

HEALTH + MEDICAL RESEARCH



REGU/REGIS Newsletter | Issue 19

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NMA Committee Seeking Feedback - Due Friday 22nd October

Suggested update to standard PICF wording (ionising radiation)

Audience: Research Office

The National Mutual Acceptance (NMA) Committee met on Wednesday 29th September.

Victoria presented a suite of documents they have created to standardise and operationalise the ARPANSA Statement on Ethics Review for Multi-centre Trials released in February 2020.

The committee is seeking feedback from all jurisdictions regarding agreement on suggested wording in the Master and Site Participant Information Sheets regarding the radiation risk statement. (document attached)

- PICF wording re ionising radiation

Provide feedback here: [NMA ARPANSA Feedback Form](#)

Feedback required: Friday 22nd October (next NMA committee meeting Wednesday 27th October)

For more information on the [ARPANSA Statement on Ethics Review for Multi-centre Trials](#)

The following documents (attached to the email) have been shared by Victoria and can be used/implemented by any NSW RO:

- Flowchart ARPANSA version 1
- Instructions for Implementation

Sandpit - REGIS Training Environment

Audience: Research Office

Sandpit is the REGIS training environment for Research Offices. This environment is available to all Research Office staff and should be used to familiarise yourself with the system, system processes and somewhere you can test scenarios without worrying about effecting the live environment. REGIS training also occurs in Sandpit.

The REGIS sandpit is accessed here: <https://regisomnistartraining.f1solutions.com.au/>

If you do not have a Sandpit account, please contact the REGIS team and request an account be setup regis@health.nsw.gov.au. If you have an account but have forgotten your password, please use the reset password option.

DO NOT use the live environment to test scenarios or system processes as you risk causing a flow on effect to live applications/projects and also risk system correspondence being sent to applicants, Head of Departments etc.

Data Migration Issues

Audience: Research Office

If your office is receiving calls from researchers with issues that are related to data migration e.g. incorrect PI or Coordinator listed as PI or Admin contact not receiving emails, you can easily update this information in the system for your researchers.

1. Incorrect PI (or Admin Contact/Coordinator Listed as PI)

Where possible we suggest having an amendment form submitted and approved, this will ensure that all required areas in the system that need updating are completed by the automated workflow.

When it is not possible for an amendment to be submitted please use the guidance provided in Issue [13 REGU/REGIS newsletter](#) for how to update the PI details.

If the admin contact or the coordinator was incorrectly listed as the PI, remember to create a new Administration Role so they continue to receive system generated emails. If you do not know how to create a new Administration role please contact the REGIS team who will guide you through.

2. Duplicate Studies in REGIS

Can REGIS stop researchers registering duplicate applications?


There are two warning messages that show up in REGIS;

1. When the applicant states the study has been reviewed by a certified HREC and then enters a recognised REGIS ID
2. When the applicant states the study has been reviewed by a certified HREC and then enters a recognised external ethics ID

A2 Ethics application ID *

2020/ETH00870

This Ethics application has previously been added to REGIS under project identifier 2020/PID00973, please contact the project owner Corinne McDonough (corinne.mcdonough@health.nsw.gov.au) to be granted access to the existing application

 This ethics application has been registered in REGIS. The application id has been used for the following project(s):

- Project Id: 2020/PID00960, CPI: Kylie Becker, HREC: Anglicare Southern Queensland Human Research Ethics Committee

A new site should be created under this PID, please contact the CPI and request a new site application be created. see quick reference guide: [Create a new site application](#)

DO NOT CREATE A NEW PID

Currently there is no functionality to transfer an application from one PID to another.

When a duplicate study is identified the Research Office will need to work with the Researcher to have a new STE created under the correct PID.

When ethics is in REGIS, the submission of and amendment for addition of site is submitted and approved to have the new SSA created. The Research Office will need to guide the researcher through how to submit the new SSA once it has generated.

Some things to let them know;

- Part A: Complete any mandatory questions
- Part B: Add any Associate Investigators and the Admin Contact who should also get the system generated communications
- Part C: No HOD required. Please click the checkbox and the minus icon
- Part D: Respond No to all questions
- Part E: Respond No to all questions
- Part F: You have two options here. 1. Ask them to upload the current approved site documents. 2. Manually download the documents from the old file (if there is one) and upload the documents into the related document section in the internal portal.
- Part G: PI will need to hit Submit SSA button

Saving Researcher CVs in REGIS

Audience: Research Office

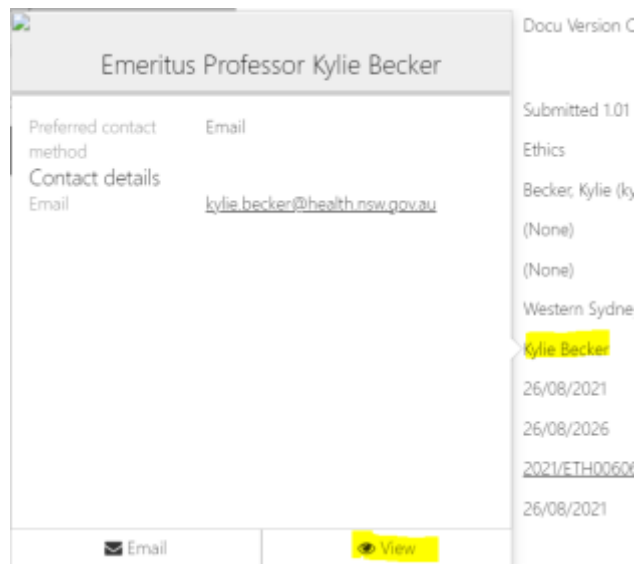
- Did you know that researchers can upload their CV into their profile and it can be accessed by all Research Offices in the internal portal? This is described in the quick reference guide: [Creating and Managing a REGIS User Account](#)

- Did you now that as a Research Office you can upload CVs or other documents (GCP certificates) into users profiles from the internal portal? All internal portal user will then have access to the document.

How to locate a CV/document in the Researchers Profile

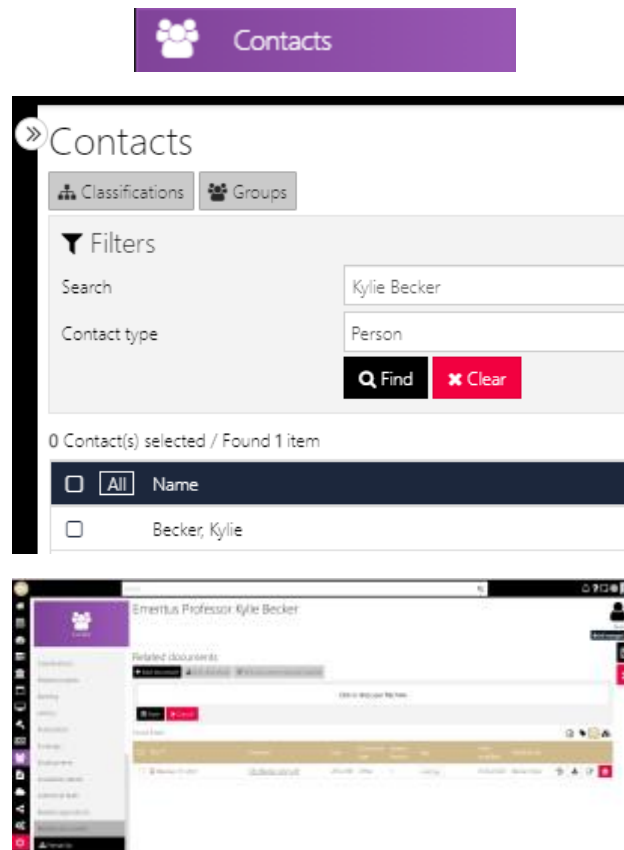
Locating CPI and PI contact details from the application and/or project;

1. In the Summary (or Overview) page hover over the Owners name for a contact pop up to appear and select View/eyeball OR be taken to ANY contacts listed in an application from Contacts menu option and then selecting the view/eyeball icon.
2. A new tab will open to their contact.
3. Navigate down to the Related Documents. If the document has been uploaded you will be able to download a copy.



How to upload a CV (or other document into a contact)

Navigate to the Contacts menu and search for the person, select them and you will be taken to their contact. Navigate to related documents and upload the CV or other document.



What is standard practice for CV collection?

In April 2021 the User Group was asked to respond to a survey about when and why CVs were collected. 14 Research Offices responded, what did we learn?

- 4 responded "we do not collect CVs"
- Of the 10 that do collect CVs no two requested CVs in the same scenarios

This variation means it is not possible to create standardised guidance in the NSW forms. Discussions at the User Group agreed that if a CV was required and was not uploaded with an application a request for information would be the tool to receive the document.

If you are a Research Office that does request CVs you may like to request your researchers upload a current CV into their profile or do this in the internal portal.

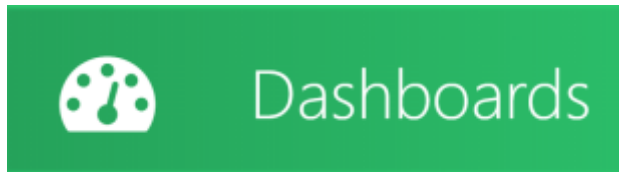
When does your office request CV? (select all that apply)

	LHD1	LHD2	LHD3	LHD4	LHD5	LHD6	LHD7	LHD8	LHD9	LHD10	LHD11	LHD12	LHD13	LHD14
New Ethics applications														
New Site Applications														
Amendment Change (PI/PI/PI)														
Amendment Change PI (PI/PI)														
Amendment addition of New Site (PI/PI)														
Amendment Change PI (Site)														
Other instances														
We don't submit CVs														

If Other, Please expand

LHD1	We request a CV for anyone listed on an SOA or SOI commitment, when we don't already have one on file for that person.
LHD2	Whenever a new Investigator is being added to a project we request a CV
LHD 10	Temporary Appointment
LHD 11	We check researcher status via ClinContract, ClinWork and grants. External researchers will upload go the contingent worker assessment or honorary appointment. Those external researchers will provide a CV to governance.

New Dashboard - Current Head of Department



Audience: Research Office

In the past, Research Governance Offices have been able to rely on the Contact Search function to generate and export a list of current Head of Departments within their LHD. The base product function has recently been changed and this is no longer possible. We have created a new dashboard that not only allows the Research Governance Offices to search and export the list of their Head of Departments but also provides the following abilities;

- Filter by (Full Name, Site, Department, Research Office, Centre, State)
- An interactive graphical representation of all sites

The list that is exported from the dashboard has been formatted with the exact same fields as the change Head of Department template. This will allow the Research Office to copy and paste the fields exactly as required to correctly update (add or remove a HOD).

If you have any questions regarding this, please email the REGIS inbox regis@health.nsw.gov.au

Updated QRG

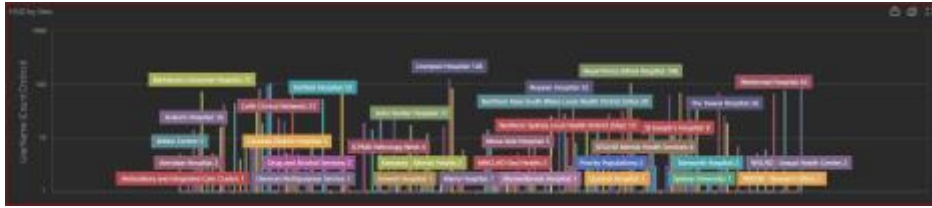
[New Head of Department Upload - Template Spreadsheet](#)

Updated Training Video

[Managing and Requesting HOD Changes in REGIS](#)



1 - Dashboard Overview



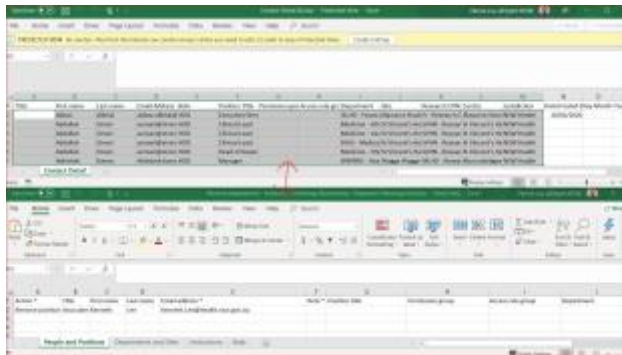
2 - Dashboard site bar-chart



3 - Dashboard Filter

A screenshot of a dashboard filter showing a table with multiple columns and rows of data. The table has a dark background and contains text in various colors. The columns are separated by vertical lines, and the rows are separated by horizontal lines. The data appears to be organized in a structured format.

4 - Dashboard Head of Departments list

A screenshot of a dashboard showing a list of Head of Departments. The list is presented in a table format with columns for name, title, and contact information. The table has a light background and is overlaid on a darker dashboard background. A red arrow points to a specific row in the table.

5 - Dashboard exporting detail and pasting to HOD template

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.