HEALTH+MEDICAL RESEARCH

NSW GOVERNMENT

REGU/REGIS Newsletter | Issue 24 | 14 December (FINAL)

In this issue

A message from the REGU Team

Audience: Research Office/Researchers

2021 was another challenging year. 100+ days of lockdown for Greater Sydney affected many of us but some much more than others, I'm looking at you Western and South Western Sydney. Being isolated from family, friends and colleagues contributed to many people struggling with their mental health and our team was not immune to this. If you were one of the many that experienced issues with mental health we hope that you were able to get the support you needed. If you're still experiencing issues,

please speak to a trusted friend, family member or your GP. This article from Reachout.com has a number of support services and suggestions that may be useful.

But it wasn't all bad news, the vaccines arrived and NSW has an extraordinary double dose rate of 93%! You should all be so proud to know that in some way you were involved in the NSW and Australia's COVID response. The work you do, really does make a difference not just in your backyard but across the world. The REGU team would like to thank you all for your unbelievable efforts in keeping research going in NSW.

We hope that you all have a lovely holiday period and have time off to rest and recharge because.....who knows what's in store for us in 2022!

James, Yagiz, Jackie, Kylie, Patrick and Corinne

Q4 Metrics: Data Pull 10 January

Is your data ready?

Audience: Research Office

On Monday 10 January OHMR will extract data from REGIS to complete the LHD performance reports (metrics). A number of dashboards currently exist that allow Research Offices to identify when key data points are missing or require attention (e.g. ethics pathway).

Jackie has been hard at work finalising two dashboards that focus on providing Research Offices real time metrics reporting support:

- Quarterly Metrics Data QC - Ethics
- Quarterly Metrics Data QC - Site

Both dashboards and instructions will be made available to you before the end of this week. Attached to the email with this link is an example of what you will be receiving.

From 2022 the OHMR team will extract metrics data from REGIS on the following dates to prepare and provide reports for the CE's performance meeting.

- **Q4**-2021: Monday 10 January 2022
- **Q1**-2022: Monday 11 April 2022

- **Q2**-2022: Monday 11 July 2022
- **Q3**-2022: Monday 10 October 2022
- **Q4**-2022: Monday 9 January 2023

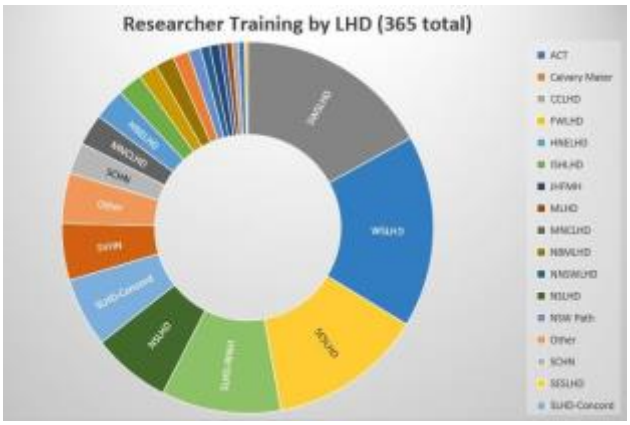
Data, e.g classifications, should not be changed in the system after this date.

REGIS Round Up

Audience: Research Office/Researchers

What happened in 2021?

Launched Researcher Education



Released Researcher Education Videos

Project Registration

- Form update to allow applicant to indicate the ethics pathway for a site, when ethics is outside of REGIS.
- Form update to allow Bellberry Early Phase Clinical Trial HREC to be processed like an NMA HREC external to REGIS.
- Project registration output form is created now available to all sites if ethics is outside of REGIS.

- External Sites are now listed in the internal portal of an ETH, state, site and PI details can be manually edited if PI changes.
- When project registration is completed and the applicant indicates that ethics is outside of REGIS the Other Sites tab is hidden.
- When Ethics is in REGIS and there are sites outside of REGIS to assist researchers in understanding the expectations and processes a message will appear at the PID submission regarding registering study in other jurisdiction platforms.
- Renaming of the NMA HREC Name and ID fields in the internal portal.

Data Quality/Reporting

- Ethics Pathway Classification: if changed in the Ethics application (or project) this now automatically flows to any STE application (or project). The tag also updates.
- Site Principal Organisation is now set on STE creation not submission.
- Changing a classification in the Application or Project will cause the same change in the other folder.
- Recategorise Negligible Risk and Low Risk studies to Low and Negligible Risk studies
- First patient milestone show as "achieved" on submission.
- New Overview page including a Live Clock and other live benchmarking
- New Live Clock dashboard
- Updated static reports
- Updated Ethics and site dashboard

Post Approval Actions

- Auto sharing of Ethics approved amendments to RGOs. Email automatically shared with ALL STEs, external portal. It is available in the STE decisions to download as a package.
- STE more information form provides the submitted documents automatically as a package.
- On approval of an annual report/milestone by the HREC it becomes part of the package that is provided to the sites.
- When Ethics is in REGIS and there is a flow of documents shared from the ETH to the STE approval email are now part of the STE document pack.

Ethics/STE flows

- When an Ethics application has an Application Decision "Not approved" the system will withdraw the site so it is not reviewed further.
- When an Ethics application is withdrawn sites are also auto withdrawn.

- A study that has had a request for more information that has not been responded to in 60 days, to follow the same flow as when a study is made ineligible and a new version not submitted in 60 days. System withdrawn. *note this was reduced to 30 days after roundtable discussions.

HOD

- HOD decision that remain pending after RGO recommendation are locked out.
- When a HOD decision is overridden the outcome of the decision now changes from pending per the overridden outcome.
- When additional HOD's are added to a new version of the site application form the new HODs receive an email requesting them to make a decision. The status of the application will show as Completed pending HOD.
- If a research office manually adds multiple HOD decisions the system will make sure all decisions are finalised before the status change.

Document upload

- Remove the document version and date and the title now should include the version and date if one exists.

Forms/TAGs

- Tags are created on in the related document section for all forms.
- HREA no longer requires the Coordinating Principal Investigator to be in position 1.
- Introduction of a token to match the form tag.
- Removed the Upload HREC approval form and modified the STE form to request ethics approval. If the initial ethics approval has been uploaded by one site it is not required to be uploaded my any other sites.

Meetings

- Additional field to add in the venue details and or electronic dial in detail e.g. skype details.
- Token so the meeting notification email can have the venue included on the meeting notification email.

Other

- Help text added in internal portal
    - Process Decision
    - Decision Notification email
    - Overview page

click the arrows to expand

What's in the pipeline for 2022

- Milestone reminders turned back on - February 2022 - see walkthrough video
- External Portal upgrade for improved user experience – early 2022
- Breakdown on live clock categories and ability to details from dashboards and reports – early 2022
- CPI/PI delegation for in system sign off/submission - early 2022
- REGIS UG enhancements
    - Focus on Document Management
    - Improving current flows from REGIS 2.2
- REGIS super users
- Investigating new format **Q**uick **R**eference **G**uides
- Additional jurisdictions and Affiliated Health Organisations becoming users of the REGIS as Research Officers.
- A new REGIS team role of Onboarding and Support Specialist
- Form updates

click the arrows to expand

Updated REGIS External Portal

Register your interest in attending a walkthrough webinar

Audience: Research Office/Researchers

REGIS will have an updated external portal, designed to improve usability, released in early 2022 (date to be confirmed).

Register your interest in attending a walkthrough webinar that will introduce users to the new look front end.

Can't wait until next year, here's a sneak peek.

Seeking Feedback on REGIS Quick Reference Guides

Audience: Research Office/Researcher

The REGIS team has received feedback that Quick Reference Guides require improving. We have created a short survey for Researchers and Research Offices to gain a better understanding on what could be improved. If you have any feedback or suggestions, please use the links below!

[Research Office Link]

[Researcher Link]

Research Office Contribution

HNELHD HREA Guidance Document for Researchers

Guidance to Completing the Human Research Ethics Application (HREA) in REGIS

This guide has been developed to assist researchers completing the HREA for applications to the HNE HREC.

The HREA and protocol are two distinct documents with different purposes

- The Protocol describes all aspects of your project - aims, hypotheses, background (justification) methodology, analysis
- The HREA allows you to demonstrate that the ethical issues raised by your research project have been considered
- As the protocol and HREA will be read together when assessing your application, do not cut and paste from the protocol when you complete the HREA.

The HREA is logic driven

- If the relevant checkboxes are not selected correctly at the initial questions, key sections of the HREA will not generate (For example questions pertaining to research methodology or participant cohort)
- Without all appropriate sections completed, the HREC cannot properly assess your application and you will receive questions

The more complete and succinct information you give the HREC in the project documents, the fewer questions you are likely to receive

- Where there is a reference to the National Statement embedded in a question, review that section prior to answering the question
- Use professional and appropriate language for the group you are describing
- People are described as "participants", not "patients" or "subjects"
- Check your spelling and grammar before submitting

A member of the research team with relevant research experience and expertise should review the HREA before submission

Section 1:	These questions are about your project and the sites where it will run
M	These are about your study methods
P:	These are about your study participants
Section 2:	These are about Recruitment and Consent, including risks and benefits to participants
Section 3:	These are about Data and Privacy
Section 4:	This section is for attaching project documents including your protocol

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1 - [Click here to be taken to the HNELHD HREA Guidance]

The Hunter New England Research Office has released a guide to assist researchers when completing the Human Research Ethics Application (HREA).

The project was led by the Deputy Chair of the Hunter New England HREC and the final document was endorsed by the Committee.

The guide is available of the HNE Research Office website and the HNE Research Ethics Team is happy to share it with other offices.

Who's next?

How is your office reaching out to your local research community? Are you holding online or face to face sessions? Do you have a newsletter? Have you created any support resources?

Share these things with your colleagues, I can guarantee there other research offices that would love to know what others are doing.

If your office is doing anything that you would like to share, please send it through to regis@health.nsw.gov.au.

Got new team members? Send through their name, role and something about them (and a photo if you want) and we'll welcome them here.

Previous Versions of REGU/REGIS Newsletter

Audience: Research Office/Researcher

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/