REGIS Comms – Tuesday 9 March

Hello All,

Welcome to issue 4 of the REGU fortnightly communication. We have been very happy with the feedback to date and to hear that this fortnightly communication is useful to you.

Please note this isn't just a REGIS communication, but a Research Ethics and Governance Unit (REGU) communication and REGIS is part of this unit. This will be our formal mechanism in keeping you up to date.

What's in this issue:

Ethics and Governance Roundtable: 30 April 2021 - SAVE THE DATE

We are pleased to announce that (further COVID outbreaks notwithstanding) the Research Ethics and Governance Unit will host a **face-to-face Roundtable** on 30 April. It will be at the **Rydges World Square**; and we have secured discounts on accommodation for those travelling and needing to stay overnight.

We will send further information out soon. An agenda will be sent out closer to the date.

OHMR supports the CT:IQ Joint Position Statement on Electronic Signatures

Through work endorsed by the national Clinical Trials Project Reference Group (CTPRG), CT:IQ has coordinated a Joint Position Statement on Electronic Signatures for Clinical Trial Research Agreements. OHMR contributed to the development of the statement and supports the content.

OHMR Recommendation to LHD/SHN Research Offices:

- Develop and publish on your website public facing guidance on how your office processes electronic signatures on CTRAs and other documents.
- Determine which position is the delegate to execute CTRAs and, if appropriate, consider stating this in your guidance.
- If you require your contracting partner to set up certain authorisations in the e-sign platform (eg/ Adobe Sign or DocuSign), include this in the guidance as well. This includes where an RGO is a reviewer (contact point) but is not the delegate authorised to execute the contract.
- Reference to such public guidance will give confidence to contracting partners in the LHD/SHN processes, such that greater acceptance of e-signatures from sponsor organisations and others should result.

- OHMR does not believe there should be any requirement to publish or communicate a Chief Executive's email address if guidance is in place.

https://ctiq.com.au/wp-content/uploads/Joint-Position-Statement_Electronic-Signatures.pdf

Upcoming REGIS Education Sessions

Thank you to everyone who completed the pre-training setup session and attended the third cycle of training.

The next pre-training setup session will be held on Thursday 11 March 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 4 will commence Monday 15 March 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
15/03/21 Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
16/03/21 Day 2: Ethics session – Review and Meeting
17/03/21 Day 3: Ethics session – Create decisions from within a Meeting and from the Application
18/03/21 Day 4: Governance session – Review and Authorisation
19/03/21 Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
22/03/21 Day 6: Optional session – Managing and updating the Head of Department List

New Staff – If you have recently attended REGIS training and have been in the role for less than 3 month it is highly recommended that you join us again for Cycle 5 commencing Monday 29 March and finishing Wednesday 7 April for refresher training (we have made sure to not schedule anything on those upcoming Public Holidays!).

There is a lot to learn in any new role and learning a new system on top of that can be a little overwhelming! As REGIS will be your main tool in the Research Office, we think that coming back after working in the system for a few weeks, or months, will allow you to have a different take on the training and also sharpen your skills.

If you would like to register for this refresher cycle, please email EHNSW-Regis@health.nsw.gov.au to register for Cycle 5.

Managing and Requesting HOD changes in REGIS

Managing and Requesting Head of Department changes is day 6 of the REGIS training. This session is stand alone and you do not need to complete any pre-work if you would like to attend the upcoming HOD session please contact Corinne through the REGIS inbox to register. Attending the live session is recommended as you

will have the opportunity to ask questions, however if you are not able to attend this session a training video has been uploaded onto the REGIS website. See the Day 6 REGIS Online Training video here.

Data migration

Patrick is currently processing all of the files that have been received. Research Office's should have a combined worksheet for final verification. **This must be returned by 12th March 10:00am.**

Below is the summary of rows from the files received, please get in touch if you believe this number is inaccurate:

AURED Applications to be migrated				**Non AURED application to be migrated**		
	Ethics	**Gov/Site**		**LHD**	**Ethics**	**Gov/Site**
CCLHD	**-**	**1**		**CCLHD**	**-**	**2**
HNELHD	**2**	**4**		**IS**	**-**	**14**
ISHLHD	**-**	**4**		**NNSW**	**-**	**3**
MNCLHD	**-**	**1**		**NS**	**-**	**9**
NBMLHD	**-**	**3**		**SESLHD**	**23**	**107**
PHSREC	**2**	**-**		**SVHN**	**4**	**2**
SCHN	**2**	**1**		**WSLHD**	**4**	**-**
SVHN	**1**	**-**				
SWSLHD	**-**	**21**				
SLHD (RPAH)	**1**	**248**				

What will happen if new applications are identified after this migration exercise?

This is the final migration that the REGIS team will be managing. Any applications that are identified after 10th March will need to be manually entered by the applicant.

All active human research studies are expected to be managed in REGIS. Except for studies that will be concluding in under 12 months.

Milestone Reminders

There were a number of Research Offices contacting us with queries regarding milestone reminders and consequently the decision to delay the reminder release by one week was made.

Reminder emails WILL BE switched on, on Wednesday 10 March. (tomorrow)

There are 3 types of reminders:

- Progress Reports (Ethics in REGIS)
- Certificate of Currency
- Progress and Final Reports external HREC

All Research Offices are **REQUIRED** to accept **ONLY** the REGIS created forms. Form will be reviewed this year where edits will be discussed and agreed upon through the User Group.

Reminder Type	**Reminder 1**	**Reminder 2**	**Overdue**
Progress Reports (Ethics in REGIS)	28 days prior to the milestone due date. System generated email sent to CPI and Administration Contact.	14 days prior to the milestone due date. System generated email sent to CPI and Administration Contact.	Every 14 days until the milestone is submitted. System generated email sent to CPI and Administration Contact.
Reminder Type	**Reminder 1**		**Overdue**
Certificate of Currency	On milestone due date. System generated email sent to PI and Administration Contact.		Every 7 days until the milestone is submitted. System generated email sent to PI and Administration Contact
Progress and Final Reports external HREC	10 days prior to the milestone due date. System generated email sent to PI and Administration Contact.		Every 14 days until the milestone is submitted. System generated email sent to PI and Administration Contact

Please see attached the system generated email template.

Please see the guidance on the 9 February communication for instructions on how to identify overdue milestones and how to action.

Understanding Classifications

Classifications are not just for OHMR to pull metrics, they are a very useful tool for Research Offices as well.

All classifications, except the ethics pathway, are created by applicants submitting project registration. The ethics pathway is created on submission of the HREA.

During eligibility or the initial review Research Offices should check the classifications and make changes if required. Classifications should be correct **BEFORE** Approving/Authorising a study so they flow from the application to the project, but can be updated at any time.

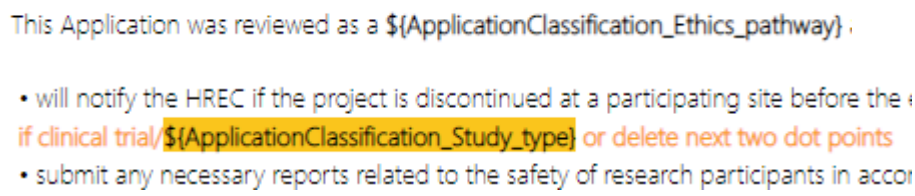
Classifications are used by the system for reporting/metrics, dashboard filtering, email templates, smart forms showing/hiding sections, creating milestones e.g. certificate of currency and first patient milestone.

Types of classifications: Category of research, Clinical Trial Agreement, Clinical trial phase, Clinical trial type, CTN/CTX, Early Phase Clinical Trial, Ethics pathway, National Mutual Acceptance, Prior ethics outcomes, Research Involves Children, Risk Category, Sponsor Type, Study type

The two most important classifications are **Ethics Pathway** and **Study type** as these will bring up additional questions in smart forms such as the progress report form, pull through in email templates, create a certificate of currency milestone and create the first patient in milestone.

How classifications are used in email templates

You can see below HREC approval email template is using the ethics pathway and study type classification. The ethics pathway makes it clear to all sites receiving the email under which pathway the study has been reviewed. The Study Type classification shows if a study is a clinical trial or other study type, if a clinical trial the Research Office know to keep the next two dot points.

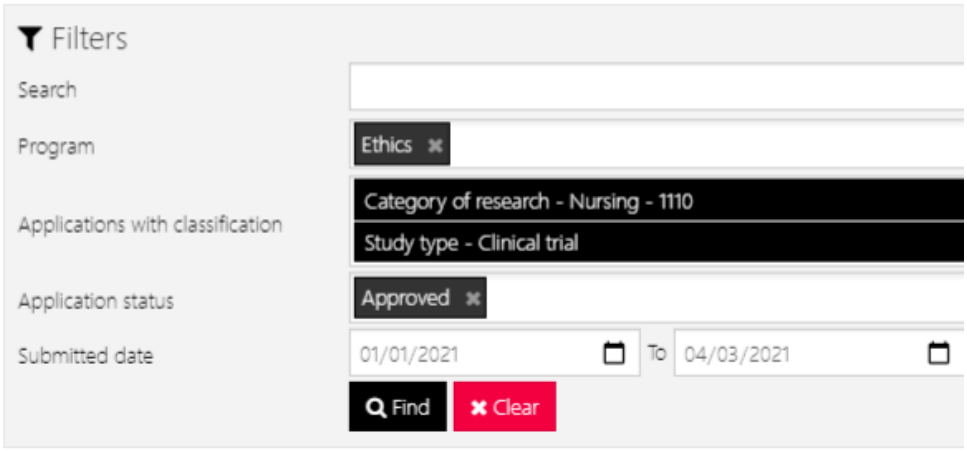


If your email template has a visible token that is because the bit of information it is trying to pull in the system doesn't exist – don't manually fill in the email, locate the source and complete.

How classifications can be used in basic application and project searches?

Classifications can be used for basic searches in the application and project search function e.g. this search is looking for:

- Program = Ethics
- Category of research = Nursing
- Study type = Clinical Trial
- Status = Approved
- Submitted from 1 January – 4 March
- = 58



Metrics calculation

We continue to receive queries on how metrics are collected/calculated in REGIS. During the process of submitting, uploading, approving or modifying an application in REGIS, date/time data points are automatically generated to capture when data was entered in the system (producing an audit trail). It does not allow a user to manually enter data to reflect when a process has occurred outside of the REGIS system.

Metric dates are calculated in two ways: **Total Time** and **Adjusted Time**.

Total Time calculates the end-to-end time for an application to be approved (that is, without a 'clock on/clock off' function). Adjusted time works by making **Interim Date Adjustments.** These calculation adjustments to the total time to account for processes where an application is worked on by both Research Office staff and the Researcher (that is, where a 'clock on/clock off' function is employed). These calculations determine whether applications are processed within the specified timeframes.

Metric 3 Calculation:

Criteria - Metric 3 is calculated by taking the total number of ethics applications approved (with or without conditions) in the reporting period. These applications are filtered by *classification* so that only applications with the Greater than Low Risk classifications remain.

Calculation - The total time is calculated by subtracting the **Submission Closing Date** of the first meeting the application is assigned to from the **Date the Decision Notification Email** is sent. The adjusted time is calculated by making **Interim Date Adjustments** and subtracting this time from the total time.

Metric 3 = ([Decision Notification Email] - [Submission Closing Date]) - [Interim Date Adjustments]

Metric 4 Calculation

Criteria - Metric 4 is calculated by taking the total number of site applications authorised (with or without conditions) in the reporting period. These applications are filtered by *classification* so that only applications with the Greater than Low Risk classifications remain.

Calculation **-** The total time is calculated by subtracting the **Start Date** (either the Submission Date, Ethics Approval Date, or the date External Ethics Approval is uploaded to REGIS) from the **Date the Decision Notification Email** is sent. The adjusted time is calculated by making **Interim Date Adjustments** and subtracting this time from the total time.

Metric 4 – (Start Date [Submission Date/Ethics Approval Date/External Approval Upload Date] - [Decision Notification Email]) - [Interim Date Adjustments]

National Teletrials Compendium on the Australian Government Department of Health's website

The Clinical Trials Project Reference Group (CTPRG) endorsed the National Teletrials Compendium on November 2020. **National Teletrials Compendium**.

The Teletrials Compendium supports a national approach to teletrials and consists of:

- The National Principles for Teletrials in Australia
- The National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia.

Compliance with the principles and standard operating procedures assures the public that:

- clinical trials protect the rights, safety and wellbeing of those who take part
- the data generated from the clinical trials are credible

Removing COVID data

Unfortunately, due to poor compliance with the completion of the COVID data this data source unusable. The COVID questions will shortly be removed from all forms. The entering of this data in the internal portal is no longer required.

Contacting the REGIS Team

Just like you we are receiving a huge number of emails daily, we are currently reviewing our processes so we can better manage the number of queries we receive and we will shortly be introducing a new way to log general (not technical) system issues and enhancement requests.

For now, the best way to log an issue or request for help with our team is through the REGIS inbox address regis@health.com.au. We do our absolute best to respond as quickly as possible, if you do not get a response in a couple of days please follow up with another email. If you have an urgent issue, please put this in the subject line.

Reporting technical issues to F1: If it is an initial request to the technical helpdesk, we do not need to be included in the email. If you need to bring an F1 ticket to our attention because you have not had a response in couple of days or you are not sure the advice is correct, please cc the REGIS inbox into the reply.

Want more information on any of the items above, have feedback or would like something added to an upcoming issue? Please contact us through the REGIS inbox regis@health.nsw.gov.au

Milestone reminder email template

Reminder

Subject: 2021/ETH00003: WILL BE due 03/03/2021 - Progress Report, Reminder 1

Body: Dear Ms Kylie Becker,
2021/ETH00003: Study title
Our records indicate that a **Progress Report** for this project **will be** due **03/03/2021**.

All Progress Report are required to be submitted in REGIS.
If you do not complete this milestone requirement the ethical approval for your project may become invalid.

How to submit a Progress Report in REGIS:
Please refer to the quick reference guide for submitting a Progress Report to NSW/ACT HREC

Access the **Progress Report** form directly by clicking this link or visit https://REGISomnistaruat.f1solutions.com.au/OmniNet/Project/MilestoneDetails?projectIdentifier=2021%2fETH00003&milestoneId=27879.

If you have submitted this milestone, please contact the research office managing this study to discuss.

Thank you
This is a system generated email please do not respond

Overdue Email

Subject: 2021/ETH00003: Progress Report due **12/09/2020** OVERDUE

Body: Dear Ms Kylie Becker,
2021/ETH00003: Study title
MILESTONE OVERDUE PLEASE SUBMIT URGENTLY

Our records indicate a **Progress Report** was due on **12/09/2020**. The submission of this milestone is a condition of HREC. Failure to submit overdue milestones may stop you from being able to submit other post approval forms e.g. amendments and may also cause ethics approval to be halted.

All Progress Report are to be submitted in REGIS.
How to submit Progress report in REGIS:
Please refer to the quick reference guide for submitting a Progress Report to NSW/ACT HREC.

Access this **Progress Report** directly by clicking this link or https://REGISomnistaruat.f1solutions.com.au/OmniNet/Project/MilestoneDetails?projectIdentifier=2020%2fSTE01477&milestoneId=27736.

If you have submitted this milestone, please contact the research office managing this study to discuss.

Thank you
This is a system generated email please do not respond