

NEW VERSION RELEASE NOTIFICATION

REGIS version 2.2 release

Date and Time:

Wednesday 30th September 2020

7am – 8:30am

Event:

REGIS (<https://regis2.health.nsw.gov.au>) will have a major new version released to the production environment.

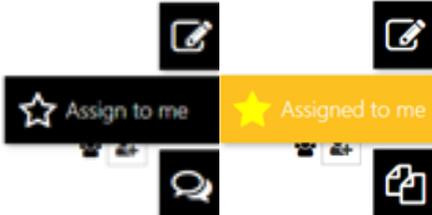
REGIS will be unavailable between 7am – 8:30am while the system is upgraded.

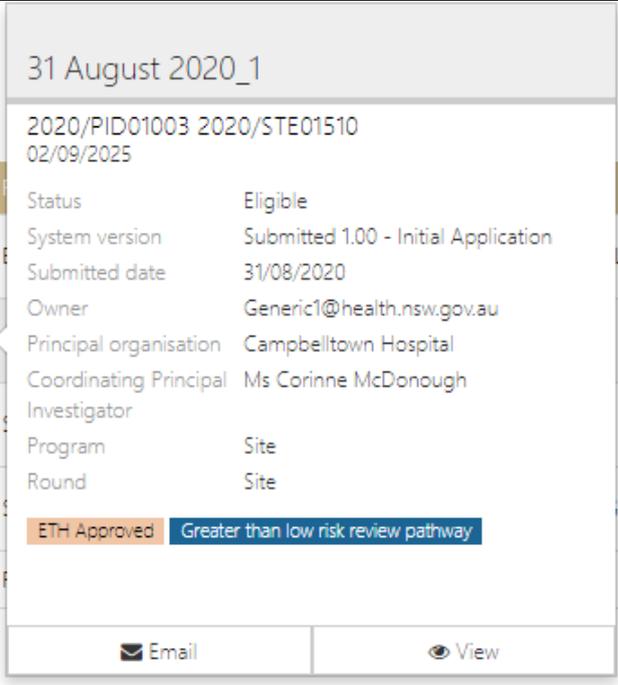
What is the impact to end users?

A number of areas identified through the REGIS Research Office User Group and applicant feedback have been addressed in the first of three major releases scheduled between

External	<p>Project Registration</p> <p>An edit has been made to project registration to eliminate duplicate applications being created in the system</p> <p>1. Part A.1</p> <p>When an applicant indicates that the ethics review has previously been submitted to a recognised HREC and enters the ethics application ID, if the ethics application ID is already in the system a warning message will appear indicating that the ethics application ID entered has been used in another project registration form. This warning message will not stop the submission of the project registration form, the applicant will need to contact the CPI before proceeding.</p> <p>A2 Ethics application ID * </p> <p>123ABC</p> <p> The ethics application Id in question A2 has been used in other project registration forms. Please check the application Id. The application Id has been used for the following project(s):</p> <ul style="list-style-type: none"> Project Id: 2020/PID00970, CPI: Corinne McDonough, HREC: Austin Health Human Research Ethics Committee <p>Sites that will no longer show:</p> <ul style="list-style-type: none"> ❖ Z pre regis ❖ Bellberry ❖ Cancer Institute 												
Internal	<p>Ethics Amendment</p> <p>A new status will appear in the internal portal when the decision 'Decision Pending – Request for more information' has been created. This decision automatically un-submits the amendment.</p> <p>Related forms</p> <table border="1"> <thead> <tr> <th>Identifier</th> <th>Title</th> <th>Submitted date ▼</th> <th>Status</th> <th>Tags</th> <th>Owner</th> </tr> </thead> <tbody> <tr> <td>029462</td> <td>Notification of an ...</td> <td></td> <td>Information Requi...</td> <td>General Amendm... Add tag...</td> <td>corinne.mcdonou...</td> </tr> </tbody> </table>	Identifier	Title	Submitted date ▼	Status	Tags	Owner	029462	Notification of an ...		Information Requi...	General Amendm... Add tag...	corinne.mcdonou...
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Internal	<p>Application decisions</p> <p>Configurations to separate Ethics only and Governance only decisions.</p>												

	<p>Ethics (ETH) will no longer see Governance (STE) decisions and Governance (STE) will no longer see Ethics (ETH) decisions.</p> <p>Application Decision – Ethics Only – updated description CE/Delegate Decision – Site only More Information SSA – Site only – updated description More Information – Ethics only – updated description RGO recommendation – Site only</p>								
External	<p>Ethics Amendment and Ethics Safety Notifications</p> <p>A new status will appear in the external portal; 'Information Required', when information has been requested against an Ethics (ETH) amendment or an Ethics (ETH) Safety Notification.</p> <table border="1" data-bbox="432 651 1388 752"> <thead> <tr> <th data-bbox="432 651 858 696">Title</th> <th data-bbox="858 651 1062 696">Status</th> <th data-bbox="1062 651 1209 696">Owner</th> <th data-bbox="1209 651 1388 696">Created date</th> </tr> </thead> <tbody> <tr> <td data-bbox="432 696 858 752">029462 - Notification of an amendment to a res...</td> <td data-bbox="858 696 1062 752">Information Required</td> <td data-bbox="1062 696 1209 752">Corinne McDonough</td> <td data-bbox="1209 696 1388 752">28/07/2020 01:46:46 PM</td> </tr> </tbody> </table>	Title	Status	Owner	Created date	029462 - Notification of an amendment to a res...	Information Required	Corinne McDonough	28/07/2020 01:46:46 PM
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	<p>Updated and New Email Templates</p> <p>A number of existing email templates have been updated to ensure the right people are receiving notifications as well as the creation of new templates for Governance Post Approval, below are a couple of examples;</p> <ul style="list-style-type: none"> • Amendment – Change CPI/PI - Rejected • Amendment – Change CPI/PI External HREC – Approved • Amendment – Change CPI/PI External HREC – Rejected • Amendment – Request Addition of Site – Approved • Amendment – Request Addition of Site – External HREC • Amendment – Request Extension of Ethics – Approved • Amendment – Request Extension of Ethics – Approved – External HREC • Amendment – General – More Information Required • Amendment – General External HREC – Authorised • Amendment – General External HREC – Not Authorised • Amendment – More Information Required – RGO Request • Amendment - Approved • Amendment – Not Approved • Governance Amendment – Acknowledgement • Governance Amendment – Change of Personnel – More Information Required • Governance Amendment – Change of Personnel – Processed • Governance Amendment – Not Approved • Governance Amendment – Request for Further Information • Milestone Acknowledgement Receipt – External HREC 								
Internal	<p>Decision Types</p> <p>Decisions will only appear for their specific program (Ethics/Site), where possible. Below list is a few examples, not an exhaustive list;</p> <p>Ethics</p> <ul style="list-style-type: none"> • HREA Approved with conditions • HREA Approved • HREA More Information Required - Approved Pending • HREA More Information Required - Decision Pending 								

	<p>Site</p> <ul style="list-style-type: none"> • SSA Authorised with conditions • SSA Authorised • SSA More Information Required - Decision Pending • SSA More Information Required - Recommendation Pending <p>Note: If a decision name has more than 60 characters, we are unable to add a program (Ethics/Site). A ticket has been logged with the vendor to address this.</p>
<p>Internal</p>	<p>Assign Applications/Projects</p> <p>Internal users (RGO/EO) can assign specific applications/projects to themselves by clicking the 'Assign to me' star icon on the right-hand menu. These applications/projects can then be filtered via the Application and Activity homepage tiles.</p> 
<p>Internal</p>	<p>User Functionality on Homepage Tiles</p> <p>Clicking on the person+ icon on an Application or Activity homepage tile presents you with a 'User' pop-out menu on the right-hand side of the screen, use this to filter applications assigned to yourself. This functionality eliminates the use of name tags in the system.</p>  <p>See QRG: Homepage Tiles</p>
<p>Internal</p>	<p>Quick View</p> <p>In 'Related Applications', users can hover over the application title and the below appears, providing a quick view of the application summary details.</p> <p>Clicking the 'Email' icon creates a new email outside of REGIS with the CPIs email address. *Note – this email will not be automatically saved in the system.</p> <p>Clicking 'View' takes you to the application summary page.</p>

	
<p>Internal</p>	<p>Application tags Tags are now automatically added to submitted applications. These tags reflect if Ethics is approved (for STEs) and the risk review pathway. The 'ETH Approved' tag is permanent and cannot be deleted</p> <p>2020/STE01512 - 31 August 2020</p> <p>2020/PID01003</p> <p>ETH Approved Greater than low risk review pathway</p> <p>Tags that indicate ethics review pathway can no longer be deleted. If a research office wants to correct this it should be changed by the researcher in the HREA <u>before</u> ETH approval or through the application and project classification.</p> <p>2020/ETH00892 - 31 August 2020</p> <p>2020/PID01003</p> <p>Greater than low risk review pathway</p>
<p>Internal</p>	<p>Application status A number of status no longer used have been hidden.</p> <p>Where possible, a program specific status has been allocated. E.g. Authorised will only show in the STE, Approved will only show in the ETH.</p> <p>Project status Where possible a program specific status has been allocated. E.g. Authorised will only show in the STE, Approved will only show in the ETH</p>
<p>External</p>	<p>Reviews and Decisions</p> <p>Auto defaults to filter only pending reviews and decisions. Meaning only items that require actioning are visible. The user has the option to filter to see all items.</p>

Approval
 This page shows all existing decisions assigned to you for review.

Download Export CSV Show 10 entries

Search

Type Approval title Title
 Please select... Please select...

Due date from Notes Decision
 dd/mm/yyyy to Pending

Type Approval title Identifier Title Due date Notes Decision Overridden Overridden decision Created date

CE/Delegate decision Ryde Hospital 2020/STE01406 Q3.6=no 3.4=Individual - not approved (a94) N/A Pending 20/08/2020 11:00:49 AM

External

Significant Safety Issue Notification Form

The smartform technology that hid the document upload section has been corrected to allow document upload regardless of responses in the form.

New Significant Safety Issue Notification

Project Details Document uploads

Document uploads

Declaration

Document Type * Document descriptor * Document version * Document date *

Upload all documents being submitted for review

Upload New

Maximum file size is 20.00 MB

Next

External

Governance Post Approval

Researchers can now submit governance post approval documents in REGIS e.g. site amendment, site safety notificaitons.

+ New form

Select the form you wish to fill out:

Reporting Local Safety Events to the Institution

Site Amendment

Cancel

Reporting Local Safety Events to the Institution form used for:

- Local Safety Event (SUSAR/USADE/URSAE)
- Significant Safety Issue (HREC External to REGIS)

Site Amendment form used for:

- General amendment
- Addition of a site
- CPI change notification
- PI change notification
- Extension of HREC approval notification
- Change site investigators or site administration contacts
- Change to contracts

	<p>Where possible, forms have been designed to auto submit to all sites with a single submission. These changes are described in form guidance and authorisation emails.</p> <p>To reduce duplication a Notificatation of an SSI from a HREC external to REGIS is only required to be submitted by a single site. The system will provide an automated receipt of notification. Individual sites will not provide receipt or review notification.</p> <p>Related PI's and Administration Contacts are copied in on related outgoing communications.</p> <p>See QRG: Governance Amendment – Completing and Submitting and Clinical Trial Safety Reporting.</p>
External	<p>Ethics approvals auto submitting to REGIS sites</p> <p>With the introduction of governance post approval, a number of ethics submissions will process through to governance automatically on HREC approval additional actions from the researcher. Guidance in forms and approval emails will describe these changes.</p> <p>Change CPI Change in NSW PI HREC extension HREC annual report Significant Safety Notification (clinical trial only)</p> <p>Change in CPI/PI (NSW): Once the HREC have reviewed and approved this request you will receive an email notification a all related applications. You are not required to submit a Change CPI/PI request notification to any related sites in REGIS. I</p> <p>On submission of this this notification to the HREC it will also be sent to each NSW Principal Investigator (site/s listed in REGIS). f NSW.</p> <p>Once reviewed by the HREC each NSW Research Office will be automatically provided with the report and the HREC notifiicator (listed in REGIS). Further guidance may be provided HREC acknowledgement email.</p> <p>Related PI's and Administration Contacts are copied in on related outgoing communications.</p> <p>See QRG: Ethics Amendment – Completing and Submitting.</p>
External	<p>Document management</p> <p>Forms are no longer restricted to a 20-character limit for the document description and the system no longer depends on electronic filenames remaining the same.</p> <p>Researchers can now add document versions and dates to electronic filenames.</p>
Internal	<p>Document management</p> <p>Applications (pre approval) Research offices can identify documents that have changed since the last submission with an * appearing next to the system version.</p> <p>Projects (post approval) an * will appear next to the system version to indicate the last submitted document form.</p>
External	<p>Walkthrough Videos and Quick Reference Guides</p> <p>A number of walkthrough videos have been created to compliment the quick reference guides.</p> <p>New quick reference guides for new functionality. Quick reference guides have been updated to reflect system changes to existing functionality.</p>

	<h2>Applicants</h2> <p>The following QRGs will help applicants register a project and complete their applications. Note some QRGs apply to more than one category.</p> <p>Quick Reference Guides</p> <p>COVID-19 data collection Researcher guidance on COVID-19 data entry v1 6 April 2020</p> <p>REGISTRATION including NMA Project Registration v5 16 March 2020 <i>This document describes when Ethics is REGIS (NSW/ACT) and when Ethics is outside of REGIS (QLD,VIC, SA,WA), replacing the NMA in REGIS document.</i></p> <p>Walk-Through Videos</p> <p>2.2 Sneak Peek Live from 30 September 2020</p>  <p>See REGIS website QRGs.</p>
Internal	<p>Draft email</p> <p>The system will save draft emails when users navigate away.</p>
External	<p>STE submission with no HOD selected</p> <p>The system now recognises no HOD STE submissions and updates the application status to 'Submitted' to allow the RGO to process this manually via the internal portal.</p>
External	<p>Site Amendment form</p> <p>Anyone with editor access on the Site Project is able to complete and submit the following Site Amendment - Changing Site Investigators and Administration Contact</p> <p>The PI is required to submit all other types of amendments.</p>
External	<p>Certificate of Currency and 40 Day Progress Report – Clinical Trial</p> <p>Any user who has access to these will be able to submit them</p>
External	<p>Notification of an amendment to a research study</p> <p>The system now recognises the active outgoing PI.</p>

Response:

For general processing guidance: Users should access quick reference guides and video walkthroughs.
<https://regis.health.nsw.gov.au/how-to/>

For technical assistance: Please contact the REGIS Helpdesk.

Technical support and issues reporting:

REGIS Helpdesk: 1300 073 447

Please ensure you record the ticket number when you call to assist any follow up contact

General Feedback:

REGIS team: regis@health.nsw.gov.au

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