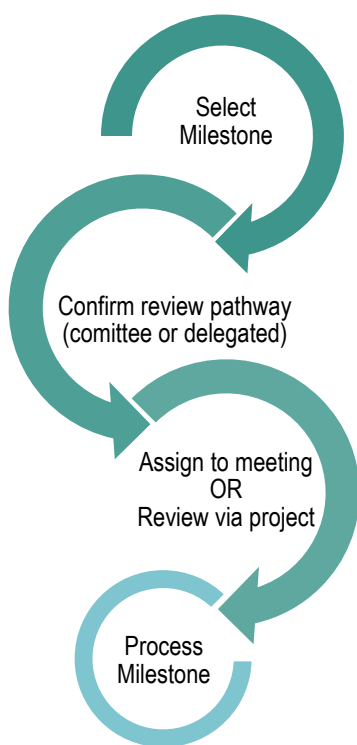**REGIS**

Processing a Progress Report

FOR RESEARCH OFFICES

Processing an Ethics Milestone (Progress Report)

The below diagram is an overview of the progress report (milestone) process in REGIS.

Select Milestone

Confirm review pathway (comittee or delegated)

Assign to meeting OR Review via project

Process Milestone

Accessing the Progress Report

Note: This QRG assumes you have already set up your homepage tiles. See QRG – Research Offices – Setting up a Homepage and REGIS User Manual guide – Homepage tiles

Step 1
Select the progress report for processing from the homepage tile.

Step 2
You will be taken to the 'Milestone' information section of the Ethics Project. Below are the menu options within the milestone:

Information: Milestone Details and Milestone Dates give an overview of the progress report.

Note: Forecast & Invoice are currently not required in REGIS.

Detail: Includes name of the milestone (progress report). Click 'Edit' to manually add more detail.

Justification: Will be blank. Click 'Edit' to manually add more detail.

Addition fields: Will list additional fields assigned to milestone.

Documents: Includes the progress report form and any other supporting documents submitted.

Click the download icon to access the form and supporting documents. Ensure that the study type is correct and all expected documents have been uploaded. Click 'Edit' and '+Add document' to add any external documents required.

Actions: Currently not required for REGIS.

Tasks: You can add a task here to assign to a team member for review.

Ratings: Currently not required for REGIS.

History: See a detailed history of the milestone.
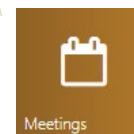
The progress report can be:

❖ Assigned to an existing meeting

❖ Processed through the ETH Project

Assigning a progress report to an existing meeting

For full committee review or executive committee review

For instructions on how to create a meeting please see: QRG - Research Offices - Creating and Preparing HREC Meetings

Step 1

Navigate to the 'Meetings' tile and select the 'Meetings' icon to search, schedule or check meetings.

Step 2. Search for the existing meeting
Filter the search by adding a Title, Meeting status or add further filters by dragging and dropping any of the 7 filters available on the left-hand side of the screen.
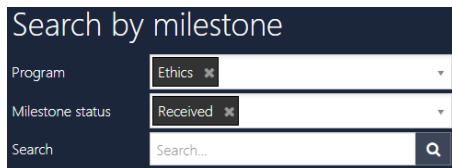
Select the meeting by clicking the 'Edit meeting' icon

Step 3
Click on the 'Milestones' heading at the bottom of the Meeting page.

Milestones in meetings relates to progress reports and final reports.

Step 4

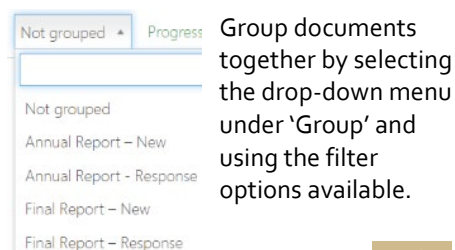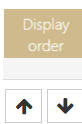Select the '+ Add milestone' and a pop out panel will appear.

Step 5

Use the Search function to find the forms. Filter by Program, Milestone status or text search. Select the progress report and click the tick icon to add the milestone.

Step 6

The system will automatically include all documents submitted with the milestone to be viewed by the meeting attendees in the external portal.

Group documents together by selecting the drop-down menu under 'Group' and using the filter options available.

You can also change the display order of documents by using the 'up' and 'down' arrows.

Adding notes and recording the decision

Step 1

Add any notes or comments from the meeting in 'Meeting details', located at the top of the screen and click save once finished.

Notes can be edited after the meeting; this information can feed through to the draft minutes created in REGIS.

Step 2 Record a decision

The 'gavel' icon records the decision:

Decision Type:

- ❖ **Progress Report with status change (Completed, Terminated/Abandoned)**
- ❖ **Annual Progress Report**
- ❖ **First Patient in Report**

Decision:

- ❖ **Decision pending – More Information required**
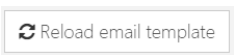- ❖ **Noted**
- ❖ **Rejected**

Step 3

Click 'Save' in the wizard and then click page save to save all decisions and outcomes and then click edit.

Step 4

Click on the email icon and edit template as required.

You can reload the email template by clicking the 'Reload email template' button. This will revert the email back to the original template, removing any information manually added.

Send the email. This will mark the annual report/milestone as achieved.

Note: Remember to share the milestone report/system generated email from the project related documents. See below section How to Share.

Step 5

IMPORTANT: For all **'Decision Pending'** or **'Rejected'** progress reports you will need to **process the milestone from the project**.
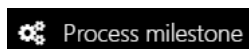
Processing the progress report from the ETH Project

Select the milestone to be processed.

See Accessing the Progress Report for the menu details.

Step 1

Select 'Information', 'Edit' and 'Process milestone'

Complete the progress report in the 'Process milestone wizard'.

Step 2. Process Milestone

Date received - the date the milestone was initially submitted. This should not be changed.

Milestone status - select appropriate status from the dropdown menu:

Achieved – milestone report noted and accepted by the HREC.

Revision – further information is required. Complete the additional information required.

These statuses require a date to be selected for when the milestone should be returned. Click the toggle to update the milestone due date.

Not Achieved – when a milestone is not submitting even after multiple requests. Complete the additional information required.

Effective Date – date decision made

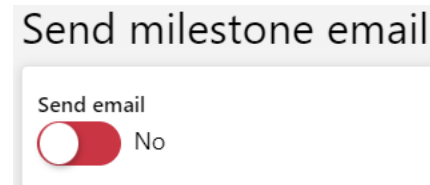Click 'Next' to proceed through sections 2-4.

Step 3. Attach minutes

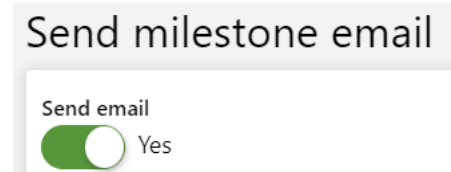Functionality currently not used.

Step 4. Rate milestone

Functionality currently not used.

Step 5. Send milestone email

If you do not wish to send an email, click the 'send email' toggle to 'No'.

To send an email, edit as required and ensure the toggle is selected to 'Yes'.

You can reload the email template by clicking the 'Reload email template' button. This will revert the email back to

the original template, removing any information manually added. Click the green 'Finish' button to send the email.

Remember to share the milestone report and system generated email from the project related documents. See below section 'How to Share'.

Change the Status of the Project.

When a milestone has a status of Completed, Closed (post analysis), Terminated or Abandoned it is noted that the Research Office should change the status of the Ethics Project.

Step 1
In the Ethics 'Project', select 'Management' and 'Status'. Select Edit and '+ Add status'. Once completed, select 'Ok' and 'Save'.

Completed - When the last participant has met the last study analysis endpoint. When reached at a single site study, this is likely the time point when data analysis can begin. When reached at the last site in a multi-site study, this is likely the time point when data analysis can begin. Participants may still be undergoing follow-up visits.

Closed (post analysis) - The study has finished normally, participants are no longer being treated or examined, but the documents are not yet archived.

Abandoned - The application has been approved/authorised, but it has been determined that the project will never commence.

Terminated - After study start but before study close, discontinuation of a research project by the investigator or sponsor, where activity will not resume. Possible reasons include: Ethical, safety, financial or other grounds. Will never progress to "Complete" or "Closed (post analysis)"

How to share with governance?

The system will automatically share an Ethics approved milestone.

Manually creating Milestone Progress Reports

Creating Milestone Progress Reports

Where an extension for HREC approval date has been applied and an additional milestone will be required the Research Office can create a new milestone.

NOTE: Studies created in REGIS have 5 milestones automatically generated. For migrated studies, milestones need to be added to the project.

Step 1.

Select the ETH Project and click 'Milestones'

9 Milestones

Step 2.

Select Edit and then click '+ Add milestone' under 'Milestone summary'.

Step 3.

Fill in the milestone details as per below;

Title: Progress Report
Type: Progress Report
Organisation: Auto populates
Current due date: Add due date

Step 4.

Click Ok and then Save.

Title *		
Type *	Please select...	
Organisation *	Sydney Children's Hospitals Network	
Current due date *	dd/mm/yyyy	
	✔ Ok	✖ Cancel

The new milestone progress report will now appear in the progress report list.