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 3rd 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 System withdrawn.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When an application (ETH or STE) has had a request for information and no response for 30 days the application will be withdrawn.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(ETH)/PI (STE) and Admin Contact at 15 and 25 days, on day 30 the system will change the status of the application to Withdrawn and send an email to notify of the action and that a new application will be required.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.

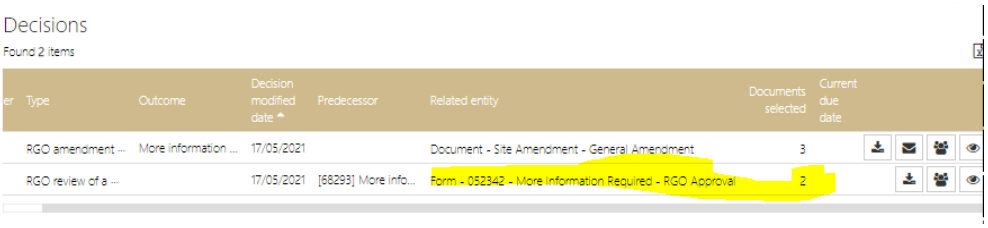
This change is not retrospective, it will not affect studies that have had a request for information before the release.

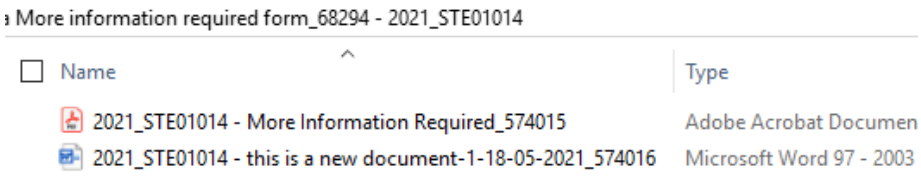
STE Decisions – More information

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.





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

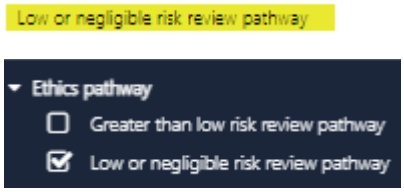
The following changes were released Tuesday 27th April.

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.

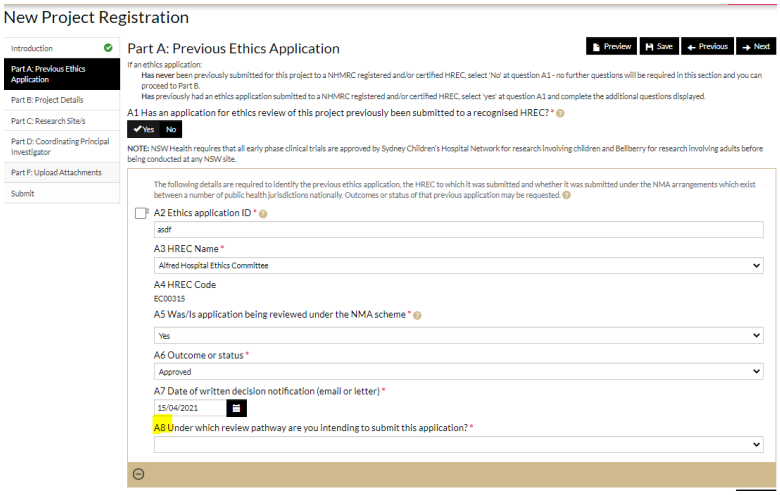


How will this affect the RO: If Research Offices are using the Ethics Pathway classification for their homepage tiles, they will need to update their homepage tiles filters on release day.
If your RO was actively using the Negligible Risk Classification and please contact our Team for details on how 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.



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 smother flow for applicants.

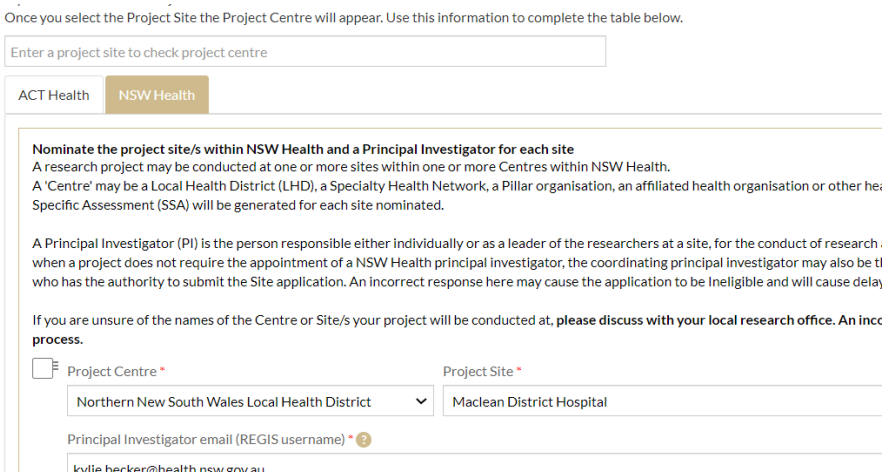
How will this affect the RO: Nil affect to NSW research Offices
How will this affect the Researcher: Researchers submitting EPCT to Bellberry will no longer have to follow the Bellberry workaround guidance.

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.

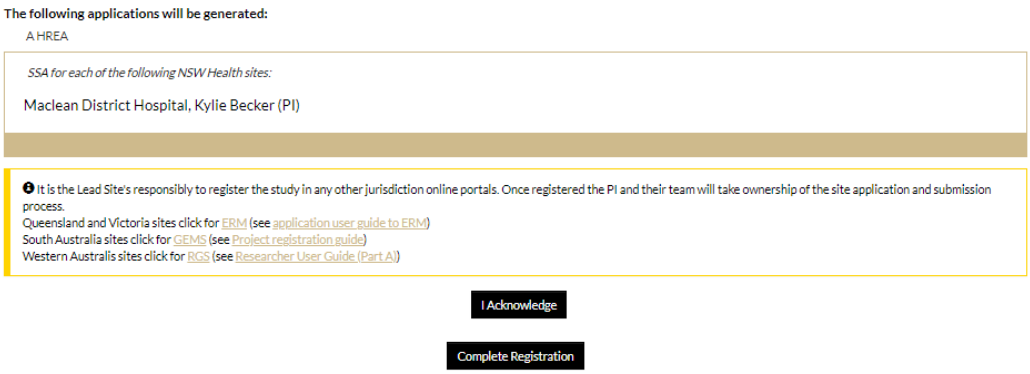
How will this affect the RO: Nil affect to NSW research Offices

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



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.



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

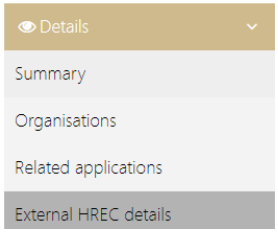
Issue: The First Patient Milestone, created to collect metrics 5 does not require the review of the RO.
Enhancement: On submission of the first patient milestone is will show as “Achieved”, a backward data clean will change the status of all submitted first Pt milestones to Achieved.

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.

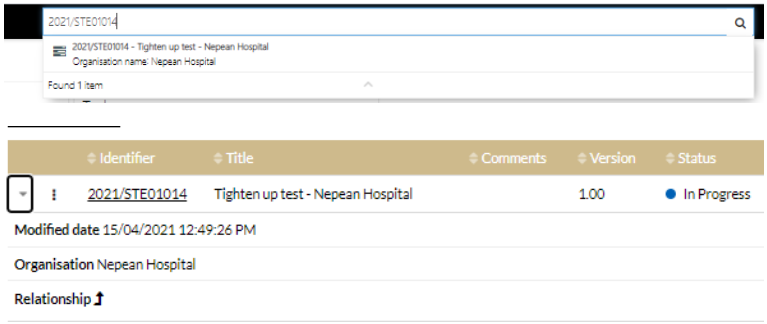
Classification Flow – all other classifications

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 Organsiation

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



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.