

Hello,

This is our 15th fortnightly email and there is a nice mix of REGU and REGIS for you all this week.

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Australian Commission on Safety and Quality in Health Care (ACSQHC) - Clinical Trials – Phase 2 Advisory Committee – Communique – Meeting 5, 30 June 2021

Audience: Research Office/Researchers

The fifth meeting of the Advisory Committee was held on 30 June 2021, the meeting details provide an overview of the National One Stop Shop and National Clinical Trials Front Door.

Stakeholders are encouraged to [register](#) with the Commission to participate in consultations.

If you would like to be added to the Clinical Trials – Phase 2 distribution list please email details to HMR@safetyandquality.gov.au

Please see the attached for an update on the ACSQHC Clinical Trials – Phase 2 Advisory Committee meeting 5.

Bellberry approval for Early Phase Clinical Trials only

Audience: Research Office/Researchers

On 29 April 2019 the Early Phase Clinical Trials Human Research Ethics Committees (HRECs) Scheme was established in NSW. Bellberry HREC (adults) and Sydney Children's Hospital Network (paediatrics) were appointed as the only two HRECs that could review and approve Early Phase Clinical Trials for NSW Public Health Organisations.

Can a Bellberry HREC approval be accepted by a NSW PHO for a non-early phase clinical trial? No. Bellberry are only accredited to review and approve early phase clinical trials in NSW.

What is the definition of an early phase clinical trial (EPCT)? Early Phase Clinical Trial definition includes all clinical trial phases up to but not including Phase II, including studies with any Phase I component.

For more information <https://www.medicalresearch.nsw.gov.au/hrec-scheme/>

Technical Helpdesk – increase in calls because RO cannot be reached

Audience: Research Office

The helpdesk has reported an increase in calls from researchers who are not able to contact their local Research Offices. The REGIS helpdesk is a technical helpdesk and cannot assist with general application queries.

Given current circumstances with many of us currently required to work from home we are suggesting that Research Offices add a standard statement to outgoing communications on the best way to be contacted during times where the physical office may not open.

Adding a standard statement to your REGIS email footer may be a suitable option.

See QRG: [Starting in REGIS](#)

REGIS application and post approval flow

Audience: Research Office/Researchers

The two attached power points were created as part of the Researcher training package to show how applications and post approval items flow through REGIS. The power points are saved as a point show to take advantage of the interactivity. If you would like a copy of the slides please let our team know.

Researchers can access a full suite of training videos here: <https://regis.health.nsw.gov.au/content-resources/>

Ethics and Governance Training

Audience: Research Office

As part of the current REGIS training, where we show a user how to navigate the system, we have received feedback that researchers would like more training in Ethics and Governance.

Many hands make light work, if you have created something for your research community, I am sure other Offices would be grateful to link in.

The REGU/REGIS team can pull together a document with any shared resources and distribute it to you all.

Please send links to REGIS@health.nsw.gov.au by Friday 13th August.

Manual status changes – reduction shows improvement in metrics calcs.

Audience: Research Office

Our team has just completed the data quality checks for the previous quarter metrics and automated calculations in REGIS have been the most accurate of any quarter.....a substantial improvement!

Why? What has changed? The number of manual status changes, that's what.

If your office is one of those still making manual status changes, please let us know so we can work with you to identify why you are needing to and what alternatives there are. There are very few reasons that you might need to make a manual status change.

Data Quality/Data Cleaning Requirement - Waiver of Consent

Audience: Research Office

Has your office used one of the **14 tags that indicate Waiver of Consent but not the classification?**

(WoC, WOC – Other, WOC 06 April HREC, WOC 10 August HREC, WOC 10 Feb HREC, woc 95, WOC 95A, WOC March HREC, WOC Pending, WOC to HREC, Waiver, Waiver Granted, Waiver of Consent., Consent Waiver Granted)

OR did you use a tag before the May release of the waiver of consent classification?

- 56 applications that have had the Waiver of Consent classification entered
- 75 applications use one of the identified Tags for Waiver of Consent
- 9 have both the classification and a tag

This means that there are 66 studies that would be missed off a report that uses the Waiver of Consent classification.

Tags are (pretty) visual labels, Classifications are for reporting/filtering

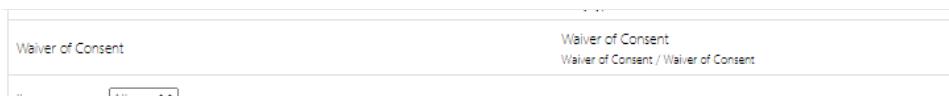
We are requesting each research office who uses or has used a tag to complete this short **data cleaning exercise by the end of this month 31 August**. It should take a Research Office no more than 15 minutes to complete this exercise.

How to identify applications that have used a tag and how to update the classification

1. From the Applications Menu
 - a. Click Search for Applications
 - b. Drag in the tag filter
 - c. Enter one or all of the tags
 - d. Find



2. The list of all applications with the tag will appear.
 - a. You can export this list to a excel file by using the export icon
3. Click on the application (or open a new tab and search for the application)
4. Navigate to
 - a. Management
 - b. Classifications
5. If the Waiver of Confirm classification does not exist add it



- a. Page edit
- b. Add classifications
- c. Locate the waiver of consent classification
- d. Select
- e. Click the tick at the bottom of the screen
- f. Page save.

If a project exists navigate to the project and repeat.

Return to the list and repeat.

Case Study – Researcher submitted amendment – stayed “in progress”

Audience: Research Office/Researchers

Issue: A researcher had submitted a site amendment and on hitting submit the form did not progress to submitted.

Outcome: The REGIS team was able to identify that the applicant had uploaded 2 of the same document.

On this occasion a document was uploaded twice and when the applicant tried to submit the form stayed in the status of In Progress.

After identifying the issue and deleting the duplicate document, the applicant was able to successfully submit the form.

<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Master PICF :	Participant Information Sheet	1.0	16/07/2020	<input type="checkbox"/> Clear content selection (2019_ETH00134 - PICF addendum-1-16-JUL-2020_356921_clean_2020Nov25.doc) [Open] Maximum file size is 20MB
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Master PICF :	Participant Information Sheet	1.0	16/07/2020	<input type="checkbox"/> Clear content selection (2019_ETH00134 - PICF addendum-1-16-JUL-2020_356921_clean_2020Nov25.doc) [Open] Maximum file size is 20MB

Upcoming Releases

Audience: Research Office/Researchers

A combined product and enhancement release was deployed to the sandpit/training environment on Monday 9 August. This release is scheduled to be deployed to the live/production environment on Wednesday 25th August.

Release notes and scheduled system outages will be advertised on the [REGIS homepage](#) and [log in portal](#).

Written Quick Reference Guides and walkthrough videos have been updated and will be published at the time of the production release.

See current written Quick Reference Guide and Walkthrough videos [here](#).

See the full suite of Researcher training videos for REGIS [here](#).

RO logging a bug from Sandpit

If you see something, say something – sandpit release is an opportunity for RO familiarize themselves with changes but it is also a vital step in making sure the production release is as smooth as it can be.

If you are in sandpit and something doesn't look right please log with Patrick

- Email Patrick.lau1@health.nsw.gov.au
 - Describe what you were doing
 - Describe what went wrong

Research Office Contribution

Audience: Research Office

This is where a research office can share.....

[See previous version online](#)

Audience: Research Office

All previous version of the fortnightly email are available from the REGIS website:
<https://regis.health.nsw.gov.au/news-and-events/regis-office-webinars/>

Issue 15 – Governance Specific

Audience: Research Office

We will focus the next issue on the governance issues we see across our desks.