Issue 13 – 13 July

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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



Experience with REGIS before training Expected experience with REGIS after training

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



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.

	2021/ETH00569	- Q68 - Decisions - manually adding a user each time		Approv Et	ed + hics	Owner	×
Project	2021/PID01039 Greater than low risk review pathway w	Add tag			_	User	s Groups
👁 Details 🔍 👻	Summary				6	corinne.mc	٩
Summary	Change project start date				습	0 users selected / Found 1 User	
Organisations	Project		All activities		26	User name User name Person name	corinne.mcdonough@health.nsw.gov.au McDonough, Corinne
Related applications	Program	Ethics *		*	Щ		
External HREC details	Title *	Q58 - Decisions - manually adding a user each time	No date (1)		Q		
▲ Management >	Short title				=		
Milestones	Owner	Becker, Kyle (syle becker@health nswgovau) %			-		
Agreements and variations	Editors						
	Viewers				ж		
	Approval date	25/05/2021			-		
	Expiry date	25/05/2026			•		
	Organisation				×		
	Principal organisation	Greater Western Human Research Ethics Committee					
	Coordinating Principal Investigator	Kyle Becker					
	Application						
	Application type	Ethics					
	Application identifier	2021/ETH00569					
	System version	Transferred 1.00 - Initial Application					
	Received date	25/05/2021					
	Responsible users						

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

	2021/ETH00569 - (021/ETH00569 - Q68 - Decisions - manually adding a user each time						Appro	ived * Ethics		
Project	2021/PID01039 Greater than low risk review pathway × Ad	id teg									
• Details	Contacts										B
📥 Management 💦 👻	+ Add contact										☆
Classifications	Role *	Coordinating Principal Investigator									P
Comments	Contact*	Kylie Becker								- 1	
Contacts	Approval date *	25/05/2021									Q
Decisions	Expiry date	28/06/2021									₽
External sites	Organisation									-	
Groups		V Ok X Cancel									
History	▼ Filters										*
Meetings	Status	All									俞
More information requests	Found 9 items										
Related documents	Role 🗸										1
Related forms	Principal Investigator	Kylie Becker		kvie becker@health.nsw.gov.au	25/05/2021			Inherited from Project 2021/STE01722 (si	8	5	
Status	Principal Investigator	Deidre Tezeno		<u>kvie becker@health.nsw.gov.au</u>				Inherited from Application 2021/STE0172	2	5	
Tasks	Coordinating Principal Investigator	Kylie Becker		kvile becker@health.nsw.gov.au	25/05/2021			Inherited from Project 2021/PID01039 (p-	8	5	
Timeline	Coordinating Principal Investigator	Kylie Becker		<u>kvile becker@health.nsw.gov.au</u>	25/05/2021				2 • •	2 🔟	1

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.

	2021/ETH00569 - (Q68 - Decisions	- manual	lly adding a user eac	h time			Person sear	ch ^{*‡}
Project	2021/PID01039 Greater than low risk review pathway × Ad	d tag						corinne.mc Found 1 item	Person - Q +
● Details →	Add contacts							Name Email Position	McDonough, Corinne corinne.mcdonough@health.nsw.gov.au HOD
Classifications	Role *	Coordinating Principal Investigator						Organisation	Central Coast Community Health Centres
Comments	Contact*	McDonough, Corinne - HOD							
Contacts	Approval date *	28/05/2021							
Decisions	Expiry date	dd/mm/yyyy							
External sites	Organisation								
Groups		V Ok K Cancel							
History	▼ Filters								
Meetings	Status	All							
More information requests	Found 9 items								
Related documents	Role 🗸							2	
Related forms	Principal Investigator	Kylie Becker		kylie becker@health.nsw.gov.au	25/05/2021			ni	
Status	Principal Investigator	Deidre Tezeno		kylie becker@health.nsw.gov.au				-	
Tasks	Coordinating Principal Investigator	Kylie Becker		kylie becker@health.nsw.gov.au	25/05/2021			n	
Timeline	Coordinating Principal Investigator	Kylie Becker		kylie becker@health.nsw.gov.au					
Milestones	Coordinating Principal Investigator	Kylie Becker		kylie becker@health.nsw.gov.au	25/05/2021			n i	

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.

Role 🗸									
Principal Investigator	Kylie Becker	<u>kylie becker@health.nsw.gov.au</u>	25/05/2021			Inherited from Project 2021/STE01722 (۲
Principal Investigator	Deidre Tezeno	<u>kylie becker@health.nsw.gov.au</u>				Inherited from Application 2021/STE01			۲
Coordinating Principal Investigator	Kylie Becker	<u>kylie becker@health.nsw.gov.au</u>	25/05/2021			Inherited from Project 2021/PID01039 (۲
Coordinating Principal Investigator	Kylie Becker	kylie.becker@health.nsw.gov.au	25/05/2021	28/06/2021			۲	ø	B
Coordinating Principal Investigator	Kylie Becker	<u>kvlie becker@health.nsw.gov.au</u>	25/05/2021			Inherited from Project 2021/STE01722 (۲
Coordinating Principal Investigator	Corinne McDonough	corinne.mcdonough@health.nsw.gov.au	28/06/2021				۲	ß	Û.
Coordinating Principal Investigator	Marshall Gayer	kylie.becker@health.nsw.gov.au				Inherited from Application 2021/ETH00			۲
Coordinating Principal Investigator	Horace Chivers	kylie.becker@health.nsw.gov.au				Inherited from Application 2021/STE01			۲
Administration	Kylie Becker	kylie becker@health.nsw.gov.au	25/05/2021				۲	ø	8
Administration	Leatrice Parish	<u>kylie becker@health.nsw.gov.au</u>				Inherited from Application 2021/ETH00			۲
ltems per page All									

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 <u>Status</u> as the main filter.

Edit dash	board tile	
Title	Eligible (eth approved)	
Display	Table *	
Program	Ethics *	
Submission type	Choose *	
Submitted only	No *	
Status	Eligible 🛪	×
With tags	*	
Without tags		
Classification	v	
Decision status	v	
Sort order	Ascending *	
Sort by	Date modified *	
Unassigned only	No *	
The hom	epage tile will only s	how applications that have the status it is filtering.

				l
	2021/STE01738 - "	Testing when Ethics approval is uploaded	Eligible	e Ma
Application	2021/PID01048 Greater than low risk review pathway		24	-
	Summary			Ľ
Summary	Application		All activities	<u>^</u>
Organisations	Title T	Esting when Ethics approval is uploaded	8 A	

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.

Application	2021/PID00488 ETH 4coroxed Low or negligible risk review pathway PGD		12001-12001-12001-1-
Details >	Timeline		
🛦 Management 💦 👻		Status undate	
imeline		Status updated from "Jalid" to "In Progress"	Wednesday, whi June 2021 4/20 PM
Dassifications		Construction of the second	
Clinical Trial - First Patient Enrol			And the design of the
Comments		Wednesday, 9th June 2021 4:20 PM	Application action Application created
Contacts			Texteriors.co.price.com/sete
Decisions			
Blaiblity		Application action	Wiednesday, 9th June 2021 10:09 AM
Groups		Conformation and a	1
listory			
leetings		Mondey, 19th April 2021 3.11 FM	Status update
Related documents			Status updated from 'Eigible' to 'Valid' Performed by Withteener
felated forms			
leviews		Status update	Manday, 19th April 2021 3:11 PM
itatus		Status updated from 'Submitted' to 'Eligible'	
asks			
lersions		10-10-10-10-10-10-10-10-10-10-10-10-10-1	Status undate
		Monday, Isth April 2021 12:52 PM	Status updated from Pending Submission' to 'Submitted'
			Contraction of the second seco

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).

Viewers	(None)
Principal organisation	
Coordinating Principal Investigator	
Approval date	
Expiry date	23/06/2026
Application identifier	2021/STE00817
Submitted date	
Responsible users	

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).

Part A: Project-Wide Information	0	Site project team members details
Part B: Site Team	0	Spesing of a security unpage weight oppending on the team memore situe and units key details. On sequency, you may notice surife question numbers are supplied.
Site project team member details	rs	
(1) Associa	te	B8.3. Describe the research activities this person will be responsible for at this site
(2)	2	B / V Φ Ε 第 33 副 田・田・田・田 Φ Λ × Ω
Associate investigator (3. Associa Investigator	te	Data collection
Part C: Departments and Services		88.4. Describe the person's expertise relevant to this research activity they will undertake at this site *
Part D: Recruitment, Reco Tissue and Data	ords,	B / L Φ E 莱 33 副 臣・臣・33 33 N A X X Ω
Part E: Site Costing and Funding		Mention is the vascular research officer at the Surgical Outcomes Research Centre as the Man tas research experience within the university sector with project development, data collection, patient recultivers and iterature review/search. Minimum as also worked with in the university bector with data management, statistical analysis and clinical research. She has published work in a peer reviewed journal Man and the state of clinical man and the state o
Part F: Attachments - Site Specific Documents	•	88.5. Is the team member a student?*
Part G: Declaration		Ves 🖋 No

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

Organisation	
Principal organisation	Z Pre REGIS SSA - NS - Research Office - Site
Coordinating Principal Investigator	Stephen Clarke
Application	
Application type	Site
Application identifier	2019/STE18083

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

Organisations				
+ Add organisation				
Found 5 items				x
Organisation name 🗸				
Z Pre REGIS SSA - NS - Research Office - Site (Principal)	Yes			 Image: Image: Ima
Z Pre REGIS SSA - NS - Research Office - Site (Principal)	Yes		← Inherited from Application 2019/STE18083 (sibling)	۲

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.

+ Add organisation	
Organisation *	Z Pre REGIS SSA - NS - Research Office - Site
Organisation type *	Site
Justification *	Updating principal org from z-pre to correct - 30/6/21
Principal	No Vok Kancel

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

Organisation *	Royal North Shore Hospital		
Organisation type *	Site		
	Updating migrated site name to correct site name 30/6/21		
Justification *			
Principal	Yes		
	✓ Ok Cancel		

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

Found 6 items							R	
Organisation name 🗸								
Z Pre REGIS SSA - NS - Research Office - Site (Principal)		Site	Updating principal org from z-pre to correct - 30/6/21		۲	Ø	Ű	2
Z Pre REGIS SSA - NS - Research Office - Site (Principal)	Yes			↔ Inherited from Application 2019/STE18083 (sibling)			۲	
Royal North Shore Hospital	Yes	Site	Updating migrated site name to correct site name 30/6/21		۲	Ø	Û	
REGIS (Principal)	Yes			linherited from Project 2019/PID15543 (parent)			۲	

The organisation is now updated.

1 - A				
Organisation				
Principal organisation	Royal North Shore Hospital			
Coordinating Principal Investigator	Stephen Clarke			
Application				
Application type	Site			

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: <u>SEBS@moh.health.nsw.gov.au</u>

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/