

HEALTH+MEDICAL RESEARCH



REGU/REGIS Newsletter | Issue 12 | 6 July 2023

In this issue

- **Upcoming REGIS Update: Milestone Reminder Emails**
- **Case Study: Ethics Not Approved - New Version?**
- **Research Office Contribution - HNELHD**
- **Researcher/Coordinator Contributions**
- **Previous Versions of REGU/REGIS Newsletter**

Upcoming REGIS Update: Milestone Reminder Emails

Audience: Research Office/Researchers



Milestone reminder emails were temporarily disabled late last year due to emails being sent to a large number of invalid, external email addresses for Progress Reports. This caused a system strain which required the temporary disabling of these reminder emails.

In preparation for the milestone reminder emails being turned back on Wednesday 26 July 2023, the recent system enhancement 'Project Status Update' will assist in reducing the number of milestone reminder emails being sent for inactive studies as the status of any active study where Ethics HREC

approval had been expired for greater than 12 months will change to Suspended, meaning no reminder emails will be sent for those studies.

Researchers can currently review if they have any overdue milestone via their homepage 'Top 5 Milestones due'. This will list the top 5 most overdue milestones and as soon as an overdue milestone is submitted, the next overdue will appear in that list. If you do not have any overdue milestones you will see the next due or pending milestone.

Top 5 milestones due			
2021/ETH00768	Progress Report	Pending	20/10/2021 (622 days overdue)
2021/ETH00771	Progress Report	Pending	04/11/2021 (607 days overdue)
2021/ETH00748	Progress Report	Pending	18/05/2022 (412 days overdue)
2021/ETH00771	Progress Report	Pending	18/08/2022 (320 days overdue)
2022/ETH00078	Progress Report	Revision	31/08/2022 (47 days overdue)

Further communications will be sent closer to the milestone reminder emails being turned back on

Case Study: Ethics Not Approved - New Version?

Audience: Research Office/Researchers

The eHealth REGIS team recently received a query regarding the possibility of creating a new version of an Ethics application that had been Not Approved. The application was not approved due to the incorrect HREC being selected as it was an EPCT application.

When an Ethics application is submitted, reviewed and deemed to have the incorrect HREC i.e. application needs to be submitted to an early phase clinical trial (EPCT) HREC, the reviewing Research Office can mark the application as Ineligible, this will allow the applicant to create a new version of the application (making it editable) and update the ETH (HREA) form to select the correct HREC.

If an Ethics application is marked as Not Approved, this is considered a 'hard stop', meaning the applicant cannot create a new version of the application and an entire new application is required (project registration, Ethics application and any Site applications).

The screenshot shows a web form titled 'HREC' with navigation buttons: 'Previous', 'Track changes', 'Preview', 'Validate', 'Save', and 'Next'. Below the title, there are instructions and two dropdown menus. The first dropdown is for 'Q4.3 Select the Organisation that hosts the HREC or other review body*' and is currently set to 'Bellberry Limited - Early Phase Clinical Trial'. The second dropdown is for 'Q4.4 Select the HREC or other body to which you are applying from the list below*' and is also set to 'Bellberry HREC - Early Phase Clinical Trial'. Below these are fields for 'HREC or Review Body Contact Information' with a note: 'You may wish to seek advice from the HREC or Organisation's review body before finalising and submitting your application. Their contact information is outlined below.' The 'Organisation' field is also set to 'Bellberry HREC - Early Phase Clinical Trial'.

1 - Applications can update the HREC within the ETH (HREA) if it is editable

Research Office Contribution

HNELHD - Nothing for this issue but we can't wait to hear from you later in the year!

*Up next is **SESLHD!** We look forward to your contribution for **Issue 13 - 18 July 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.](#)

Research Office Training: Cycles are scheduled for **August and October**. [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: A preliminary date has been set for the forthcoming Ethics and Governance Bi-Annual Roundtable, Friday 22 September. Further details 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