

HEALTH+MEDICAL RESEARCH



REGU/REGIS Newsletter | Issue 14 | 27 July 2023

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Ethics and Governance Bi-Annual Roundtable - Agenda Items

Audience: Research Office

At the last roundtable we saw some exciting work and initiatives from research offices, in particular the presentation and open discussion from WSLHD and CCLHD research offices which were extremely well received and based on that, we want the upcoming September roundtable to be LHD focused!

We believe this is the perfect opportunity for you and your team to showcase the remarkable initiatives, breakthroughs, success stories or collaborations that have been happening within your office.

Presenting at the roundtable is a great platform for you to share knowledge, exchange ideas and connect with other offices, it is also about learning from other offices experiences too!



*If you or your team would like to present or start an open discussion, please email REGIS@health.nsw.gov.au with your presentation or discussion title (presentations can be sent closer to the roundtable date) by **COB Friday 1 September**.*

TGA Consultation



Proposed regulatory changes for clinical trials of medical devices

Audience: Research Office/Researchers

As many of you would know, last year the TGA released a consultation paper seeking comment on a new process for reviewing 'high-risk medical device trials'. They have engaged in consultation with all jurisdictions, including the NSW Early Phase Clinical Trial HRECs.

The outcomes of the TGA's consultation on oversight of medical device clinical trials have been published at [Proposed regulatory changes for clinical trials of medical devices - Therapeutic Goods Administration - Citizen Space \(tga.gov.au\)](https://www.tga.gov.au/consultation-proposed-regulatory-changes-clinical-trials-medical-devices-therapeutic-goods-administration-citizen-space).

Thank you to all NSW stakeholders who engaged with the TGA's process or submitted a response to the consultation paper.

Good Clinical Practice (GCP) Inspection Program Metrics report and Webinars

Audience: Research Office/Researchers

In 2022, the TGA implemented an ongoing risk-based Good Clinical Practice (GCP) Inspection Program. The findings of the inspection program provide confidence in the quality of Australian clinical trials and their compliance with GCP. The [first report of the program](#), which covers the first six months of the program, has now been published. The report provides insights into inspection findings and compliance expectations.

You are invited to join a TGA webinar, which will provide an overview of the [GCP inspection program](#), insights into inspection findings, tips on how to get ready for an inspection and an opportunity for Q&A.

Please register for **one** of the sessions and submit your questions ahead of the webinar through the registration link below.

Webinar date

Link to register

07 August 2023 16.00-17.00 (Canberra, UTC+10)

<https://www.tga.gov.au/resources/event/webinars/insights-tga-good-clinical-practice-gcp-inspection-program-session-one>

09 August 2023 12.00-13.00 (Canberra, UTC+10)

<https://www.tga.gov.au/resources/event/webinars/insights-tga-good-clinical-practice-gcp-inspection-program-session-two>

HREA Feedback for NHMRC - extended to 18 August

Audience: Research Office/HREC Members

NHMRC are currently making changes to the HREA and as such, we would like to provide the opportunity for our HREC stakeholders to comment on any part of the HREA that they would like to see changed, everything from typos to word clarification to document flow.

The survey will be reactivated to allow more for feedback, which we will then collate and provide to NHMRC.

You can access the survey using the below link.

REGIS: Milestone Reminder Emails - Turned Back On

Audience: Research Office

The milestone reminder emails for Ethics Progress Reports were turned back on, on Wednesday 26th July.

Over the recent months we have been preparing users for this by deploying our recent system updates. These updates have assisted in removing inactive studies and Ethics milestones progress reports that were greater than six months overdue from the system, providing you with a true indication of active and compliant studies.

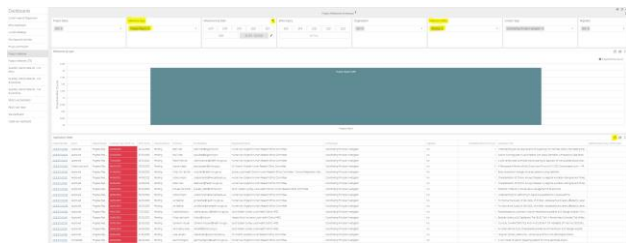
With the reminder emails being turned back, you can now monitor Ethics studies where progress reports are overdue and/or close to being 'Not Achieved'. You can use the 'Project Milestone' dashboard to monitor and plan how to manage progress reports.

Project Milestone dashboard - Filtering options

- Milestone Type – Progress Report
- Milestone Due Date – this can be filtered to your preference *i.e. 28 days prior to today will show you milestones that are overdue and would have had the first overdue reminder email sent*
- Milestone Status – Pending

You can then export this data (see image for highlighted export icon) or review the data on the screen by filtering the 'DueDate' column, this is done by clicking it to see the most overdue progress reports requiring action.

The frequency of the Ethics progress report reminder emails is as follow; the first email reminder will be sent 28 days from the milestone due date and then every 28 days after that until the milestone reaches 180 days overdue, at this point the system will automatically change the milestone status from 'Pending' to 'Not Achieved'. This is noted in the system generated emails.



With the system better monitoring and updating inactive studies and milestones, research offices can now plan to actively or passively manage overdue milestones.

- Active Management: Use the 'Project Milestone' dashboard to review milestones in the 'Pending' status that are overdue, these are highlighted red. You can then speak with the

researcher to advise them that urgent submission of progress report is required, or their study may be Suspended.

- **Passive Management:** Use the 'Project Milestone' dashboard to review milestones in the 'Pending' status that are close to 180 days overdue and/or milestones in the status of 'Not Achieved'. You can then speak with the researcher advising them that their milestone is close to being 'Not Achieved' and their study is at risk, or will be, Suspended unless the progress report is submitted urgently.

The eHealth REGIS team will be conducting a lunch and learn focussed on the recent system updates and how research offices can best utilise the dashboards available to manage study activity.

Research Office Contribution

ISLHD - Increasing Engagement with Heads of Departments and Clinical Stream Leaders

Over the last 6 months, the ISLHD Research Office has increased its efforts to ensure good engagement with our Heads of Departments (HoDs) and clinical stream leaders. The intention is to support the HoDs understanding of their responsibilities when it comes to research, enhance oversight of the scope and quantity of the research being undertaken within their streams, and also to facilitate timely turn-around for Head of Department approval.

Our 3 main methods for increasing engagement have been:

1. Using a template to send HoDs an email when we receive an SSA requiring their support. The email provides a brief overview of the project (listing any staff or resources from their stream) and requests their support via REGIS or return email.
2. We have streamlined requests from HoDs to know what research projects are being conducted by generating monthly reports for HoDs to show current authorised projects within their stream.
3. Our Research Development staff have been attending clinical stream department meetings to increase awareness of research and research services across the district.

*Up next is **MNCLHD!** We look forward to your contribution for **Issue 15 - 15 August 2023***

Researcher/Coordinator Contributions

Are you part of a research team that has created some great resources or worked through an issue or teamed up with your Research Office to streamline a process? We know this newsletter is going out far and wide AND we also know YOUR colleagues would love to hear what you've been doing. Feel free to send in a short blurb about what you're up to and we'll sing your success from the rooftops!

Upcoming events and dates

Audience: Research Office/Researcher



2023 Events and Dates

Researcher Training: The final training cycle for 2023 is scheduled for **September**. [Register your interest here.](#)

September: A preliminary date has been set for the forthcoming HREC Chairs Meeting, Friday 8 September. Further details to be provided closer to the date.

September: The forthcoming Ethics and Governance Bi-Annual Roundtable is scheduled for Friday 22 September. Further details and registration link to be provided closer to the date.

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/>

REGU/REGIS Newsletter: Inspiring other units within OHMR and LHDs since February 2021