REGIS Comms – Tuesday 29 June

Hello All,

Can you believe we are halfway through 2021!

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Sharing information with your research community

We know that this communication is being shared with the wider research community, and we love that (we have no secrets). We have started to receive a number of direct enquiries from researchers to explain/expand on information which is not relevant to their operations. Moving forward we will update our heading to indicate who the intended audience is.

Upcoming Education Sessions

Research Offices
Audience: Research Offices

Registrations are now open for the August Research Office training and we encourage you to register your interest using the link below.

Who should attend training?
- Any fresh staff that have not attend these sessions should be attending.
- Anyone who has not attended training in the last 2 years.
- Anyone who has attended previously and wants a refresher.

<div align="center">

Register now for **Research Office**
training: https://ohmrredcap.health.nsw.gov.au/surveys/?s=ARNFJRFXTE

</div>

Researchers should not use this link, please utilise the suite of training webinars available.

Training Cycle Agenda	August
Set up session	11
Day 1: All Users AM/PM sessions are mandatory AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.	16
Day 2: Ethics session – Review and Meeting	17
Day 3: Ethics session – Create decisions from within a Meeting and from the Application	18
Day 4: Governance session – Review and Authorisation	19

Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone	20
Day 6: Optional session – Managing and updating the Head of Department List	23

Researcher Training - Researcher Video Training Suite Available

Audience: Research Offices/Researchers

The full suite of eleven (11) educational training webinars which have been designed as a training resource for new or experienced Researchers (external users) is now available for all! The package can be watched as a whole, in sequential order, or as standalone individual webinars to allow users to focus on themes relevant to their roles within REGIS.

Research Offices are recommended to watch the videos as well, we guarantee you will learn something that will make your life easier!

https://regis.health.nsw.gov.au/content-resources/

1. REGIS General Overview (1:02:20)
2. Project Registration (18:02)
3. Creating and Submitting a HREA (ETH) for a NSW/ACT Health HREC (ethics in REGIS) (18:27)
4. Creating and submitting an SSA (STE) when Ethics is managed by a NSW/ACT HREC (ethics in REGIS) and when Ethics in managed by another jurisdictions NMA HREC (QLD, VIC, SA, WA) (18:43)
5. Resubmitting an Ineligible application and when HOD not supported (16:01)
6. Responding to a request to information to an initial application (15:42)
7. Creating and submitting Ethics forms/documents (Amendments and Safety Reporting) and responding to a request for information (22:32)
8. Submitting a progress report to a NSW/ACT HREC (and a short overview of external HREC progress reports submitted in REGIS) (21:10)
9. Overview of Governance post-approval activities in REGIS (17:52)
10. Creating and submitting Governance forms/documents (Site Amendments and Safety Reporting) and responding to a request for information (23:28)
11. Submitting Governance milestones (16:49)

Applications not appearing in Dashboards and Reports - Attachments on approval emails

Audience: Research Offices

Friendly reminder as noted in issue 9 - When sending out the application Approval/Authorisation emails please do not add attachments.

Issue: Research Offices have reported instances of applications not appearing in the dashboard or in reports.

Outcome: Research Offices are manually adding attachments to approval/authorisation emails and the emails are not being sent. Emails being sent is the critical measure/filter for reports, dashboards and metrics.

Action Required: Research Offices should upload any signed contracts into the Related Documents section of the STE Application and then select them to appear in the authorisation email link.

How to upload signed contracts into the Related document section

Option 1: Where draft or unsigned versions already exist in REGIS.

Related documents

	Title ▲	Filename	Size	Document type	System Version	Tags	Date modified	Application version	Modified by	Relationship						
☐	CTRAv1site1.doc	CTRAv1site1.doc	147.0 KB	Clinical Trial Agree...	1 *	Add tag...	18/05/2021	1.00 - Initial Applic...	Becker, Kylie							

	Title ▲	Filename	Size	Document type	System Version	Tags	Date modified	Application version	Modified by	Relationship						
☐	FoIsite1.doc	FoIsite1.doc	47.5 KB	Medicines Australi...	1 *	Add tag...	18/05/2021	1.00 - Initial Applic...	Becker, Kylie							

Click page edit on the right-hand menu

Select edit item to unlock the data details

Click the Replace file toggle to "Yes"

✔ **Filename:** Indemnity_signed.pdf.pdf **Size:** 1443.61 KB

Click or Drag and Drop to add the signed file
Update the title so it appears exactly how you want it to appear in the approval email and click

Title * | Form of Indemnity Signed XX Date

save.

The title and system version will update, you can view previous version by clicking the view document version history icon

Medicines Australia Form of Indemnity

|	Title ▲	Filename	Size	Document type	System Version	Tags	Date modified	Application version	Modified by	Relationship						
☐	Form of Indemnity...	Indemnity_signed.pd...	1.4 MB	Medicines Australi...	3 *	Add tag...	18/05/2021	1.00 - Initial Applic...	Becker, Kylie							
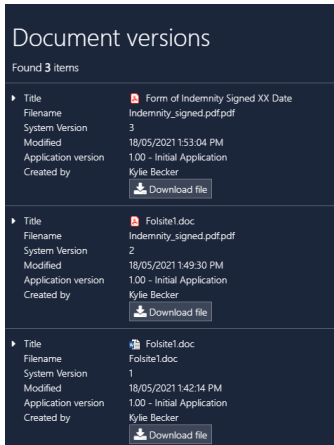
Option 2: Where the document does not yet exist in REGIS.

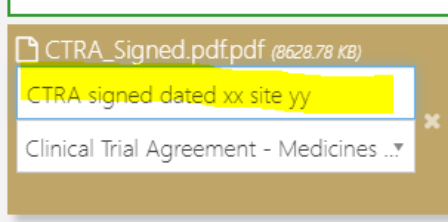Click page edit on the right hand menu
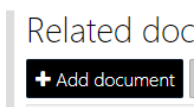
Click the "+ Add document" button

Click or Drag and Drop to add the signed file/s – you can select multiple documents at the same time.
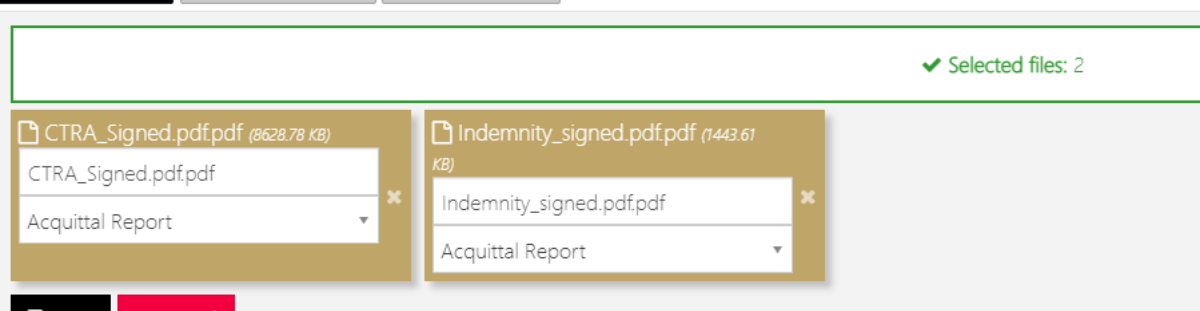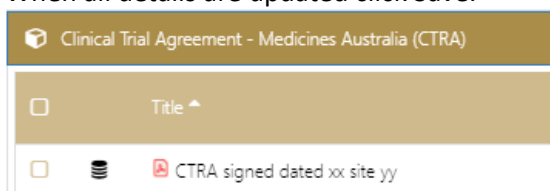

Update the title to what you want to appear in the approval letter.

Click the dropdown to update the document type, start typing to reduce the options

When all details are updated click Save.

Parallel Submission/Review of the Ethics and Site application

Audience: Research Offices

Our office has had a few queries/requests from Research Offices and Researchers regarding the flow of applications through the system. This information is provided as for your information.

NSW Health supports parallel submission and review of ethics and governance applications, and REGIS has specifically been designed to allow for parallel submission, e.g. the Eligible and Valid status to differentiate an Eligible application with Ethics approval and an Eligible application pending Ethics approval and the introduction of the ETH approval tag.

Parallel review of a governance applications is one of the ways for a Research Office to bring down the total time of submission to study start up for their researchers.

The [NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review](#) notes; The SSA and HREC ethical and scientific review may occur in parallel, however the decision to authorise or not authorise the commencement of a research project is only made by the public health organisation when the responsible HREC has granted approval and the SSA has been satisfactorily completed.

What the data tells us in REGIS is that most applicants wait for the HREC approval to be completed before they submit their site application. The reasons for this:

- Researchers are not aware they can submit the site application at the same time as the ethics application.
- Researchers choose to compartmentalise the two administrative processes.
- Research Offices actively tell applicants not to submit the site application until ethics is approved.

We know operationally an RGO may prioritise applications with HREC approval simply because of the number of applications that they have to review and applications with HREC approval can be seen through to the end. However, there are aspects of a governance application that can be reviewed before the HREC approval, not for all studies, but for many.

RGO's can make a More Information Request/Decision on a "Valid" Application

Audience: Research Offices

The below information has been provided to share information and to start a conversation in your office. It is an example of how you can use the system in your daily operations.

When completing the Eligibility, a pending ethics approval is not an acceptable reason to mark the application Ineligible. *To see the acceptable reasons to mark an application as "Ineligible" please see* [QRG: Review Eligibility of a Site Specific Assessment](#)*.*

While completing the eligibility the system will search for a recognised Ethics approval, where Ethics is in REGIS this will be the Related Document type "Decision Notification email" and where Ethics is from another jurisdiction/outside of REGIS it will be the "Ethics Application Decision Notification." If neither of these document types exist, the status of the application will appear as "Valid."

REGIS has been designed to support parallel submission and review of applications and one of the strategies an RGO can use to bring down the review times is to "frontload" the review as much as possible. When Ethics is not yet approved metrics calculations have not yet started (have I got your attention now?). As an RGO you may choose to start your review and note items that require a request for information.

***You can make a request for information on a "Valid" application***

Decisions → Edit → Select Decision More information required - SSA and decision type Decision pending(MUST BE DECISION PENDING)→ send email
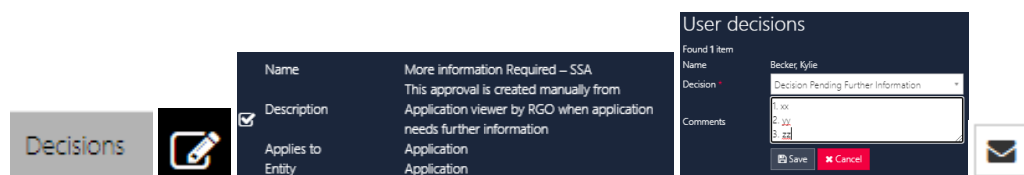

One of the big takeaways from COVID is that communication and management of expectations is a key to building and maintaining relationships with our clients (researchers). So, clearly communicate this in the email. See example below.

Please note this was a preliminary review of the current application and documents, there may be a need for our office to request additional information once the final HREC approval letter and document have been received.

Once you make the request for information the status of the application will change to Information Requested/In Progress. (The change from Information Requested to In Progress is immediate)
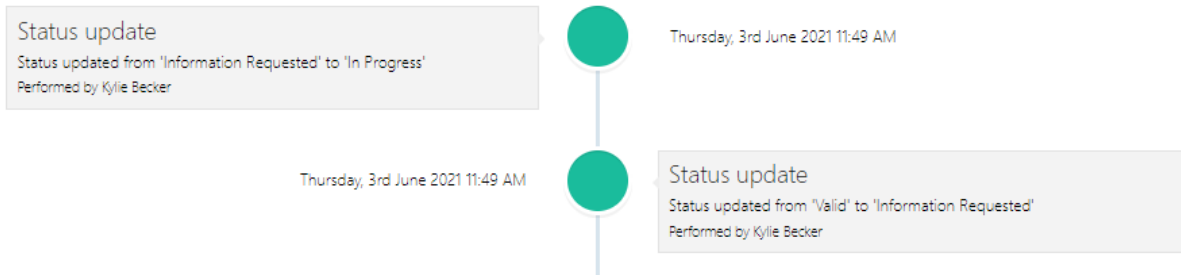
When the applicant submits the response, the application will come back as "Information Provided."
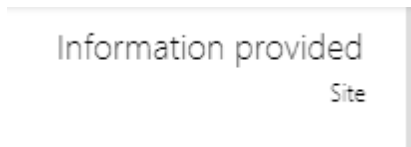
You will be able to tell immediately if Ethics has been received if there is an "ETH approved" tag.

2021/STE01322 - Testing w

2021/PID00916

Low risk review pathway

If you after you have reviewed the response, you would like the application to return to the "Valid" status, you should complete a new eligibility (because a new version was submitted). If you do not want to send the applicant another eligibility email, click the send email toggle over to No and complete the wizard.
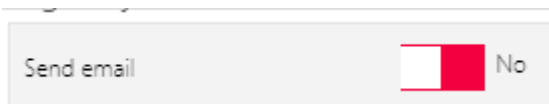
Application status will return to Valid (without the need for a manual status change - because we do not do manual status changes).

All completed eligibility reports are available under Management → Eligibility

But how will I know that I have completed a preliminary review once ethics is approved?

The following tag is available to be used Prelim review done

DON'T CREATE A NEW TAG BECAUSE YOU DON'T LIKE THE COLOUR OR THE EXACT WORDING ISN'T AVAILABLE.

Updating a Sponsor

Audience: Research Offices

Project --> Organisations --> page Edit --> locate the Organsiation Type "Sponsor" --> select edit item --> Select the x next to the current org and then select the options icon (3 dots) and search for the new Sponsor.

You should enter enough details in the justification so someone else will know what happened.

e.g. Sponsor updated from XX to YY on date. See noted document in related document section.

If you are Ethics and Site please update in both sections. Each Site will need to manually update the information.

Unlocking applications

Audience: Research Offices

Issue: Applications are locked, and Researcher Officers cannot action. REGIS team is asked to unlock the application.

Outcome: When a Research Office user unlocks an application (clicks big/page edit) that application will become locked to other users to stop overwriting. If the page is not correctly closed by either clicking save or cancel it remains locked by that user.

Action Required: Research Officers have the ability unlock applications.

Applications → Unlock application → Locate application and select unlock 🔓 .

If Application identifier does not appear in the first 10 listed, expand page to "All" and use your computers text find function (Ctrl f), enter the application ID and the text will become highlighted on the page.
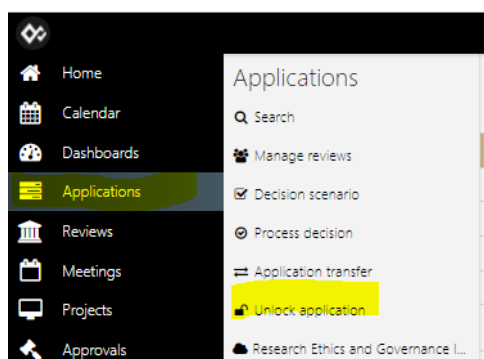
New Heads of Department template

Audience: Research Offices

The spreadsheet required to be submitted to the REGIS team to update HOD's has been updated to reduce data entry errors. All the research offices are required to use the updated Heads of Department template.

The template has been revised to clearly indicate which field is required to be filled to complete a row of request. Using this template should remove the ambiguity previously some research offices may have experienced.

This template must now be used when requesting changes.

https://regis.health.nsw.gov.au/media/1758/qrg-ro-new-hod-upload-process.pdf

https://regis.health.nsw.gov.au/media/1577/blank-template-lhd-date-of-request-sample-data-sheet.xlsx

Past newsletters available on REGIS website

Audience: Research Offices

Have you found yourself thinking "hmmmmm where did I see that awesome hint on XX" and realised it was the newsletter and you have deleted it! Worry no more, we are in the process of uploading all previous newsletters to the REGIS websites. You're welcome!

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

Research Office Contribution

Nothing this week.