

NEW VERSION RELEASE NOTIFICATION

REGIS version 2.1 release

Date and Time:

Monday 16 December 7am-9am

Event:

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

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 September 2019 and January 2020.

External	<h3>Project Registration</h3> <p>A number of edits have been made to project registration to streamline the process and guide applicants.</p> <ol style="list-style-type: none">1. Introduction Important notes to confirm that project registration cannot be edited once submitted.2. Part A When an applicant indicates that the ethics review has previously been submitted and an ethics application already exists in REGIS an error message will appear the registration will not be able to progress. <i>"This Ethics application has previously been added to REGIS under project identifier 2019/PID13065, please contact project owner Jane Smith (jane.smith@email.com) to be granted access to the existing application."</i> <small>A2 Ethics application ID * <input type="text" value="2019/ETH12161"/></small> <small>This Ethics application has previously been added to REGIS under project identifier 2019/PID13605, please contact the project owner Kylie Becker (kylie.becker@health.nsw.gov.au) to be granted access to the existing application.</small> <p>Note: This functionality does not yet check for ethics IDs that are created outside of REGIS.</p> <ol style="list-style-type: none">3. Part B when study type = clinical trial Question 4.1 help text updated to include description of Xenotransplantation Question 4.2 & 4.4 Note/Guidance regarding Early Phase Clinical Trials Question 4.6 Link and help text added to describe risk category When early phase clinical trial Additional NMA Paediatric HREC's now recognised and accepted.4. Part C General Re ordering text to describe sections. Other health jurisdiction or organisations tab additional guidance text added to describe what sites should and should not be added here. Other health jurisdiction or organisations tab change the Project
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Centre free text field to State/Jurisdiction dropdown to better guide applicants and provide clearer information to the research offices.
When no sites selected in Part C new guidance appears noting that no sites were selected and not site applications will be created. There system requires the applicant to select "My application has no sites" to acknowledge this. This is to reduce the number of project registrations being submitted without the required sites.

Site team names the system no longer asks for any site team member names. Only the Principal Investigator is required to be entered here.

5. **Part D**

Indicating CPI guidance text added to indicate that "an incorrect response WILL cause the application to be ineligible and will cause delays in processing".

6. **Part E**

Site team members section hidden.
Question regarding is PI a student removed from PR.

7. **Part F**

Extensive instructions on how and what to upload at this section.
Encouraging applicants to "Register" all documents to be submitted to a HREC.
Document and total upload limit descriptions.
Error message if the applicant uploads multiple documents with the same electronic filename.

You cannot upload more than one document with the same filename

8. **Submit**

Addition of warning message on submit page.

PROJECT REGISTRATION CANNOT BE CHANGED ONCE IT IS SUBMITTED.
BEFORE YOU CLICK "COMPLETE REGISTRATION" MAKE SURE YOU CAN SEE EACH TYPE OF APPLICATION YOU EXPECT TO BE CREATED IN REGIS.

If you are submitting a HREA to a NSW/ACT HREC you should see "A HREA" below.

If you are submitting to a NSW site EACH site selected under the NSW tab at Part B should be listed below.

If you do not see the information expected below please refer to the [quick reference guide for completing Project Registration](#)

Update to the submit wait message

REGIS is creating your documents in the background, this may take a few minutes. Please don't refresh or navigate away from this page.

Please Wait

9. Review and update to the preview/output form to ensure all questions and responses are visible.

This change will affect any "In Progress" Project Registrations. Applicants may notice that previously completed sections are now showing as incomplete. The updated sections will need to be completed to submit the Project Registration.

This change will not affect any Project Registrations that are "Registered".

External	<p>Decision Status Timing</p> <p>A new status will now appear on the external portal when a final application decision has been made but the approval notification/email has not yet been sent.</p> <ul style="list-style-type: none"> ● Approved (Pending Decision Email) ● Authorised (Pending Decision Email) <p>This is to provide further transparency on the process of the application process and to ensure there is no confusion regarding when an applicant can begin their study.</p> <p>This change will affect any STE applications that are currently in the review pathway. No action is required from the applicant.</p>
Internal	<p>Decision Status Timing</p> <p>A new status will now appear on the internal portal when a final application decision has been made (either through a meeting or application → decision) but the approval/authorisation notification has not yet been sent.</p> <p>This change will affect any STE applications that are currently in the review pathway. Research Offices should update their Homepage Tiles to accommodate this change.</p>
Internal/External	<p>Email Templates Updated</p> <ul style="list-style-type: none"> • Milestone Report Form Submitted – a system generated email sent to the project owner when a milestone is submitted. Milestone = annual progress report, final report, clinical trial first patient recruited. • Milestone Achieved – created by the research office when a milestone/annual report is approved. • Milestone Revised – created by research office when a milestone/annual report requires changes. <p>This change will affect the information in the email and no action is required.</p>
External	<p>User Profile</p> <p>Removed the social media menu item.</p> <p>No action is required.</p>
Internal	<p>New version of form cannot be created when application is in status</p> <p>When application in the following status a new version of the application cannot be created by the applicant.</p> <ul style="list-style-type: none"> • Approved • Approved with Conditions • Not approved • Authorised • Authorised with Conditions • Not Authorised • Assigned to meeting

	<ul style="list-style-type: none"> Under review (this status does not show in the external portal – however if this is the status in the internal portal a new version cannot be created.) <p>In the unlikely event of an applicant having a study in any of these status and wanting to submit a new version of the application, please contact the research office for guidance. New versions of the application form are not required to submit an amendment.</p>
External	<p>HREA</p> <p>Updates to the form mapping.</p> <ul style="list-style-type: none"> Mapping NMA (NMA mapping, workflow) Mapping removed review pathway mapping exists, but question no longer asked at Registration. Production bug - question P3.1 is showing in output form when shouldn't/ is not showing when it should. Submit wait message HREA <p>This change will affect any HREA in REGIS that has been created but not yet approved. Applicants may notice that previously completed sections are now showing as incomplete. The updated sections will need to be completed to submit the HREA.</p>
External	<p>Reviews</p> <p>An improved HREC reviewer form has been uploaded.</p> <ul style="list-style-type: none"> Additional instructions on how to complete the review and where the information will go. A more comprehensive form to guide the reviewer through sections of the national statement and allows them to give specific comments. The form now asks the reviewer to make a recommendation at the end of the form <p>This change will affect pending and new reviews in REGIS.</p>
External	<p>User with Project Contact Type "Sponsor" can submit SSI form</p> <p>To better align REGIS with the NHMRC Safety Reporting guidelines a REGIS user with the delegated role of Sponsor against the study will be able to submit the SSI form.</p> <p>Before a Sponsor is able to submit this form the research office managing the application will need to create the role in REGIS, anyone assigned as "Sponsor" will need to have a REGIS account and have Edit access to the Ethics Project.</p>
Internal	<p>RO can created Sponsor Project Contact Type</p> <p>Research Offices will be able to create the user role/contact type in the ETH project. This will allow the person/s allocated to submit the SSI form.</p> <p>RO will need to manually allocate this role until the automation of this action is completed.</p>
External	<p>Decision Pending status</p> <p>Application can be withdrawn by applicant when in this status.</p> <p>No action required.</p>

Internal	<p>External Document Type</p> <p>Two new external document types have been created. This is a precursor to a future enhancement which will automatically map a submitted review to the document type "Review" and documents uploaded in the milestone against the audit question as "Audit".</p> <p>This will assist Research Offices in managing documents in REGIS.</p> <p>No action required.</p>
External	<p>STE (Site) Form</p> <p>Updates to the site application form.</p> <ul style="list-style-type: none"> • Site Team Members email is now searchable • Button – "team member not in REGIS" allows for text box for email • Separate mapping of contact into First name and Surname • CPI incorrect button has been moved to the CPI details. Further instructional text has been added "If the Coordinating Principal Investigator listed here is incorrect use this button to add correct details." • Part B - "Site Team Members" additional instructional text. "Add each site team member in this section. If the team member HAS a REGIS account add their email and their Name will prefill, if the team member DOES NOT have a REGIS account select the "Team Member Not In REGIS" button and then complete section" <p>This change will affect any STE applications in REGIS that has been created but not yet authorised. Applicants may notice that previously completed sections are now showing as incomplete. The updated sections will need to be completed to submit the STE.</p>
Internal	<p>Enabling of approval mapping</p> <p>Decision Type; Annual Progress Report Approval Option: Maybe Email template: Milestone revised email</p> <p>No action required.</p>
External	<p>Documents updated to accommodate this release</p> <p>Quick Reference Guides</p> <ol style="list-style-type: none"> 1. Project Registration 2. Status Definitions 3. Completing a review <p>REGIS User Manual</p> <ol style="list-style-type: none"> 1. Chapter 1 Homepage Tiles <p>Updated reference guides will be available on Monday 16th December 2019 on the REGIS website.</p>

Please see the following pages for further details on each item.

Response:

Business as usual please ensure any issues are reported directly to the REGIS help desk as soon as they arise.

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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REGIS SME

