Australian Clinical Trial Handbook](#)
- [Human Research Ethics Committees and the therapeutic goods legislation](#)

The updated Handbook provides policy guidance on the clinical trials schemes administered by the TGA. Guidance on the notification process for the Clinical Trial Notification (CTN) scheme is available at [Clinical trial notification form – user guide](#). Guidance on the application process for the Clinical Trial Exemption (CTX) scheme is currently under review.

### **Supplementary guidance for safety monitoring and reporting in clinical trials**

NHMRC has released supplementary guidance on safety monitoring and reporting in clinical trials. These documents provide guidance on the use of data safety monitoring boards, risk-based management of clinical trials and reporting serious breaches of the protocol or good Clinical Practice.

[The supplementary guidance can be found on NHMRC’s website.](#)

### **New South Wales REG Information System (REGIS) and Victorian Specific Module**

[REGIS](#) is the Research Ethics and Governance Information System to assist in managing the ethics and governance of human research projects in NSW and ACT public health organisations. REGIS will replace AU-RED and the Online Forms portal as one system, accessible by researchers and public health organisations administering research.

The transition to REGIS will occur from February to April 2018, starting with lead soft launch sites on Monday, 12 February 2018.

Victoria has updated its [Victorian Specific Module \(VSM\)](#) due to changes to the new Victorian *Medical Treatment Planning and Decisions Act 2016*.