REGU/REGIS Update – Tuesday 23 March

Welcome to issue 5 of the REGU fortnightly communication.

What's in this issue:

- Tasmania and Northern Territory join National Mutual Acceptance (NMA)
- Upcoming REGIS Education Sessions
- Principal Investigators – do they need to be an employee of the LHD?
- LHD PHO's can accept University HREC approval for Access Request
- Data migration update
- Issues Log - NEW SECTION

Tasmania and Northern Territory now part of National Mutual Acceptance Scheme

The NMA scheme has recently been bolstered to include all Australian states and territories. This means that NSW NMA certified HRECs, in their capacity as a lead HREC, can approve the addition of sites in the Northern Territory and Tasmania.

To conduct research in the Northern Territory applications will need an additional review by a specialist ethics committee formed by Menzies School of Medical Research.

If there are further questions about conducting research in Tasmania and Northern Territory please do not hesitate to contact the Tasmanian Research Governance Office or Menzies HREC. Guidance on the Northern Territory site specific assessment (SSA) process and forms are available from the NT Health research website, contact nthealth.rgo@nt.gov.au

Upcoming Education Sessions

If you are actively using REGIS day to day and have not attended REGIS training, please register for the upcoming sessions.

Thank you to everyone who completed the pre-training setup session and attended the fourth cycle of training. The next pre-training setup session will be held on Thursday 25 March 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 5 will commence Monday 29 March and is held over 6 days (the 6 days will be spread over 2 weeks to take into account the Public Holidays). 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
Monday 29/03/21 Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
Tuesday 30/03/21 Day 2: Ethics session – Review and Meeting

Wednesday 31/03/21 Day 3: Ethics session – Create decisions from within a Meeting and from the Application (processing Amendments, Safety Reporting and Milestones)
Thursday 01/04/21 Day 4: Governance session – Review and Authorisation
Tuesday 06/04/21 Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
Wednesday 07/04/21 Day 6: Optional session – Managing and updating the Head of Department List

New Staff/Refresher – 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 for refresher training.

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.

Alternatively, if you have attended one of the 4 previous cycles held in 2021 and would like to refresh yourself on certain processes in the system, we encourage you to attend any of the days scheduled below for cycle 5. You will not be required to attend the pre-training setup session as you would be attending this cycle as a nonparticipant.

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

Principal Investigators – Do they need to be an employee of the LHD?

Short answer: No. There is no NSW Health policy that requires a PI to be an employee of the local 'site'.

The long answer (because context is important): We recently received a query from a team at NSW Health who had engaged an external consultant to complete a statewide review/evaluation. They were busy locating 15 Local PIs but were concerned about the PI declaration as this "Local PI" would only be PI in name and would not actually be conducting the research activity, in fact they would be participants.

> *So...they aren't actually PI's, they are local contacts.*

NSW Health policy, a Principal Investigator is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation. This can cover a broad spectrum of responsibilities for any given research project (from an interventional clinical trial involving the administration of a product to someone coming on site to conduct a survey/interview or evaluation). The PI is the person who best fits the policy definition.

The PI does need to be able to attest to each of the items on the SSA declaration and does need to have a REGIS account in order to submit the SSA. A PI may need to be an employee in *some circumstances* (interventional clinical trial, for instance) but does not have to be if, in the circumstances, being responsible for conducting the study does not require an appointment to do so.

What is probably more useful is to source a person to be a 'local contact' who can assist with coordinating certain aspects of the on site visit (booking rooms, etc), however, they do not have to be a PI if they have no substantive involvement in the study.

LHD PHOs can accept University HREC approval for Access Request

OHMR has discussed an interpretation to current policy at a recent Roundtable, which we reiterate here.

Where a researcher wishes to access a site for their research and this access would only involve the submission of an Access Request; RGOs are permitted to accept a University HREC approval to satisfy the ethics component of the governance requirements.

The rationale is that: (i) given an Access Request is required, these projects will not be conducting any research on the PHO site, therefore minimal risk to the site will be involved, which a PHO HREC would need to take into account; and (ii) given the research will be conducted elsewhere, if prior ethics review has been obtained (eg/ from a University HREC), this can be recognised as satisfying the ethics requirements for an Access Request, in lieu of necessitating a further ethics submission by the researcher for a further review by a PHO HREC.

Future policy will contain a more explicit statement around this interpretation.

Data Migration update

Thanks to everyone who participated the Data Migration process, REGIS team is happy to confirm the final template has been delivered to F1 for UAT trial run and the final Data Migration will be in production on 7th April.

What is happening now?

The submitted studies are being verified in UAT, any studies with incorrect information will be identified, and the REGIS team will go through the error report and manually correct the data fields.

What happens after prod release?

On / post 7th April your submitted studies should be available in REGIS, perform the following checks and remedy any missing classifications or detail:

- Ensure the total number of submitted studies are available in REGIS
- Ensure classifications e.g. Ethics pathway, sponsor, study types are correct, otherwise, please use the EDIT button to add these to the system
- Ensure the contacts (CPI, PI, Administration) are correct, otherwise, please use the project contacts from the left menu to add or correct any required contacts
- Ensure the Site is correct, otherwise, please use the project Organization from the left menu

NEW SECTION - Issue logged

What is the issue logged section? In an effort to better manage the volume of queries and issues that we receive daily our team is currently piloting an Issue Log with the User Group. The log is reviewed weekly by the REGIS team and we decide on the best way to respond. If we think the issue logged is something that would be of interest to multiple RO we will provide the response here.

*An **issue** is an item that has been logged with the helpdesk and the user has been directed back to REGIS team or an area where you are seeking guidance or clarification.*

If an item is urgent please don't long in the issue log, please contact our team directly.

To log something in the issues log please speak to your User Group representative.

Date logged: 16 Mar 21

Issue described in log: General Amendment – Document Sharing Issue with amended docs approved by another HREC not being made visible - I think we need a time frame on when this will be resolved as it is a big issue and resource drain.

Outcome: This is by design, not a bug. When ethics is in REGIS (NSW/ACT HREC), an ethics approved General amendment is currently the only amendment type that requires the **Ethics Office** to manually share the approved documents (including the approval letter). The researcher **does not** need to upload the ethics approved documents.

RGO can't see the documents? Call the RO managing the Ethics and request that they share the documents.
https://regis.health.nsw.gov.au/media/1748/qrg-ro-processing-ethics-amendments.pdf

Please note a system enhancement is scheduled prior to the end of the financial year to align the automated document sharing for General Amendments.

Date logged: 16 Mar 21

Issue described in log: Annual Reports Understanding when it is shared

Outcome: Once the HREC/Exec have approved the progress report in REGIS a decision is created in each authorised site, the decision includes the Progress Report Form.

Currently the Ethics Office is required to share the approval email.

Date logged: 16 Mar 21

Issue described in log: SSI understanding when it is shared

Outcome: On submission of this the notification to the HREC a system generated email is sent to each NSW Principal Investigator (site/s listed in REGIS).

Once reviewed by the HREC each NSW Research Office will be automatically provided with the report and the HREC notification.

Currently the Ethics Office is required to share the approval email.