

# REGIS System Enhancement – Release Notes.

A number of system enhancements/configuration changes which will be released into REGIS through a series of small/controlled system releases between now and the end of the financial year. These changes have been designed to be minimally disruptive and provide an overall improved user experience.

The second release has been scheduled for 7:30am Thursday 3<sup>rd</sup> June.

## ETH & STE application – more information requested – no response 30 days

**Issue:** The system should be updated to harmonise processes. An application that has a request for information should follow the same flow as when a study is made ineligible and a new version not submitted in 60 days. System withdrawn.

**Enhancement:** When an application (ETH or STE) has had a request for information and no response for 30 days the application will be withdrawn.

A system generated reminder will be sent to the CPI (ETH)/PI (STE) and Admin Contact at 15 and 25 days, on day 30 the system will change the status of the application to Withdrawn and send an email to notify of the action and that a new application will be required.

**How will this affect the RO:** No active changes to RO processing.

**How will this affect the Researcher:** A Researcher now has 30 calendar days to provide a response to a request for information for a new application. If a response is not provided the system will withdraw the application.

***This change is not retrospective, it will not affect studies that have had a request for information before the release.***








## STE Decisions – More information

**Issue:** Currently when a more information form is submitted by an applicant (this could be from a site amendment or site safety form) the submitted documents do not automatically appear to download.



**Enhancement:** The system will automatically include the documents in the decision download. RGO's no longer have to manually identify and select the documents.

**How will this affect the RO:** RGO's will automatically be provided the output form and any attachments that were submitted with the more information form.

Decisions  
Found 2 items

er	Type	Outcome	Decision modified date ↑	Predecessor	Related entity	Documents selected	Current due date	
	RGO amendment ...	More information ...	17/05/2021		Document - Site Amendment - General Amendment	3		   
	RGO review of a ...		17/05/2021	[68293] More info...	Form - 052342 - More information Required - RGO Approval	2		  

More information required form\_68294 - 2021\_STE01014

<input type="checkbox"/> Name	Type
 2021_STE01014 - More Information Required_574015	Adobe Acrobat Document
 2021_STE01014 - this is a new document-1-18-05-2021_574016	Microsoft Word 97 - 2003

**How will this affect the Researcher:** Researchers should notice no difference.

### Notification of an amendment to a research study – HREC extension

**Issue:** Currently a RO needs to manually create a milestone if there is a HREC extension. Many RO are not doing this. A new milestone to be auto created on extension.

**Enhancement:** When a HREC extension is approved additional milestones are created automatically. If 12 Months or more milestones added per rule each 12 months. If less than 12 months new milestone with new end date.

**How will this affect the RO:** RO will no longer need to manually create Ethics progress report milestones.

**How will this affect the Researcher:** Researcher will now have a milestone available for every 12 months.

### ETH Application – Not approved – STE flow

**Issue:** When an Ethics application has an Application Decision Not approved the decision needs to be communicate to the Sites.

**Enhancement:** When an Ethics application has a Not Approved decision any site applications should be “Withdrawn”

**How will this affect the RO:** When an ethics application is “Not Approved” the system will automatically change the status of any Site applications to Withdrawn.

**How will this affect the Researcher:** Researchers will see the application status of Withdrawn

### ETH Application – Withdrawn – STE flow

**Issue:** When an Ethics application has been withdrawn this needs to be communicated to the sites and the site application needs to be locked out. Currently this is should be done manually by the reviewing HREC communicating to the sites but it is not and often the Sites continue reviewing the site application when they don’t need to.

An ethics application can be withdrawn 3 ways:

- By the researcher through communication to the HREC
- By the Research Office manually changing the status
- By the system when a study has been ineligible for 60 days

**Enhancement:** When an ETH is withdrawn any related sites should also be withdrawn by change of status.

**How will this affect the RO:** When an ethics application is “Withdrawn” the system will automatically change the status of any Site applications to Withdrawn.

**How will this affect the Researcher:** Researchers will see the application status of Withdrawn

### External Portal - HOD Decisions – After authorisation

**Issue:** Currently a Head of Department decision that has not been made remains open even after the STE recommendation is made. If a HOD decision is made after the authorisation the application status changes and causes confusion.

**Enhancement:** Once an STE has a recommendation by RGO decision completed any outstanding HODs cannot make a decision through the external portal.

**How will this affect the RO:** Nil change

**How will this affect the Researcher:** Nil change

The following changes were released Tuesday 27<sup>th</sup> April.

### Classification/HREA – Ethics Pathways (Negligible Risk)

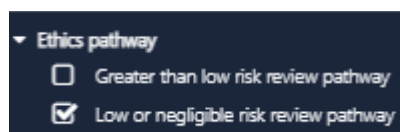
**Issue:** Researchers are incorrectly selecting Negligible Risk Review Pathway in the HREA and the data is not being corrected by the majority of Research Offices.

**Enhancement:** To reduce the number of options for the applicant and to streamline data quality for the RO a new ethics pathway classification of “Low Negligible Risk Review Pathway” will be created; this will be selectable at Project Registration and in the HREA.

The Low Risk Review Pathway and Negligible Risk Review Pathway options will be removed.

A backwards data clean of all Low Risk and Negligible Risk studies will be completed and changed to the Low and Negligible Risk classification and tag.

Low or negligible risk review pathway



**How will this affect the RO:** If Research Offices are using the Ethics Pathway classification for their homepage tiles, they will need to update their homepage tiles filters on release day.

***If your RO was actively using the Negligible Risk Classification and please contact our Team for details on how to flag your Negligible Risk studies before the system release.***

**How will this affect the Researcher:** For HREAs that are “In Progress” at the time of the release and the Low Risk or Negligible risk option has been selected at question 4.5 an error may show and question 4.5 may need to be changed.

## Ethics pathway automation - site only in REGIS

**Issue:** If ethics is outside of NSW/ACT (REGIS) there is no option for the applicant to indicate the ethics pathway for the site applications. This can be difficult for the RO to classify as the details are not always clear in the Ethics documents provided with the application. This has also meant a large number of site applications do not have an ethics pathway classification in the site dashboard.

**Enhancement:** During Project Registration, when it is indicated that Ethics is outside of REGIS a new question will appear requesting the ethics pathway. This will automatically fill the application classification and create a system generated tag.

New Project Registration

Introduction  Part A: Previous Ethics Application  Part B: Project Details  Part C: Research Site's  Part D: Coordinating Principal Investigator  Part F: Upload Attachments  Submit

**Part A: Previous Ethics Application**

If an ethics application:  
Has never been previously submitted for this project to a NHMRC registered and/or certified HREC, select 'No' at question A1 - no further questions will be required in this section and you can proceed to Part B.  
Has previously had an ethics application submitted to a NHMRC registered and/or certified HREC, select 'yes' at question A1 and complete the additional questions displayed.

A1 Has an application for ethics review of this project previously been submitted to a recognised HREC? \*

No  Yes

NOTE: NSW Health requires that all early phase clinical trials are approved by Sydney Children's Hospital Network for research involving children and Bellberry for research involving adults before being conducted at any NSW site.

The following details are required to identify the previous ethics application, the HREC to which it was submitted and whether it was submitted under the NMA arrangements which exist between a number of public health jurisdictions nationally. Outcomes or status of that previous application may be requested.

A2 Ethics application ID \*

asdr

A3 HREC Name \*

Alfred Hospital Ethics Committee

A4 HREC Code

EC00315

A5 Was/Is application being reviewed under the NMA scheme? \*

Yes

A6 Outcome or status \*

Approved

A7 Date of written decision notification (email or letter) \*

15/04/2021

A8 Under which review pathway are you intending to submit this application? \*

**How will this affect the RO:** This will reduce the manual data entry requirements for RGOs. For applications where Project Registration was created and submitted after 21 April RGOs will no longer need to manually enter the Ethics Pathway Classification. Researcher Offices will still need to confirm the details/data is correct and may need to change the classification prior to authorisation.

**How will this affect the Researcher:** Where Project Registration is "In Progress" and ethics is outside of REGIS researchers may see a new question that requests the ethics pathway to be entered.

## Early Phase Clinical Trials – Bellberry HREC

**Issue:** A pilot to allow NSW EPCT applicants to submit directly to Bellberry's application portal (eProtocol) and upload the ethics approval into REGIS has completed. A workaround was required by applicants when completing Project Registration to allow only the STE's to be created.

**Enhancement:** Form changes in Project Registration are now being implemented to allow a smoother flow for applicants.

**How will this affect the RO:** Nil affect to NSW research Offices

**How will this affect the Researcher:** Researchers submitting EPCT to Bellberry will no longer have to follow the Bellberry workaround guidance.

## Project Registration – Ethics outside of REGIS – hiding "other" tab

**Issue:** When project registration is completed and the applicant indicates that ethics is outside of REGIS there is no value to the applicant adding in sites outside of REGIS.

**Enhancement:** To improve researcher experience the "other" sites tab will hide when ethics is outside of REGIS.

**How will this affect the RO:** Nil affect to NSW research Offices

**How will this affect the Researcher:** Streamlined user experience as questions that do not require a response are not showing.

Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Enter a project site to check project centre

ACT Health NSW Health

**Nominate the project site/s within NSW Health and a Principal Investigator for each site**  
A research project may be conducted at one or more sites within one or more Centres within NSW Health.  
A 'Centre' may be a Local Health District (LHD), a Specialty Health Network, a Pillar organisation, an affiliated health organisation or other health organisation. A Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (PI) is the person responsible either individually or as a leader of the researchers at a site, for the conduct of research. When a project does not require the appointment of a NSW Health principal investigator, the coordinating principal investigator may also be the person who has the authority to submit the Site application. An incorrect response here may cause the application to be ineligible and will cause delay.

If you are unsure of the names of the Centre or Site/s your project will be conducted at, please discuss with your local research office. An incorrect response here may cause the application to be ineligible and will cause delay.

Project Centre \* Project Site \*

Northern New South Wales Local Health District Maclean District Hospital

Principal Investigator email (REGIS username) \*

kylie.becker@health.nsw.gov.au

### Project Registration – Ethics in REGIS and Other Jurisdiction sites indicated

**Issue:** Researchers have reported they are unsure of administration responsibility when studies are being registered in multiple jurisdiction portals. The suggestion that a NSW Lead Site is required for REGIS is now required, which is incorrect.

**Enhancement:** Additional guidance has been added at the submission page of the Project Registration when ethics is in REGIS AND external sites have been indicated at Part C.

The following applications will be generated:

AHREA

SSA for each of the following NSW Health sites:

Maclean District Hospital, Kylie Becker (PI)

It is the Lead Site's responsibility to register the study in any other jurisdiction online portals. Once registered the PI and their team will take ownership of the site application and submission process.

Queensland and Victoria sites click for [ERM](#) (see [application user guide to ERM](#))

South Australia sites click for [GEMS](#) (see [Project registration guide](#))

Western Australia sites click for [RGS](#) (see [Researcher User Guide \(Part A\)](#))

[I Acknowledge](#)

[Complete Registration](#)

**How will this affect the RO:** Nil affect to NSW research Offices

**How will this affect the Researcher:** Researcher completing Project Registration in REGIS will now receive further guidance on the expectation of a Lead Site for any NMA study.

### First Patient Milestone

**Issue:** The First Patient Milestone, created to collect metrics 5 does not require the review of the RO.

**Enhancement:** On submission of the first patient milestone it will show as "Achieved", a backward data clean will change the status of all submitted first Pt milestones to Achieved.

**How will this affect the RO:** RO will no longer receive notification of first patient milestones. Any milestones in the "Received" status will transfer to "Achieved"

**How will this affect the Researcher:** Nil affect.

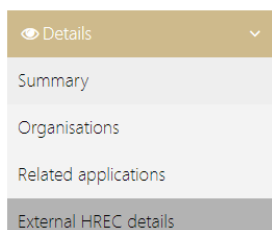
### Project Registration – Internal Portal – Additional Fields

**Issue:** As part of 2.2 additional fields were added the PID to allow external HREC details to be recorded. This was to help the OHMR team with mandatory reporting.

**Enhancement:** Field rename changed in Project Menu from Additional Fields for External HREC details.

**How will this affect the RO:** Nil affect

**How will this affect the Researcher:** Nil affect



### Classifications flow – Ethics Review Pathway

**Issue:** Ethics Pathway Classification – if changed in the Ethics application (or project) this should flow automatically to any STE application (or project). System generated tags should also change.

**Enhancement:** When Ethics is in REGIS, if Ethics pathway is updated on the Ethics application or project then the change is to be propagated to all related sites (updates classifications and tags).

When Ethics is not in REGIS, if Ethics pathway is updated on a Site application or project then the change is to be propagated to all related sites (updates classifications and tags).

**How will this affect the RO:** RO can have improved confidence that if the ethics pathway classification has been updated on the Ethics application, they will be updated on the Site applications too.

**How will this affect the Researcher:** Nil affect.

### Classification Flow – all other classifications

**Issue:** If a classification is changed manually by the RO it should flow to the application/project.

**Enhancement:** When a classification is changed in the Application and a Project exists it should also change in the project. When a classification is changed in the Project and an Application exists it should also change in the Application. (this does not include the Ethics pathway classification as this will be managed by a different pathway, described above).

**How will this affect the RO:** Reduced manual data quality requirements as data updates in multiple areas through one action.

**How will this affect the Researcher:** Nil affect.

### STE Principal Organisation

**Issue:** The Site Principal Organisation is not set until the STE is submitted the first time. RO have established there are instances where researchers are starting their research without governance authorisation but they cannot easily identify this.

**Enhancement:** Have the principal organisation included on the creation of the STE not on submission. Have this changed made retrospectively – for applications that have not yet been submitted but are in progress.

Identifier	Title	Comments	Version	Status
2021/STE01014	Tighten up test - Nepean Hospital		1.00	In Progress

Modified date 15/04/2021 12:49:26 PM

Organisation Nepean Hospital

Relationship ↑

**How will this affect the RO:** Applications will become available to view by the RO on creation instead of first submission. This will improve monitoring of studies that may have begun without site authorisation.

**How will this affect the Researcher:** Site/Governance authorisation is a requirement of HREC approval. Researchers may experience increased communication from RO where the system shows an approved Ethics application but a site application that remains “In Progress”. HREC approval may be halted until site authorisation can be confirmed.