REGIS 2.2 Major Enhancement Release

(scheduled September 2020)

REGIS will have a major enhancement release in September 2020. Enhancements have been driving our REGIS user group, Researcher interest group, REGIS website feedback and direct communication with the OHMR Research Ethics and Governance Unit.

Governance Post Approval

This is a major addition to the system which allows the entire project to be managed in REGIS. Researchers will now be able to submit all site specific post approval forms and documents through REGIS.

	+ New form	×
	Select the form you wish to fill out:	
	Reporting Local Safety Events to the Institution	
)/9	Site Amendment	
ails		
5	×	Cancel
revo	ur forms. Click the link to open an existing form use the 'new form' button	helow to star

* note this image is an example only and does not show all site forms available.

Where possible, the system will reduce the duplication of multiple site submissions of the same document. Within REGIS (NSW/ACT), documents will flow from the HREC to the RGOs without the researcher having to resubmit.

This streamlined approach expands on the <u>progress report form (released 6 July 2020</u>) where there is now a single form that addresses all the NSW HREC and Site annual reporting requirements for NSW. With the governance post approval enhancement this will mean one form, one submission, actioned by HREC and all NSW sites.

Document Handling (External portal/Researcher)

Electronic filenames: Document management in the system will no longer be restricted by the electronic filename. Researchers will be free to name their electronic files as they choose.

Character limit on forms: Applicants will no longer be restricted to 20 characters when describing the document type.

HREA form change: Researchers will notice that the document upload section of the HREA has been updated to reflect the format of Project Registration and the Site Application Form.

Selecting the document type, adding the correct description, version and date here will reflect on the approval letter. Approval emails can be created faster and with fewer errors as this is pulling directly from the details entered by the Researcher.

Document Type *	Q4.2.2 Description of attachment *	Document version*	Document date *	Q4.2.1 Upload attachment *
Participant Information She 🗸	master for study arm one. Based off the international master vers	1	19/08/2020	Clear content selection (Master_PISCF_Arm 1_Interventional_1Jan19.doc) [Open]

Document Handling (Internal portal/Research Office)

Easier identification of updated documents: Expanding on the 4.9 update to system versioning documents that have been updated through the submission of a new version (response) will be identified with a red asterisk *, allowing the Research Office to quickly identify which documents need to be reviewed.

Identification of documents uploaded internally: An image will sit next to a document that has been manually uploaded in the internal system, allowing the Research Office to identify these easier.

Additional fields to manage documents: This allows the Research Office flexibility in managing documents on behalf of the applicant from the internal portal.

Title *	Protocol_draft.docx-1-01-JAN-2018		
Document type *	Study Protocol		
Document version	1		
Document date	20/01/2001		
Document descriptor	Protocol_draft.docx		
Replace file	No		
	Save Cancel		

Project Registration - identifying previously registered studies

To reduce the number of projects being created under multiple PIDs the project registration form will identify when an ethics application ID has already been used to register a study. A warning message will appear with details on who to contact and how to proceed.

Having multiple sites being managed under multiple PIDs will drastically reduce the streamlined processes created by the governance post approval enhancement.

Ethics review/approval easily identifiable to RGO

A system generated tag will appear on site applications as soon as the system recognises ethics approval. Research Offices can use this tag to filter homepage tiles and manage workflows more efficiently. The tag cannot be manually deleted once created.

ETH Approved

Amendment Processing additional statuses

Forms will have additional statuses available. Information Provided and Information Received. This will allow Research Offices to filter home page tiles and manage workflows more efficiently.

Ability to save draft emails in REGIS

Where a User Generated email can be created the system will save a draft of the email if the user navigates away.

Support and Education

A number of support videos have been created to assist researchers in completing tasks in REGIS. These are available next to their corresponding quick reference guides (qrg).

These are available now and more will be released with the 2.2 release. Check them out now.

2020 Enhancements (pre 2.2)

Head of Department sign off directly from email

Heads of Department no longer need to log into REGIS to provide support to site applications. They can action directly through the system generated email request.

This enhancement was released in June 2020.

A survey of the HOD's using this new functionality was incredibly positive with the majority noting this functionality would reduce their timeframes in providing this sign off for researchers.

Other enhancements expected in 2020

Delegation of application submission

We are currently looking at system processes to enable CPI's (Ethics) and PI's (Site) the ability, where appropriate, to delegate submission of documents to the HREC/RGO.

Changes here are anticipated to be released in 2020.

Amendment form

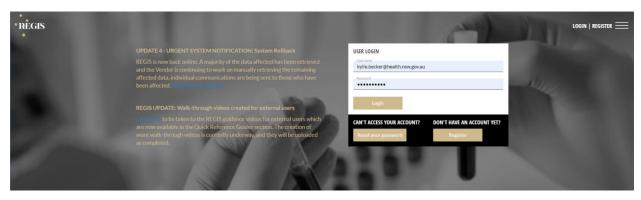
The amendment form for Ethics applications was reviewed and released in May 2020. The review removed questions that were no longer required and improved guidance and instruction text for researchers.

Progress Report form

This form underwent a major transformation and is now used as a single progress (annual and final) report form for ethics and sites within REGIS. The form design was created with the upcoming 2.2 governance post approval enhancements in mind. This form can be shared by any user in REGIS that may need access to complete it and is submitted once. <u>Watch the walkthrough videos here.</u>

System Notifications and Announcements

Current notifications, announcements and news about REGIS are also available on the REGIS website, next to the user login. <u>https://regis.health.nsw.gov.au/</u>



For more information:

- e. regis@health.nsw.gov.au
- w. regis.health.nsw.gov.au