

REGIS Comms – Tuesday 9 Feb

Hello All,

Thank you to those who responded to the communication sent out last week. Based off the feedback fortnightly communications seem to be the preferred so moving forward this will be a fortnightly email. REGU and other teams in OHMR may also add items to these communications.

There were 4 people who indicated through the links in the previous email that they would like webinars on the specific items listed. If you think a webinar would be useful please make sure you click the link and provide a response. To make appropriate use of everyone's time a webinar will only be scheduled if 10 or more requests are received.

CPI/HREA attachment

We forgot to attach! Please see the CPI/HREA document that was intended to be attached to the previous email.

Upcoming Education Sessions

Thank you to everyone who completed the pre-training setup sessions and attended the first cycle of training, it was great to see such a large number attend which included people with many years of experience in the Research Office as well as people with a few weeks experience.

The next pre-training setup session will be held on Thursday 11 February from 9:30am-12:30pm. You cannot attend the training cycles until you have attended a pre-training setup session. If you did not receive the invitation for this setup session, please email EHNSW-Regis@health.nsw.gov.au to register for this session.

Training Cycle 2 will commence Monday 15 February and is held over 6 consecutive days. Day 1 is mandatory for all attendees and then you can choose to attend all days, Ethics only days or Governance only days. If you did not receive the invitations for these cycles, please email EHNSW-Regis@health.nsw.gov.au to register for this cycle.

Training Cycle Agenda
15/02/21 Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
16/02/21 Day 2: Ethics session – Review and Meeting
17/02/21 Day 3: Ethics session – Create decisions from within a Meeting and from the Application
18/02/21 Day 4: Governance session – Review and Authorisation
19/02/21 Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
22/02/21 Day 6: Optional session – Managing and updating the Head of Department List

Upcoming Releases

Milestone Reminders

It has come to our attention that annual report reminders have not been sending out from REGIS. This will start to happen from **Wednesday 3rd March**.

Researchers will receive, from 3 March, system generated emails to say they have not submitted their progress reports.

5 Progress Report milestones are created in REGIS on the approval of the ETH. They are due at each anniversary of the ethics decision notification being sent. If your Research Office has or still is accepting annual reports outside of REGIS then your researchers may have several milestones showing in the system as overdue when they should not.

How do I identify overdue milestones?



You can use the Report “Progress Reports Overdue” to identify overdue progress reports for your Research Office.

To export the report select “Export To”  and then select the format you want to download to, a temporary download will appear in your downloads folder.

How do I correct the information in the system if an annual report was processed outside of REGIS?

Navigate to the ETH project --> Select Milestone --> click on the overdue milestone --> Click Edit --> select Process milestone --> Enter the date the annual report was received outside of REGIS and the date it was noted by the HREC --> select next --> select next --> select next (this is not a typo) --> click on the send email toggle so it switches to “No” --> select the green click.

If you would like to upload the annual report and HREC approval you can upload into the documents section of the milestone before the “select process milestone”.

You may need to manually share the documents, so sites have access to them.

Remember the changes made in the system will not be seen in the report until the next day.

I would like a webinar on correcting overdue milestones

Data Migration

Patrick will hold a Research Office webinar to discuss the upcoming data migration. Invitations have been sent out today.

If you have not scheduled a one-on-one catch up with him and you intend to, please do this ASAP.

HREC Extension – need to add new milestone

When a Research Office processes an HREC extension approval in REGIS a new milestone should be manually created in the ETH project. This is done in the ETH Milestones section, +Add milestone.

Edit --> + Add milestone --> Add title (this is what the applicant will see so you can choose to make it more descriptive e.g 2020/ETH00871 Progress Report) --> select type --> Add current due date --> OK.

I would like a webinar on how to create milestones manually

Coordinators not receiving emails - normally occurs for migrated studies

If your office is contacted by a researcher noting that the admin contact/coordinator isn't receiving REGIS communications, you should check to see if they are listed in the role of **Administration** in the Contacts section. If they are not listed you can manually add them, if they are listed in a different role such as Administration Contact you can change their role to the correct role.

How to change the admin contact role from “Administration Contact” to “Administration”: Locate study --> Management --> Contacts --> select edit --> Locate the role “Administration Contact” --> click on the “Edit contact” icon --> at the top of the screen change the role by selecting the drop down --> click ok --> click Save

The Administration role without a relationship inherited from other entities is the one directly related to the application/project. Remember if the study is approved/authorised add them in the Project not the Application.

This will be address in the near future with a system wide update but in the meantime if you get a call from a researcher/admin contact you will be able to manually correct it.

I would like a webinar on how to manually update contacts

New Research Office Users

New Office staff requiring REGIS access should now create their own accounts in REGIS and Sandpit.

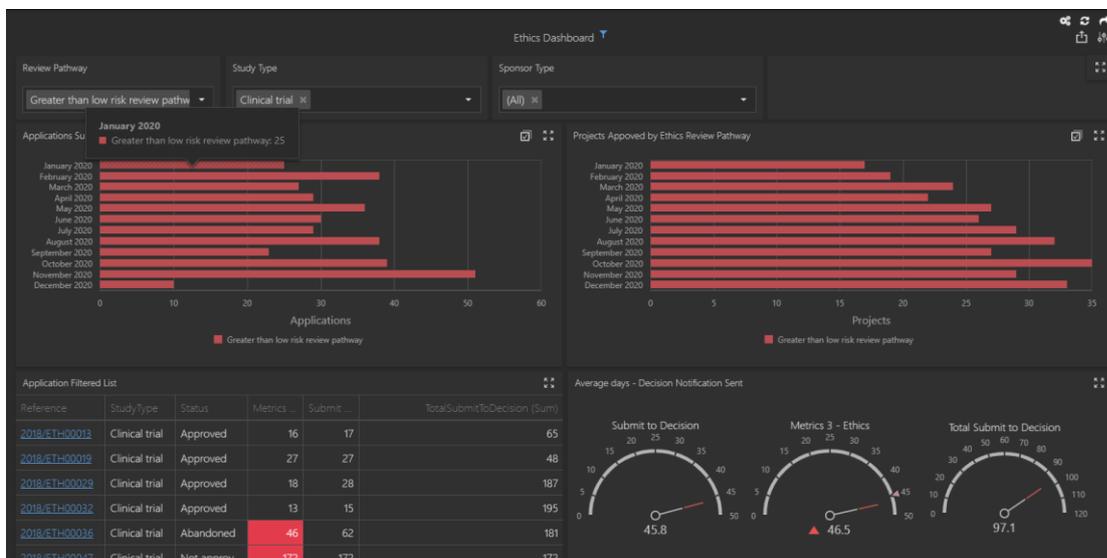
Production log in: <https://regis.health.nsw.gov.au/>

Sandpit log in: <https://regisomnistartraining.f1solutions.com.au/>

Navigate to the Register an account link. Once created please email the REGIS inbox (EHNSW-Regis@health.nsw.gov.au) and our team will add the required accesses and confirm when completed.

Ethics and Site Dashboard

We have had a couple of calls from RO who are seeing data in the Application Filtered List that should not be there. On these occasions it has been due to the RO not selecting the specific data from the Applications Submitted or Project Approved tables before exporting the data



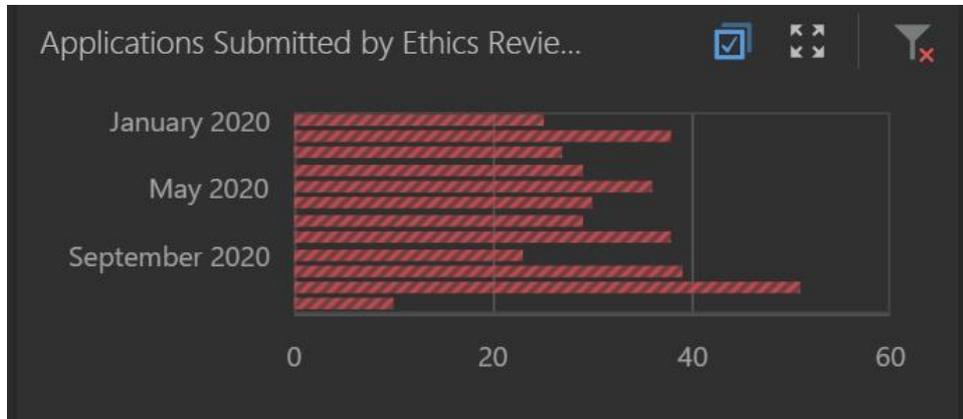
In the screenshot above the RO has entered a date parameter of 1 Jan 2020 – 31 Dec 2020. They have filtered the review pathway to GTLR and the Study Type to Clinical Trial.

The table on the left shows all applications **submitted** within the parameters set above (submitted between 1 Jan 2020 – 31 Dec 2020, classified as GTLR, classified as CT)

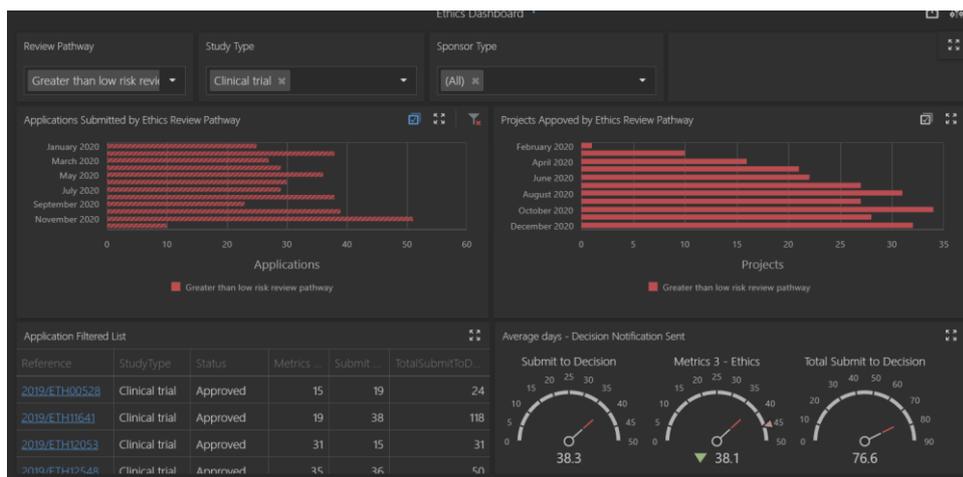
The table on the right shows all applications **approved** within the parameters set above (approved between 1 Jan 2020 – 31 Dec 2020, classified as GTLR, classified as CT).

Currently the Application Filtered list and Average days gauges are showing data from BOTH the tables. If the RO exports the data at this point the filtered list will show all data from BOTH tables. To filter to specifics the RO needs to select from either the approved or submitted table.

e.g. to get a list of all SUBMITTED studies the RO needs to select the multi select option in the application submitted table and select each month to include in the list.



All months in the application submitted table have been selected, this is indicated by the rows showing as shaded/crossed



This will now change the data shown in the application filtered list to ONLY the applications approved and this is the data that is shown in the application filtered tab in the output.

The RO needs to also remember to CLEAR the filter before attempting to filter for a different data set e.g. approved studies.



I would like a webinar on the Ethics and Site Dashboard

NHMRC Report

The NHMRC report is available for the RO as a dashboard "NHMRC Redesign".

Please see the attached guidance document that describes how to use the dashboard.

I would like a webinar on the NHMRC dashboard

Governance Amendments – Ethics Exists in REGIS

A question was raised at the last cycle of training asking what the RO should do if an applicant submits a governance amendment (general) without listing the ETH amendment form ID.

We know that as a RO you are trying to process items as quickly as possible without going back to the researcher/applicant, however if the applicant is not providing the RO with the information required to fulfil the request it is not unreasonable to request more information.

On this specific occasion the instructions are detailed for applicants in the QRG, the walkthrough video and form.

If you think there is a better way for the system to handle a process, please forward your suggestion on to your user group representative.

Correspondence for Noting/Acknowledgement

Currently, there is no functionality in the system for general noting/acknowledgement of correspondence. This is expected to be part of a future enhancement.

We are aware some RO are accepting a general amendment in the absence of a formal pathway.

Ethics - If you are accepting through this pathway, please make it clear in the approval/noting email that this is NOT a general amendment but a noted document by changing the subject line and email body. Please also change the automatically created document tag from "General Amendment" to "Noted" or "Acknowledged". This will make it clear to related sites who will receive the documents.

Governance – If you receive a site general amendment documents for noting add a document tag

Enhancement update

Requested as feedback from last week's email "*Updated timeline/ETA for highly requested improvements e.g live clock (tallying days) on projects pending review/authorisation*"

The User Group is the body that considers all the enhancement requests received throughout the year and prioritises each item as a Must Have, Should Have, Could Have or Won't Have. This is currently done annually and is provided as a recommendation to OHMR who work with the vendor to assess items such as system ability, cost/benefit and overall budget.

Last year's enhancements, released in September 2020, focused on the introduction of governance post approval and document management as the main priority.

The User Group received and was asked to provide their prioritisation of approximately 150 items at the end of last year and are scheduled to meet on February 16 to discuss the outcome of the votes. Reporting and metrics are on this list and is anticipated that this item will be addressed in an enhancement this year.

How to provide an enhancement request

Until now we have accepted suggestions and enhancement requests via a number of formats including direct emails, phone conversations and via the REGIS website. Feedback from the UG during the initial prioritisation was that several enhancement requests did not make sense, which made the task of prioritisation difficult.

We do not want anyone's ideas being missed or discounted (there have been some good ones), so we have created a feedback form for enhancement requests. Research Office staff are asked to provide this completed form to their UG representative who will pass it onto the REGIS team once they are confident they also understand the request.

Please see attached the new REGIS feedback form

Data Quality/Cleaning

We have received feedback that receiving and checking 3-6 months' worth of data for errors and inconsistencies is a burden on top of regular workload. To reduce this burden, REGU will be sending data to be checked monthly.

It is recommended that RO build quality checks into their everyday procedures which will reduce the number of cleansing requests. January's data will be sent this week with instructions for what to look for and how to make the appropriate changes.

I would like a webinar on data quality checks