

Hi All,

Welcome to issue 16 of the REGU/REGIS newsletter with a governance spin but something for everyone.

In this issue

- Release delayed (release notes updated)
- Senior Policy Officer – Advanced Therapeutics – Position Advertised
- REGIS Training and Communication – Subject Matter Expert – Position Advertised
- Application and Post Approval Flow – updated resource on website
- What to do if a HOD does not respond
- Manual status changes “Completed pending HOD”
- Deleting Classifications – Ethics Pathway
- Site Milestones - identifying if a site milestone needs to be created (report attached)
- Site Milestones - understanding what to do when a multisite annual report is submitted
- SSA – Understanding/Identifying when Ethics is approved

## Release delayed by 1 week to 1 September

**Audience:** Research Office/Researcher

The release scheduled for Wednesday 25 August (enhancement and product update) has been delayed by 1 week. The new release date is Wednesday 1 September.

See: **Updated [Release notes](#)**\* and supporting [walkthrough video](#) that describes the major change to the related document upload sections.

\*there are 4 new items added to the release notes for Research Offices

## Senior Policy Officer - Advanced Therapeutics

**Audience:** Research Office/Researcher

Applications are now open to join the Advanced Therapeutics Team. If this of interest to you, or someone you know, please see the advertisement, role description and targeted questions to address at the following link: <https://iworkfor.nsw.gov.au/job/senior-policy-officer-264233>

**Please note the closing Date: 3<sup>th</sup> September, 11:59pm 2021**

If you have any questions, please contact Julia Warning, Principal Policy Officer at [julia.warning@health.nsw.gov.au](mailto:julia.warning@health.nsw.gov.au)

## REGIS Training and Communication - Subject Matter Expert

**Audience:** Research Office/Researcher

Applications are now open for the REGIS Training and Communications Subject Matter Expert. This role has commenced advertising internally to NSW Health.

In order to view the job posting, you are required to log into the NSW Health Career portal to view the internal job posting. NSW Health Career portal - <https://jobs.health.nsw.gov.au/>

Once you have logged in with your Stafflink credentials – search “REQ253023”

**Applications close midnight Monday 30<sup>th</sup> August 2021.**

## Application and Post Approval Flow

**Audience:** Research Office/Researcher

The application and post approval flow documents shared with the last email is now amalgamated into a single document and is available on the [REGIS website](#) on the training and resources page under **handy links**.

## What to do if a HOD does not respond?

**Audience:** Research Office/Researchers

There may be a number of reasons a HOD does not respond to the REGIS request to provide their support to a site application:

- They don't know about the study
- They are on leave or have left the organisation
- They indicate they are not the correct person to provide support

**Researcher:** Applicants are strongly encouraged to discuss their project/study with any/all HOD before submitting the applications for HOD support. Applications that are discussed with the HOD prior are getting signed off faster.

If after multiple requests you have not been able to get a HOD to sign off in REGIS you can “submit to RGO without HOD support” by following the quick reference guide: [Head of Department HOD Not Supported](#) page 2 “submit without HOD support”. This option should only be used after discussing your issue with the Research Office.

**Research Office:** If a Head of Department does not respond through the REGIS it is important to **not manually change the status** but to **override the decision** so it is not left blank. Follow the guidance in the quick reference guide: [Reviewing the site application](#) page 2 Overriding a HOD decision – individual. Select the “Able to support” option but add comment that this person will not/has not provided support.

If an alternative HOD has been identified create a new HOD decision.

## Changing the Status to Completed pending HOD and no HOD decision existing

**Audience:** Research Office

**Issue:** We are seeing a number of manual status changes in the system to Completed Pending HOD but there is no corresponding HOD decision in the system. Manual status changes are the number 1 reason the metrics calculations are not accurate.

**Outcome:** If the Research Office identifies an additional HOD sign off is required they should create the decision in REGIS. If a HOD responds via an alternative method e.g. email, the Research Office can override the decision noting to alternate form of support.

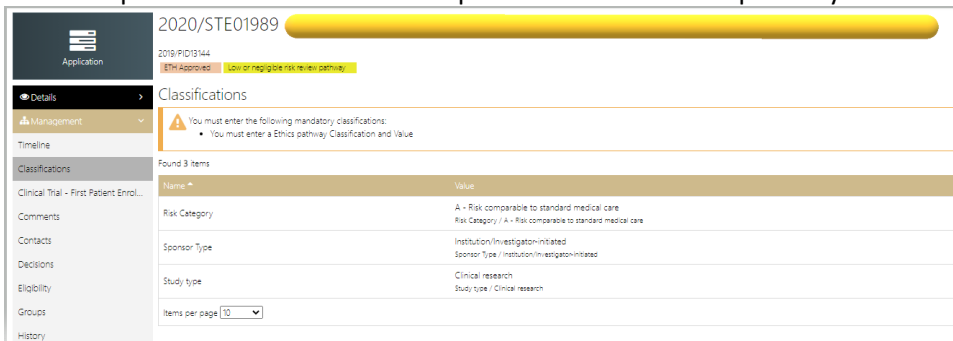
We know there was an issue where status were not changing as expected, however this has been addressed. Please contact the REGIS team if you would like to discuss specific Research Office needs.

## Deleting Classifications - Ethics Pathways Missing

**Audience:** Research Office/Researchers

**Issue:** Through our own data quality exercises we are seeing a number of instances where the Ethics Pathway classification has been deleted.

The example below shows a live example of where the ethics pathway was deleted.

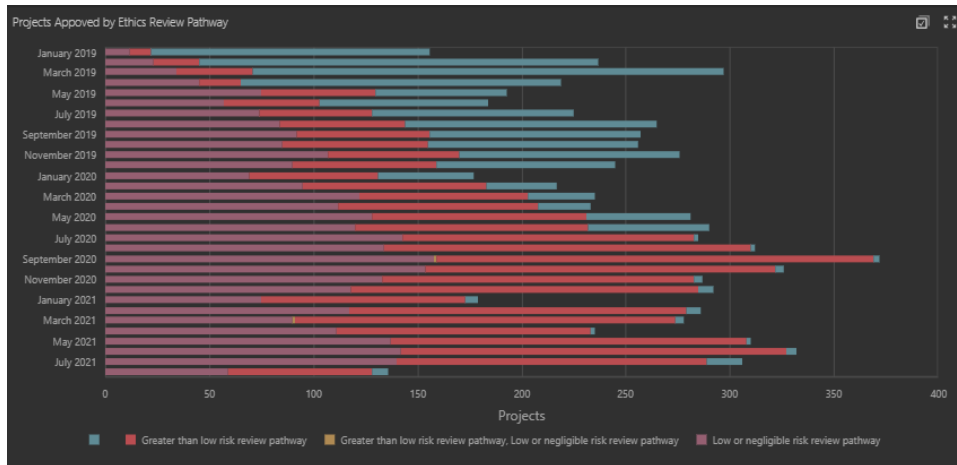


The screenshot shows the REGIS interface for application 2020/STE01989. The application status is '2019 PID1344' and 'ETH Approved'. A yellow banner at the top indicates a 'Low of the eligible risk review pathway'. The 'Classifications' section shows a warning: 'You must enter the following mandatory classifications: You must enter a Ethics pathway Classification and Value'. Below this, a table lists three classifications:

Name	Value
Risk Category	A - Risk comparable to standard medical care Risk Category / A - Risk comparable to standard medical care
Sponsor Type	Institution/Investigator/Initiated Sponsor Type / Institution/Investigator/Initiated
Study type	Clinical research Study type / Clinical research

How to identify missing classifications using the dashboards. It's really easy!!!!

Below is a REGIS wide representation of all Site applications approved in REGIS, the blue indicates where an Ethics pathway classification does not exist.



How to update see QRG: [understanding dashboards](#) page 2 “Using the dashboard to Quality Check (QC) Data”

Confirming the ethics pathway is correct/exists should be done BEFORE approval/authorisation emails are sent out. This information is used as part of the template so it should be obvious that it is missing.

If you would like to discuss your office processes or issues in this area please contact the REGIS team.

## Site Milestones - identifying if a site milestone needs to be created

**Audience:** Research Office

**Issue:** Migrated studies were created with a single milestone and Research Offices are now realizing they may not have manually created a new milestone after the initial one was approved.

**Outcome:** The REGIS team has created a report (attached project and milestones v3.xlsx) that will allow Research Offices to identify studies where a milestone has been processed and no other milestones created.

### How to identify STE projects that have not had a milestone submitted in the previous 12 months

Filter the following columns by:

- **Primary Organisation Name** (column E) by: select your sites
- **Milestone Status** (column G) by: Achieved and Pending
- **Over 12 month since last processed** (column M) By: Over 12 months and Less than 12 months

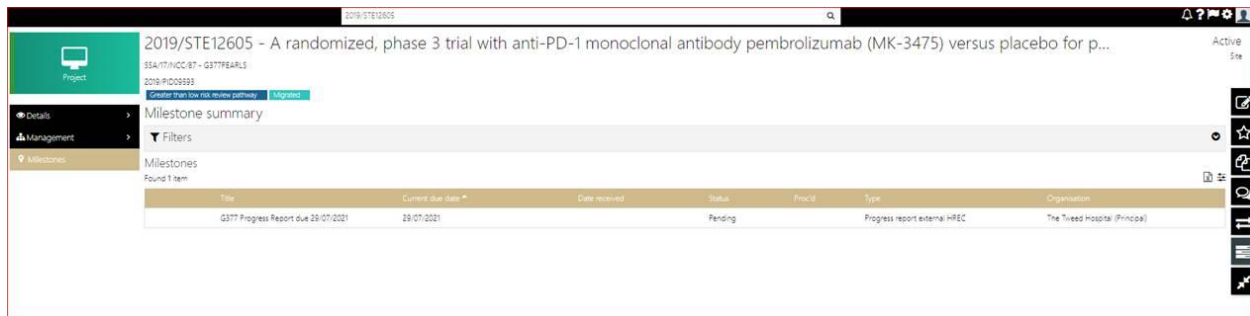
This will give you a list of all site applications that have had a milestone processed and may need a new milestone created.

C	E	F	G	H	I	M	R	S
ProjectIdentifier	PrimaryOrganisationName	Milestone Type	Milestone	Milestone Organisation	Milestone	Over 12 month since last processed?	HREC Expiry	
2018/STE00203	Hunter New England Local Health	Progress report external HREC	Achieved	Hunter New England Local Health District (Site)	Annual Proc	Over 12 months	22/08/2024	
2018/STE00563	Sydney Children's Hospital Randwick	Progress report external HREC	Pending	Sydney Children's Hospital Randwick	2018/STEC	Less than 12 months	18/12/2023	
2018/STE00569	The Children's Hospital at Westmead	Progress report external HREC	Pending	The Children's Hospital at Westmead	2018/STEC	Over 12 months	19/12/2023	
2019/STE00142	The Children's Hospital at Westmead	Final report external HREC	Achieved	The Children's Hospital at Westmead	2019/STEC	In the future	31/01/2024	
2019/STE00143	Sydney Children's Hospital Randwick	Progress report external HREC	Achieved	Sydney Children's Hospital Randwick	2019/STEC	Less than 12 months	31/01/2024	
2019/STE00155	John Hunter Hospital	Progress Report	Achieved	John Hunter Hospital	2020 Annual	Over 12 months	1/03/2024	
2019/STE00201	Westmead Hospital	Progress report external HREC	Pending	Westmead Hospital	Annual Proc	Less than 12 months	8/02/2024	

(please note there are several columns being hidden, eg, original due date, PI information, last modified, last processed etc, you are welcome to unhide these columns)

### How to address:

Locate the STE project in REGIS, navigate to the Milestone section of the project. If a milestone has been processed and a new milestone has not been created, create a new milestone.



Title	Current due date*	Date received	Status	Principal	Type	Organisation
G377 Progress Report due 29/07/2021	29/07/2021		Pending		Progress report external HREC	The Tweed Hospital (Principal)

Remember when a milestone is processed in REGIS you should check to confirm that the next milestone exists. If it does not exist, you will need to manually create it.

See quick reference guide: [Processing a governance milestone](#) page 2 for steps to manually create a milestone.

## Site Milestones - understanding what to do when a multisite annual report is submitted

**Audience:** Research Office

**Issue:** Site annual reports (when ethics is from another jurisdiction) have been identified as one of the processes that to address in a future enhancement.

**Current Process:** Where multiple STEs exist in REGIS and Ethics is managed outside of REGIS the site annual report milestone is created in the first site only.

When noting a site annual report (ethics external to REGIS) please navigate to the milestone section of the STE project to make sure there isn't a duplicate milestone for that year e.g. a milestone due in the same time period of the one that was submitted by another site. If a duplicate milestone exists you can delete it.

## SSA – Understanding/Identifying when Ethics is approved

**Audience:** Research Office

**Issue:** When Ethics exists outside of REGIS (QLD, VIC, SA, WA) applicants are required to upload the HREC approval letter/email as evidence. The system requires this to be the document type “Ethics application decision notification”. Applicants often upload the HREC approval as “other” or “Ethics application (HREA or other)”.

If the applicant uploads a HREC approval as any other document type the system will not recognize a HREC approval and the RGO can not make the recommendation to CE. The ETH approved flag will not be created. That applicant believes they have provided all the documents, are waiting on a review and the RO are waiting on evidence of HREC approval.

During the review of an application if it is identified ethics approval has been given the incorrect document type. If it has there are 2 ways to correct.

1. **Recommended if a request for information will be sent:** During the ineligible notification or request for information process the RO should add to the request that the applicant to change the Ethics approval letter from document type XX to “Ethics application decision notification” by changing the dropdown option.
2. **Recommended if no further input from the applicant will be required:** Updating the document type from the internal portal.

*Note if the RO makes this change and a subsequent request for information is sent to the applicant and a new version of the application is created the document type is not updated on the applicant side and will revert back to the original/incorrect document type if the applicant is not guided to update the form.*

How to correct a HREC approval document type




1. Click page edit (big edit icon on right hand menu) for the individual document icons to appear. Select edit document item.

Can't see the icon? Make sure the document is not visible to the external portal (eyeball must be crossed)

Title	Filename	Document type	System Version	Tags	Application version						
052610_Project Registration.pdf	052610_Project Registration.pdf	Application Attachment	1		103 - Application Resub...						
2021/STEO1774 v1_00 - v1_01 Changes	2021_STEO1774.v1_00 - v1_01.Chang...	Change Tracking	1		101 - Application Resub...						
2021/STEO1774 v1_01 - v1_02 Changes	2021_STEO1774.v1_01 - v1_02.Chang...	Change Tracking	1		102 - Application Resub...						
2021/STEO1774 v1_02 - v1_03 Changes	2021_STEO1774.v1_02 - v1_03.Chang...	Change Tracking	1*		103 - Application Resub...						
approval letter	ethics approval.docx	Other: Please specify	1		103 - Application Resub...						

Change the document type from its current type to “Ethics application decision notification”

## Related documents

**+ Add document**  Assign to review  Bulk download  Bulk document disposal update

Title *	approval letter
Document type *	Other, Please specify
Disposal hold	ethics
Protective marking	<u>Ethics</u> application (HREA or other)
Disposal class	<u>Ethics</u> application decision notification