Issue 13 – 13 July

In this issue:

- Manually changing the
- Researcher Training - Stats
- Manually changing the CPI or PI when an amendment form can't be submitted
- The case of the missing application (homepage tile)
- Changing Site Names for Migrated (z-pre REGSIS) sites
- Classifications – what are they good for?
- Transferring a study from one NSW/ACT HREC to another NSW/ACT HREC
- Research Office Contribution
- Previous issues available online

OHMR not attending LHD performance meetings for August quarter

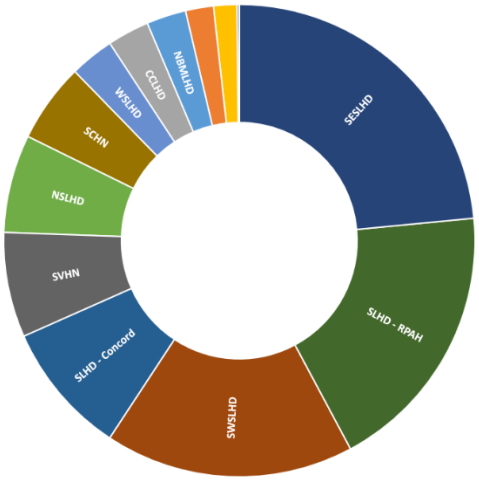
Audience: Research Office

OHMR attended the most recent round of LHD/SHN Performance Meetings and informed Chief Executives of the move towards reporting end-to-end metrics instead of the previous clock-based system. There was a positive reception to the move from the executive teams.

While OHMR will sit out this round of performance meetings, there will continue to be informal communication with Research Offices, Research Directors and CEs on past six-monthly performance. OHMR will create a six-monthly report (Jan-Jun 2021) that shows how each LHD/SHN would have performed under the new metrics as well as some informal 'breakdown' reporting (time spent in each party's hands).

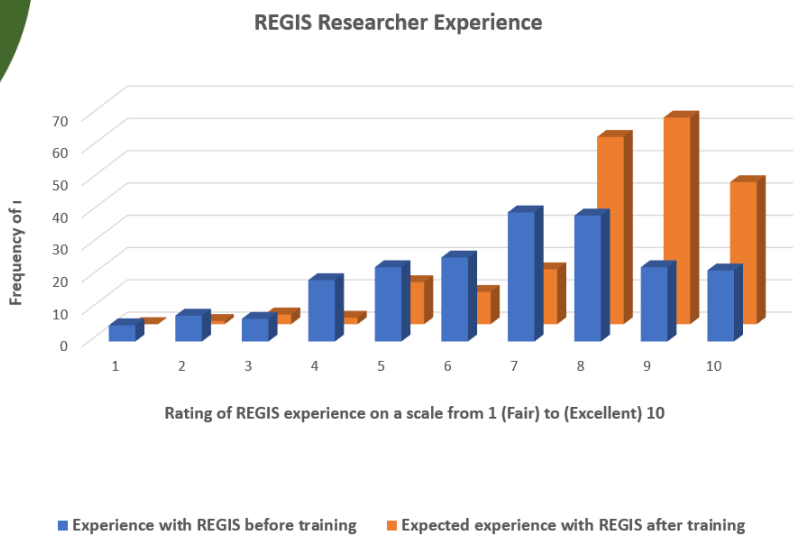
Researcher Training – Stats

Audience: Research Office/Researchers

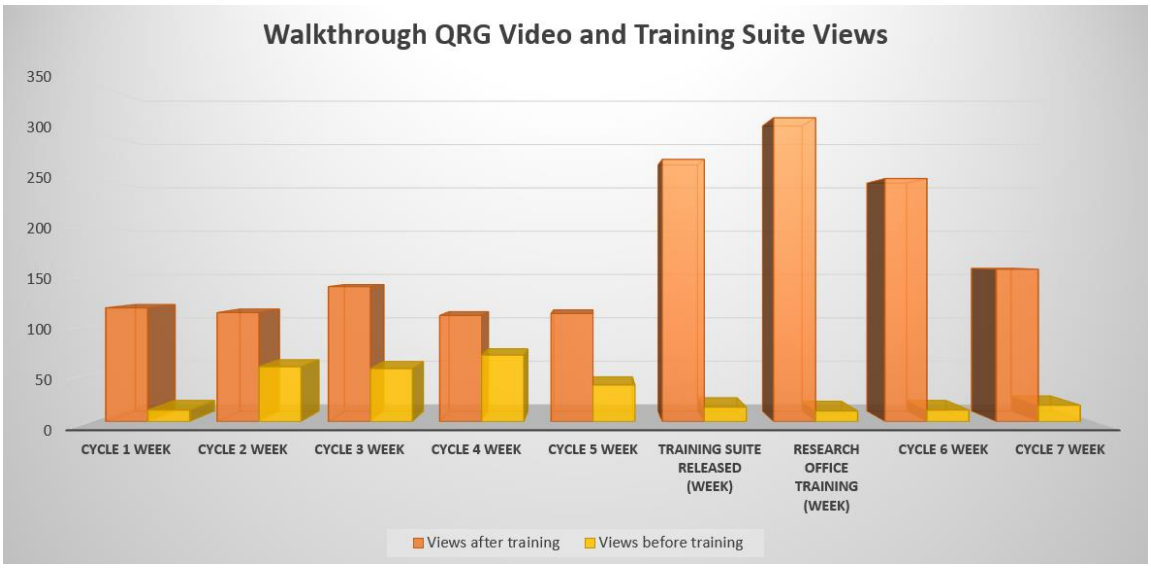


So far, there have been 7 full cycles of Researcher training sessions held online which consists of 77 individual sessions with over 1200 individual attendees so far!

We have seen great attendance from users across many LHDs and PHOs as well as an increase in confidence and user experience with the system after attending training.



We have also seen an increase in views of the walkthrough QRG videos and Training Suite webinars which are currently available on the [REGIS website]



Link to suite of Training Videos - https://regis.health.nsw.gov.au/content-resources/

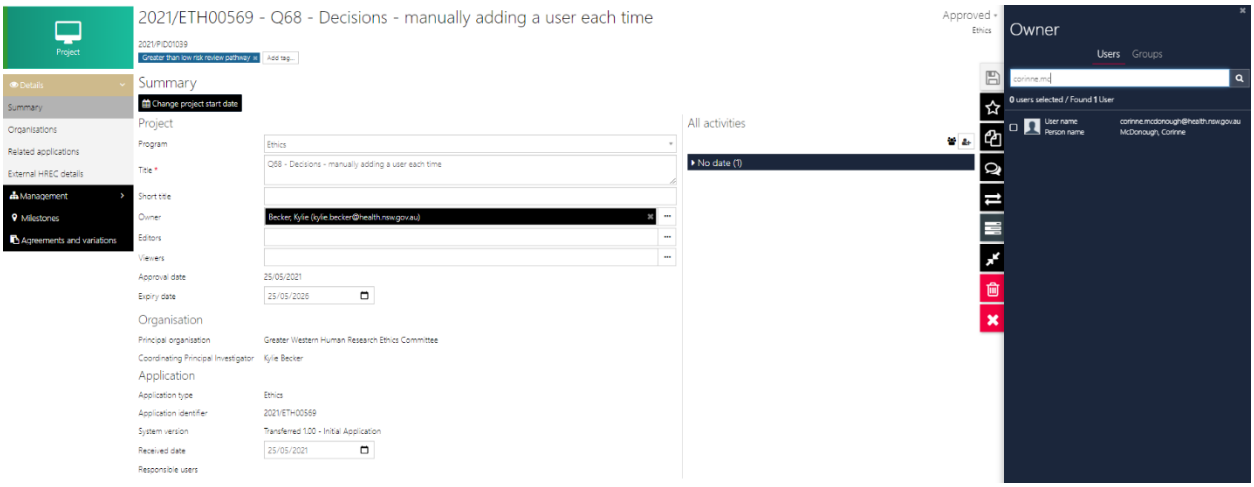
Manually Changing the CPI or PI when an amendment form can't be submitted

Audience: Research Office

A Research Office recently had a scenario where a CPI had to take unexpected sick leave and they were unable to submit an amendment request to change the CPI on their project. The submission of a form is the preferred process as the system will manage all the system updates on approval but REGIS has the flexibility to a RO to manually make the changes in the system when situations like this come up.

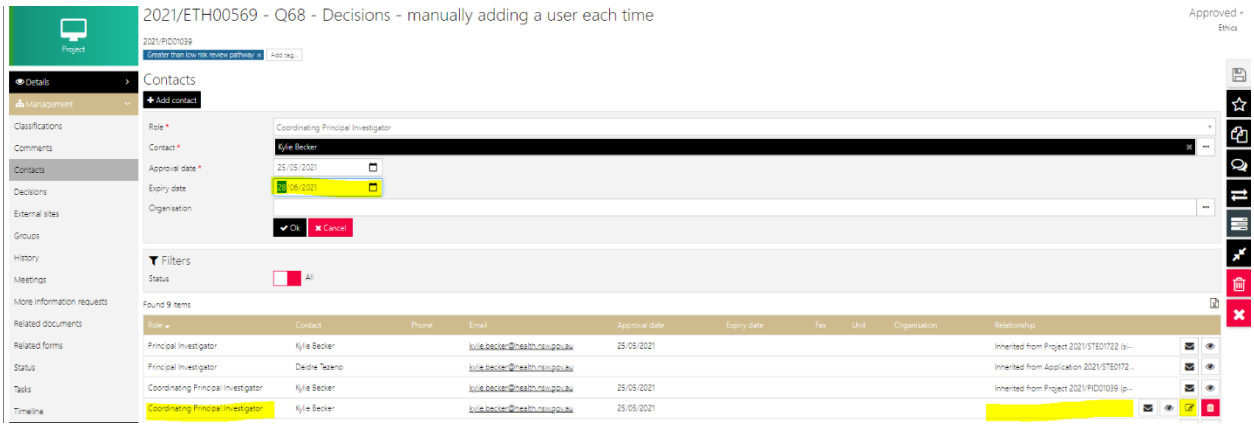
1. Update the Owner in the Summary section of the **Application and Project**.

In edit mode (edit icon right side menu) click on the three dots next to the current owner, in the black pop out panel search for the new person (they must have a REGIS account), select the new owner and save.

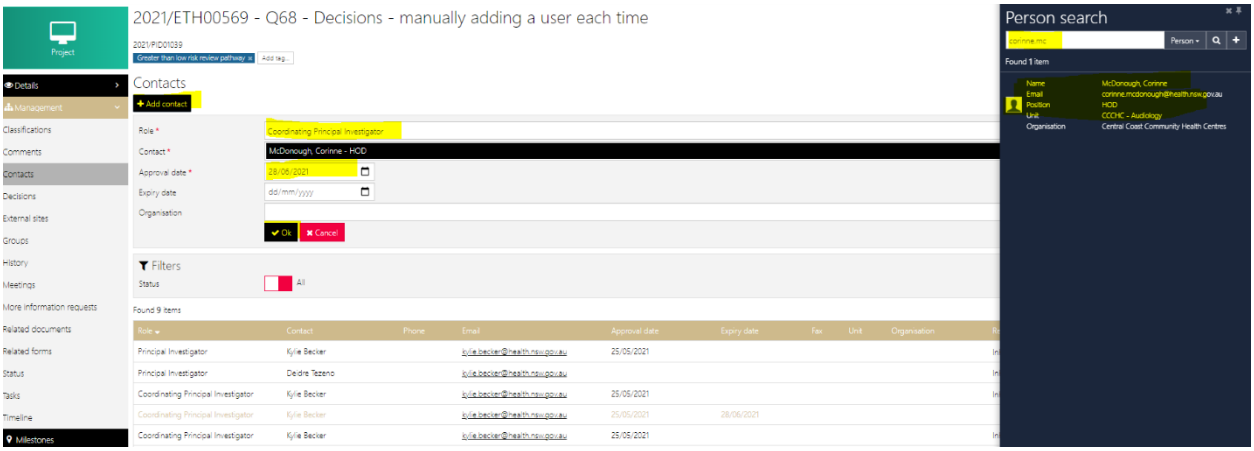


2. Update the Contact section in the **Project.**

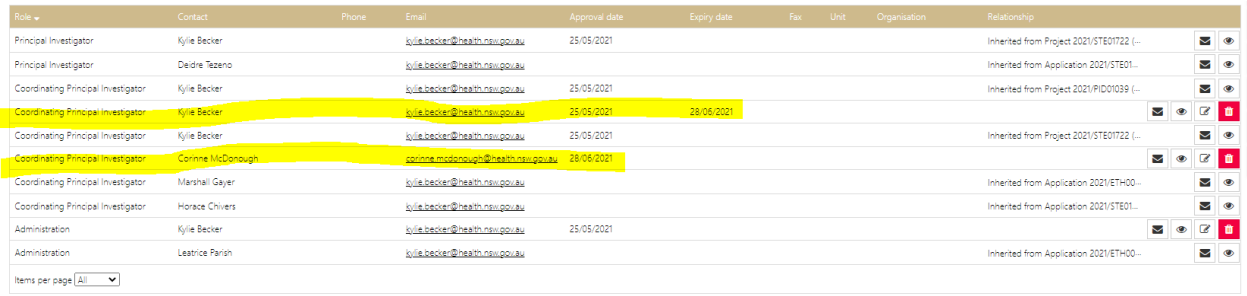
In edit mode, locate the Role you are wanting to update. Hint, where it looks like multiple roles exists you can only select the one without a Relationship, click edit item. Expire the current person in that role



Add the new person to the role, click on the “+Add contact” button, select the role type (it should be the same as the one you expired), select the new person (must have a REGIS account), enter their approval date, click ok, click page save.



You know the steps have been completed when the person you want to remove has an Expiry date and the new person has an Approval date.



Remember to check if the person you are expiring has multiple roles e.g. is CPI and Administration. You should expire all their roles.

Where a CPI requires expiring the details will also need to be repeated in each STE Project.

Where a CPI is being changed, they will also need to be removed as the PI of one or more sites. Update the Contacts and Owners in each of the STEs.

The case of the missing application (homepage tile)

Audience: Research Office

An RGO had contacted me because a study that had been sitting in their Eligible tile had disappeared. On their investigation they could see the application was now in the status of “In Progress” but Ethics had been approved so the ETH tag existed.

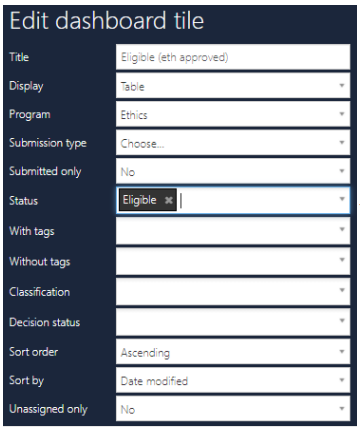
They asked me “Can you let me know why it has that status and has not appeared in my “Eligible” tile again?” and “Doesn’t “In Progress” mean that it is with the Investigator?”

Our team was happy to provide them this information but we also want to share how we trouble shoot issues and how you can too.

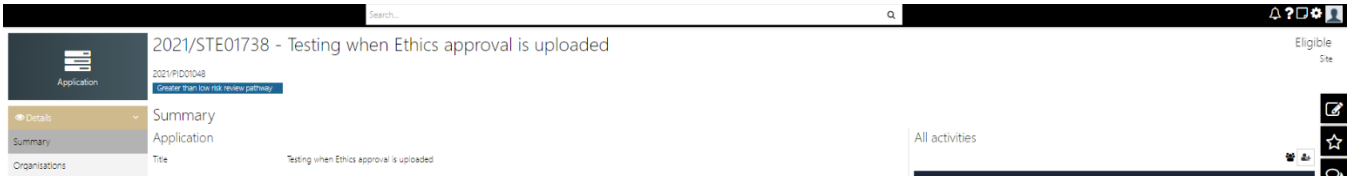
1. Why hasn't it appeared in my Eligible tile?

Homepage tiles are set up to filter a combination of information in the system e.g. status, classifications and tags.

Most of the homepage tiles that mange an application (submission to approval/authorisation) are an Application Tile and use Status as the main filter.



The homepage tile will only show applications that have the status it is filtering.



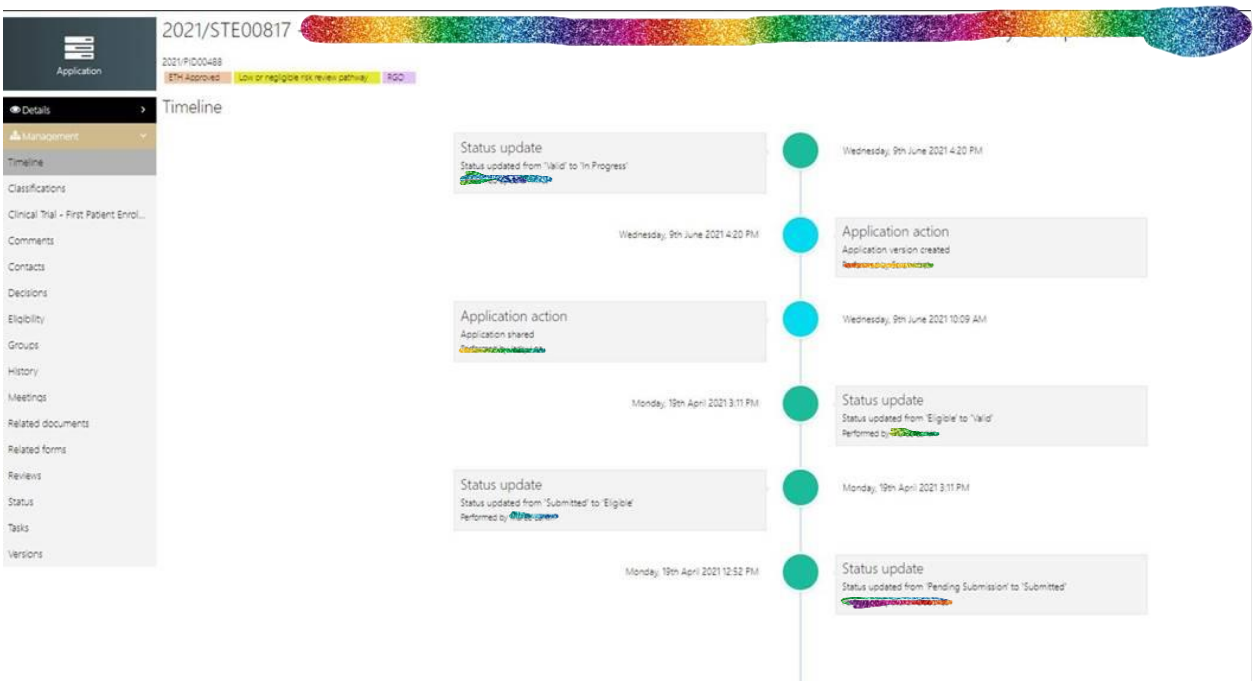
2. Doesn't "In Progress" mean that it is with the Investigator?

Yes, it does. The "In Progress" status is the only status that the Research Office loses access to the application. When a study is in the Status of "In Progress," it will not appear in the Eligible tile.

But why was this STE application in the "In Progress" status?

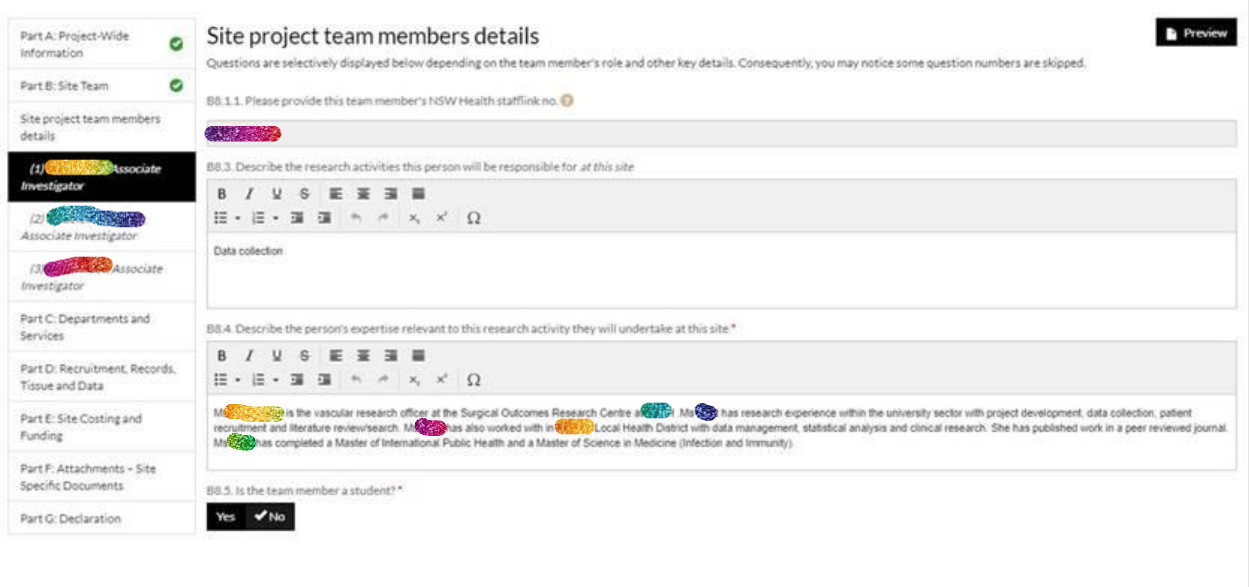
This is where we put our investigator hat on and do a little digging….

First we look at the timeline to get an idea of what might have happened. We can see that the RO completed Eligibility in April, in June the PI has shared access with a new person, who on the same day has created a New Version of the application, which changed the status to "In Progress," but the application was not resubmitted.



A little more investigating by using the current application view on the summary page (click this to see a pop out of the current view of the application).

Comparing this against the STE that was submitted and available in the Related documents section, shows there have been changes made to the SSA that have not been submitted (adding in the person who created the new version as an AI in the project teams section).



In this case the researchers are lucky that the RGO has picked this up and can contact them and ask them to resubmit the application form.

All of these steps taken can be done with the access a RO has, no Admin access required.

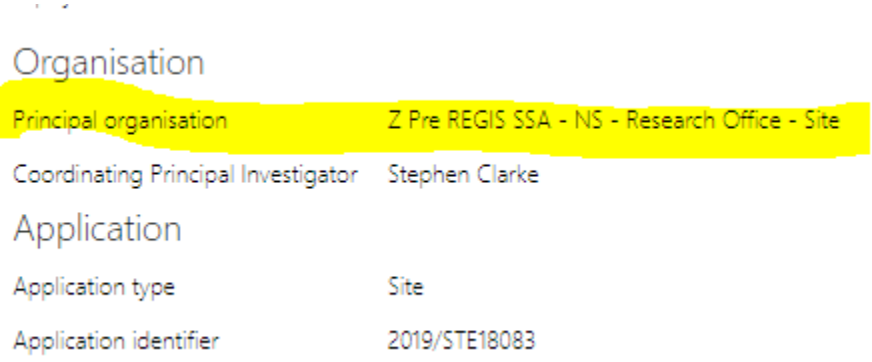
Changing Site Names for Migrated (z-pre REGSIS) sites

Audience: Research Office

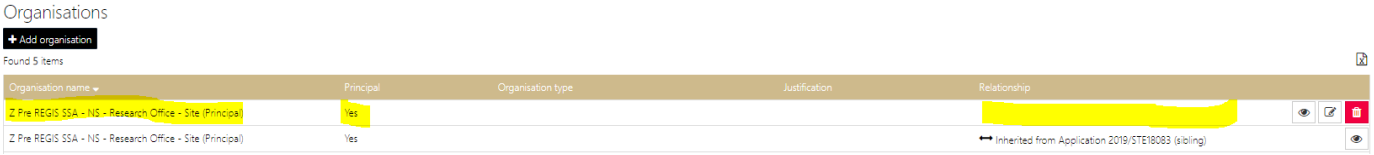
There are 2102 site applications in REGIS that have a Z-Pre REGIS site name. All of these sites are migrated studies.

If your office would like to update site names when these come across your desk here's how:

You can identify on of these studies in the Summary page where the Principal Organisation is listed

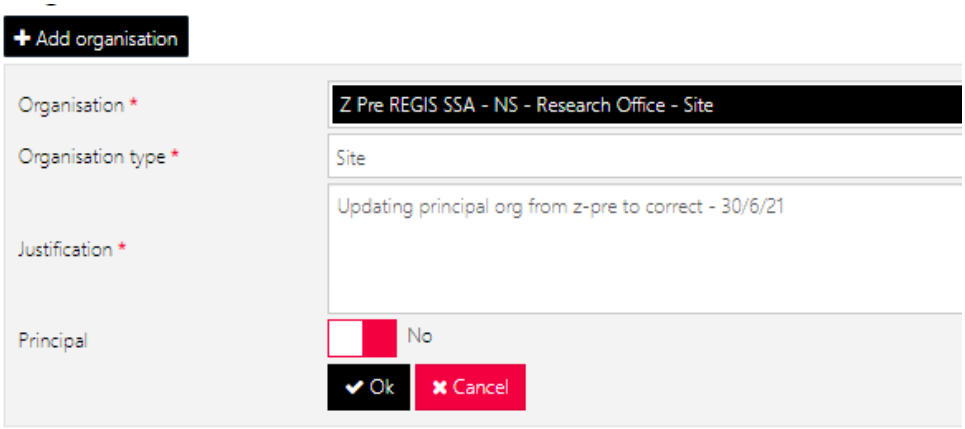


To update the Principal Organisation (in edit mode) navigate to Organisations and locate the Organisation that has Principal=Yes and no Relationship. Click edit item



A wizard will pop out, you will need to select an Organisation Type = Site, entre in the justification (reason) for the change, and change the Principal toggle to NO

Once the changes are made click Ok.



Now “+Add organisation”

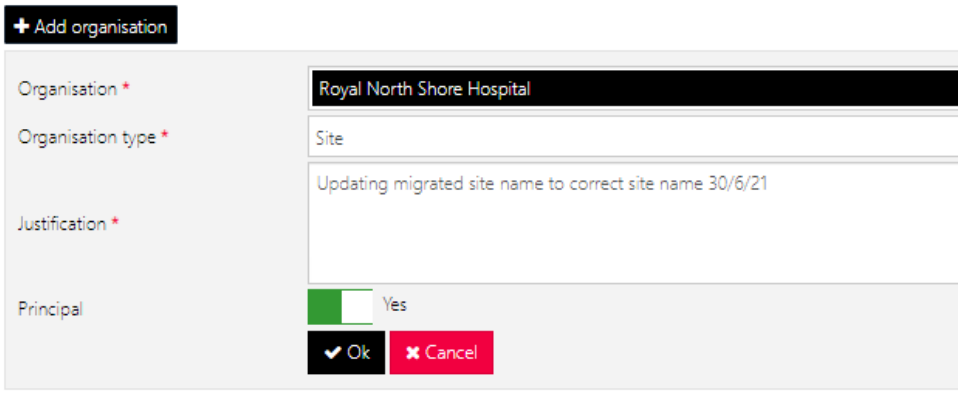
Organisation is the Site Name, click the options icon (three dots) for a pop out to appear, search and select the site e.g. Royal North Shore Hospital.

Organisation type = Site

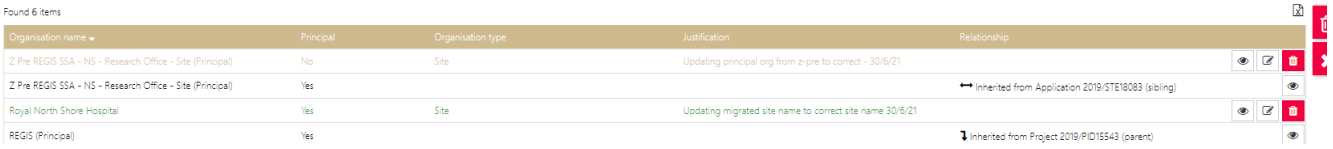
Justification = the reason why change is being made

Principal = Yes

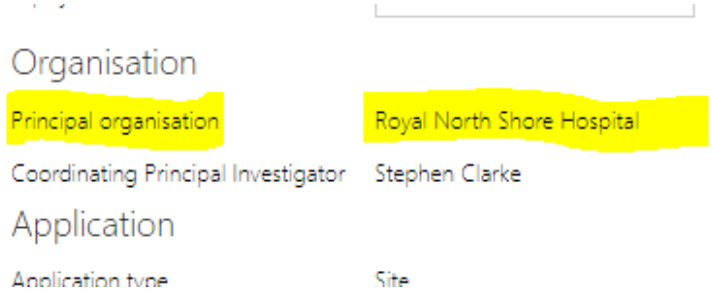
Click ok



The changes will show in the table but for the changes to save you need to click page save.



The organisation is now updated.



Note: This change has been made in the project only so a researcher will continue to see the z-pre REGIS on the external portal as they see the application details. If a researcher is requesting to see the updated details after you have made the change please send an email to the REGIS inbox regis@health.nsw.gov.au requesting the database be updated.

Classifications – what are they good for?

Audience: Research Office

Classifications are one of the tools that are utilised when pulling data out of the system but they are also used for other areas in the system.

Email templates – the ethics pathway classification, clinical trial and waiver of consent classifications are utilised in the approval emails to indicate when standard statements should and shouldn't be used and to clearly indicate the ethics pathway. If you see a token (${ProjectClassification_Ethics_pathway}) in an email it's probably because information is missing. If you're not sure what to do CONTACT US!

Forms – Study Type Clinical Trial: REGIS utillises a smart form technology to understand if certain questions should be made available in forms. E.g. the NSW progress report form and External HREC progress report form will read the study type classification IF it is a clinical trial the researcher will be asked more questions that if the classification is clinical research.

Dashboards – the ethics and governance dashboard, both created directly from User Group feedback, use classifications to filter to allow the RO to report on activity of new applications.

Research Office Contribution

Audience: Research Office

Participant Information Statements (HNELHD)

At the request of the Hunter New England Human Research Ethics Committee, the HNE Director of Research initiated a discussion with OHMR concerning the increasing length and complexity of Participant Information Statements, particularly (although not exclusively) for sponsored clinical trials. The discussion covered a couple of issues:

- That it was increasing difficult for the HNE HREC to ensure participant information statements met both the requirements of the National Statement and the goals of consumer engagement and health literacy;
- Whether it would be timely for the NHMRC templates for Participant Information statements, issued in 2012 and currently preferred by all NMA certified HRECs, to be reviewed

OHMR raised this issue at the National Mutual Acceptance meeting attended by all jurisdictions, and it has been agreed to be tabled for discussion at future meetings. This will also be raised as a discussion item at the upcoming HREC Chairs meeting.

In the meantime, the OHMR would be interested to hear the experience of other HRECs so we can try to scope the issue. We would be keen to get the views of and possible solutions from other HRECs regarding PICF length and readability.
Please provide any comments or suggestions in this short: redcap survey

SEBS Panel – Expression of Interest

REGU is putting out an expression of interest to Research Governance Officers (and/or those currently reviewing/processing CTRAs) if they would like to contribute to the SEBS Panel's monthly meetings. While a legal background would be useful, it is not essential. The involvement could be tailored to an individual's background, skills and experience.

Ideally, there would be an expectation for the RGO to perform a review of an application allocated during the month and to present this to the monthly meeting. There is scope to take up to two RGOs.

If interested, please email the SEBS Inbox to express interest: SEBS@moh.health.nsw.gov.au

The Southern and Eastern Border States (SEBS) is a multijurisdictional panel that reviews and approves applications by external sponsors for amendments to the MA CTRA & MTAA CIRA suites of templates. It forms a single negotiation point for commercial and non-commercial sponsors to have clauses approved for use across public health organisation sites in participating jurisdictions.

Previous issues available online

https://regis.health.nsw.gov.au/news-and-events/regis-office-webinars/