



REGU/REGIS Newsletter | Issue 18

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Manually Updating CPI/PI Contacts



Audience: Research Office

We are seeing an increase in Research Offices manually updating the CPI or PI contact incorrectly which causes issues with post-approval activities submissions.

Typical Scenario: The REGIS team receives an email from a Research Office advising that there is an issue as the CPI or PI cannot see the 'Submit' button when submitting an amendment, safety report, progress report or milestone. Upon investigation it is identified that the CPI or PI details have been manually updated incorrectly by the Research Office. The REGIS team are then required to fix this.

What to do when the CPI or PI needs to be changed: REGIS manages the change of CPI and PI through an amendment. When the CPI or PI (as appropriate to where Ethics exists) correctly submits an amendment for a Change in CPI/PI and it is approved by Ethics and/or Governance the system will automatically update the CPI/PI details as appropriate, upon approval.

The only scenario where the Research Office should manually add a contact is on an Ethics Project when there has been a request to add an Editor as currently there is no option to add an Editor via an Ethics amendment. For any changes to the CPI, PI, Site Investigators or Editors (for a Site Project) this should be done via an amendment. If a Research Office is contacted by the study team and they request the CPI or PI to be changed as they have unexpectedly gone on leave or similar, then please contact the REGIS team and we can assist in these scenarios.

User Management

Audience: Research Office

The REGIS team has created a [quick reference guide](#) to assist research offices with managing user accounts, this includes guidance on how to add or remove a Head of Department or CE, how to request

internal portal permissions for new research office team members and defining the difference between internal and external users.

All new users need to register themselves in REGIS using the [Register](#) option on the REGIS website homepage.

National HREC Conference



Audience: Research Office/HREC

Human Research Ethics Committee (HREC) Members across Australia are invited to attend a free virtual Human Research Ethics Conference on 1, 2 & 3 December 2021. The purpose of the HREC Conference is to provide valuable, up to date information on areas related to HREC members. Participation in the Conference will also fulfil the annual training requirements for HREC members.

Themes will include;

- Consent
- Privacy
- Emergency care
- Horizon scanning
- Ethics and law
- Processes and best practice
- Use of data
- Vulnerable groups in research
- Non-medical research involving humans

- The future of ethics in Australia
- Research involving Aboriginal and Torres Strait Islander
- General ethical issues

Human Research Ethics Committee Members can register their interest using [this link](#).

REGIS Helpdesk Calls



Researchers are encouraged to contact the research office reviewing their study for any Ethics and/or Governance related queries. If you cannot reach your reviewing research office by phone we recommend sending an email as a large number of research offices are currently working remotely due to the COVID-19 situation.

Audience: Research Office/Researcher

There has been an increase in calls to the REGIS Helpdesk for non-technical issues, with a large volume of calls related to Ethics and Governance processes and queries. The REGIS Helpdesk provide technical issue assistance and cannot assist with Ethics and Governance processes or queries.

Researchers are encouraged to contact the research office reviewing their study for any Ethics and/or Governance related queries. If you cannot reach your reviewing research office by phone we recommend sending an email as a large number of research offices are currently working remotely due to the COVID-19 situation.

Research offices are encouraged to utilise the guidance resources available for completing processes in the system. If a research office has a non-technical REGIS query, please email the REGIS team via EHNSW-Regis@health.nsw.gov.au.

Global Shortage of Tocilizumab



Audience: Research Office/Researcher/HREC

Guidance on clinical trials using Tocilizumab (Actemra): Due to serious global shortages of intravenous tocilizumab (Actemra), the [Therapeutic Goods Administration \(TGA\) are recommending urgent conservation of stock](#). Roche is currently experiencing shortages of multiple presentations of Actemra in Australia. This is due to significant increases in global demand for Actemra in response to the COVID-19 pandemic. [COVID-19 Clinical Trials Supplementary Guidance](#) is posted on the [Commonwealth Department of Health website](#) and specifically advises that Sponsors of clinical trials using commercial stock of Actemra IV in the protocol:

- Delay and/or pause recruitment of new patients into existing clinical trials between now and January 2022
- Delay commencement of new clinical trials where any stock of Actemra IV is required as a rescue or comparator medication
- Advise TGA and Roche if any stock of Actemra IV supplies will be required between September 2021 to January 2022 for ongoing trials
- Advise TGA and Roche if delayed clinical trials activity frees up existing stock, or if you are aware of any unused Actemra stock that may not be needed between now and January 2022 that could be redirected, even if short-dated or recently expired.

The linked advice is reproduced by the NSW [Clinical Excellence Commission on its website](#). Contact for queries is contained in the advice.

Pause in ERM Training

Audience: Researcher

There will be a pause in ERM training for Applicants, Sponsors and CROs. The training schedule will resume again with dates to be announced in E-Bulletin at a later date. In the interim, ERM guidance can be found on our [Clinical Trials and Research](#) website. Look for the **Applicant user guide to ERM** and **ERM Training Tools**.

New REGIS Researcher Training Dates Available

Audience: Research Office/Researcher

The first ten cycles of REGIS Researcher training finished earlier this month and will now run as monthly cycles from Monday 11th October 2021. Use [this link](#) to register your interest and [click here](#) for more information on what the individual sessions will cover.

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/>

Research Office Contribution

Audience: Research Office

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