

REGIS Comms – Tuesday 23 Feb

Hello All

Please find below the fortnightly REGU/REGIS email.

Please note the survey to express interest in webinars will remain open until the Friday after the email is sent. If 10 or more people indicate they are interested in a webinar it will be scheduled for the week after.

Upcoming Education Sessions

Researcher/Coordinator Education

Thank you to everyone who completed the pre-training setup session and attended the second cycle of training, it has been great to see the continued large number of attendees.

The next pre-training setup session will be held on Thursday 25 February from 9:30am-12:30pm. You cannot attend the training cycles until you have attended a pre-training setup session. If you did not receive the invitation for this setup session, please email EHNSW-Regis@health.nsw.gov.au to register for this session.

Training Cycle 3 will commence Monday 1 March and is held over 6 consecutive days. Day 1 is mandatory for all attendees and then you can choose to attend all days, Ethics only days or Governance only days. If you did not receive the invitations for these cycles, please email EHNSW-Regis@health.nsw.gov.au to register for this cycle.

Training Cycle Agenda
01/03/21 Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
02/03/21 Day 2: Ethics session – Review and Meeting
03/03/21 Day 3: Ethics session – Create decisions from within a Meeting and from the Application
04/03/21 Day 4: Governance session – Review and Authorisation
05/03/21 Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
08/03/21 Day 6: Optional session – Managing and updating the Head of Department List

New Staff – If you have recently attended REGIS training and have been in the role for less than 3 month it is highly recommended that you join us again for Cycle 5 commencing Monday 29 March and finishing Wednesday 7 April for refresher training (we have made sure to not schedule anything on those upcoming Public Holidays!).

There is a lot to learn in any new role and add learning a new system to that and it can be a little overwhelming! As REGIS will be your main tool in the Research Office, we think that coming back after working in the system for a weeks, or months, will allow you to have a different take on the training and also sharpen your skills.

If you would like to register for this refresher cycle, please email EHNSW-Regis@health.nsw.gov.au to register for Cycle 5.

Researcher/Coordinator Education

We will soon be providing Researcher/Coordinator education sessions in REGIS.

Our Researcher Interest group have indicated that they are looking for individual sessions of no longer than 1.5hrs. We are in the final stages of putting together a suite of education sessions.

We have put a "Register you interest" link on the REGIS log in page however if you have a communication channel to your researchers, please feel free to share the link

<https://ohmredcap.health.nsw.gov.au/surveys/?s=JLKPHELKN3>

We are also looking for interested RO to join these sessions to provide general Ethics and Governance advice should it be raised.

[We are interested in hearing more on how our office can partner in the education sessions.](#)

Upcoming Releases

Reminder that on the 3rd March the milestone reminders will be switched on. If you have overdue milestones in the system due to external processing researchers will received reminder emails. Helpdesk has been advised that if they receive calls from researchers who are receiving emails to redirect them to the Research Office to action. Receiving reminders is not a bug or system issue and needs to be addressed by the Research Office.

Please make sure data has been corrected before 3rd March.

Details on how to identify overdue milestones and how to address/correct are in the 9 February email.

Progress Report form

An issue has been identified with the progress report output document not showing all NSW site in the site section. An updated version of the form will be released on the morning of Wednesday 24th. There are no changes to the form that the researchers complete in REGIS. The change only relates to the information that was previously missing or not showing on the output document that the Research Office review will now appear. See below for a full description of the issue.

Ethics Approval Emails

We have received feedback that the initial approved HREC documents are not consistently being shared with RGO's. This functionality has been available in REGIS for over 24months. It is **CRITICAL** that the Ethics Office follow the steps for approving in the system to allow the RGOs access to the approved documents and Researchers are not asked to upload the documents again. Also, researchers really dislike being asked to reupload documents that are already in the system.

How do I approve an Ethics application in REGIS to share documents with RGO's and external portal?

There are 2 QRG's that describe how to approve an application available:

- [Processing Approvals & Authorisations – Not associated with Meetings \(Initial Application\)](#)
- [Managing HREC Meetings and Decisions](#)

Approving applications is stepped through in Day 3 of REGIS training, if you need/would like a refresher, please contact Corinne via email EHNSW-Regis@health.nsw.gov.au about attending the next Day 3.

Bulk sending of emails

We have had a lot of interest in the bulk sending of emails functionality which is stepped through in Day 3 of REGIS training, if you are interested in seeing this in action or need a refresher, please contact Corinne via email EHNSW-Regis@health.nsw.gov.au.

Site Close Out

Currently REGIS does not have a defined/automated pathway for site close out. This will be addressed in the next round of major enhancements later this year. This is the recommended manual pathway.

Step 1. Researcher submits notification of site close out to RGO, via email, external to REGIS.

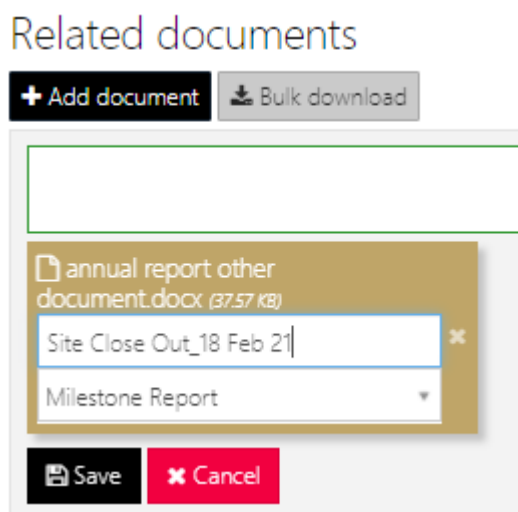
Step 2. RGO notes site close out, via email, external to REGIS.

The researcher will still need to submit HREC noted annual/final reports to the RGO.

- If Ethics is in REGIS this will flow automatically on noting of the NSW progress report.
- If Ethics is outside of REGIS a site final report milestone should be manually created for the researcher to allow them to submit. See [page 2 for manually creating milestone](#)

Step 3. Upload site close out and RGO notification to Related Documents with document type “milestone report”. You can upload an email file, a .zip or multiple documents.

When adding the documents the title will default to the file name, you can change this to a title of your office’s choice. Change the document type by clicking on the bottom field and typing “milestone” this will reduce the document type options. Then Click Save.



Step 4. Manually change the status of the STE Project to Completed.

Completed: *When the last participant has met the last study analysis endpoint. When reached at a single site study, this is likely the time point when data analysis can begin. When reached at the last site in a multi-site study, this is likely the time point when data analysis can begin. Participants may still be undergoing follow-up visits*

[I would like a webinar on the manual site close out](#)

Using Quick Reference Guides

<https://regis.health.nsw.gov.au/how-to/>

New Staff - There is a full suite of Quick Reference Guides available, if you are new(ish) we highly recommend that you use the guides to make sure you are doing things the right way.

Not so new staff - please encourage and direct your new staff to follow these guides, this makes sure new staff aren't learning bad habits and unnecessary "work arounds" (and we know there are a few).

OHMR/REGU items

EEA Policy now obsolete

Research Offices are no longer required to enter into an EEA for a review to be accepted at a non NSW PHO site. This does not affect agreements currently in place.

Human Research Ethics Committees: Ethical Review for External Entities

Obsolete: This document is no longer current

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2008_046

If you have any questions regarding this please direct to MOH-ResearchEthics@health.nsw.gov.au

Interpretation: [Health Care Interpreters PD 2017 044](#)

OHMR has received a query on the use of translated Participant Information and Consent Forms (PISCFs) for non-English speaking participants.

Apparently, one or more commercial sponsors are reluctant to allow non-English speaking participants to be recruited onto their sponsored trials in one NSW Health site, as the sponsor SOPs require a PISCF to be translated into the language of the potential participant, and so are in seeming conflict with NSW Health policy (PD2017_044). While no specific reference has been given, we suspect they are referring to a paragraph on p21:

Non-English consent forms are not used by NSW Health due to a number of risks, including problems with the consistency of content and compatibility with medical record systems.

OHMR has sought advice from the Community Care and Populations Unit of Health and Social Policy Branch (the policy owner). The advice is that:

- Interpreter Policy Directive [[PD2017_044](#)] does not exclude the use of translated participant information sheets and consent forms in clinical trials conducted in NSW public health organisations.
- The reference to non-English consent forms is specific to surgical/medical procedures and does not extend to participant information sheets and consent forms for clinical trials.

If Research Offices, or their clinical trial unit partners, receive similar claims from sponsors, reference may be made to this official advice from NSW Health

RESEARCH GEMS (South Australia's new system)

South Australia released its new online application management system at the end of last year. They have joined NSW with an Omni product they have call it [RESEARCH GEMS](#) . REGIS and GEMS are **VERY** similar and

RGO's may start to see forms that look like NSW forms coming from SA. For now SA Ethics needs to be treated like any other outside of REGIS Ethics.

Currently REGIS and GEMS do not talk to each other, this is an issue that OHMR raised with SA (and the Vendor) mid last year as a critical issue. There is a project to have the two systems speak to each other but there is no timeline for implementation, we will keep you posted.

Feedback/Requests from last email

It has been lovely to hear that our new email has been useful to many of you. Webinar requests are still unbelievably low. Reminder that we will not schedule webinars unless we have 10 individuals indicate it would be useful. The link will take you to a single REDCAP survey and you just click the option/s you want. The survey is open for the week that the communication goes out (closing on the Friday) so if a webinar is required it can be scheduled the week in between emails.

[Offer a suggestion or a request for a future email](#)