REGIS

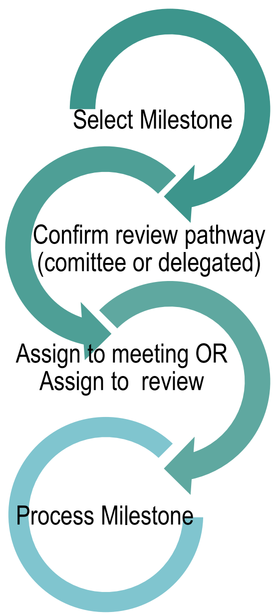
Processing a Progress Report

QUICK REFERENCE GUIDE

FOR RESEARCH OFFICES

Processing a Progress Report (Milestone)

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



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 from the homepage tile, that you want to process.

Step 2

You will be taken to the Milestone section of the Ethics Project (post-approval).

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

Forecast & invoice, currently not required for REGIS.

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

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

Documents: See this progress report form and any other supporting documents submitted.

Download the form and supporting documents by clicking the download icon.

Click 'Edit' and the Hamburger to manually '+Add external documents'

Actions: Currently not required for REGIS.

Ratings: Currently not required for REGIS.

History: See a detailed history of the milestone.

Milestone review: Click 'Edit' and the Hamburger to manually '+Add new review'. A milestone review is a separate functionality to the Review function accessed through the start icon.

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

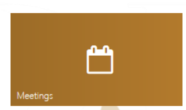
Step 1

Click 'Start' menu (hamburger icon)

This icon will present you with tiles to navigate to your chosen section.

Step 2

Select the Meetings tile from the Start dropdown

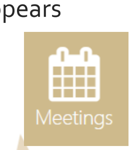


Choose Meetings tile

Hint: right click your mouse on this icon to select open a new tab.

Step 3

Click on the next Meetings tile that appears



Click on the Meetings icon to find or manage meetings

Step 4. Search for the existing meeting

Filter the search by adding a Title or Meeting status. You can also add further filters by dragging and dropping any of the 5 filters available on the left-hand side of the screen.

Select the meeting by clicking 'Edit Meeting'.

Step 5

MILESTONES

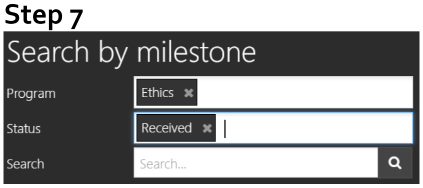
Click on the Milestones tile on the left-hand side of the Meeting page. Milestones in meetings relates to progress and final reports.

Step 6

Click the hamburger icon and then select to 'Add milestone'

✚ Add milestone

Step 7



Use the Search function in the black pop out panel to find the forms. Filter by program, status or text search.

Click save

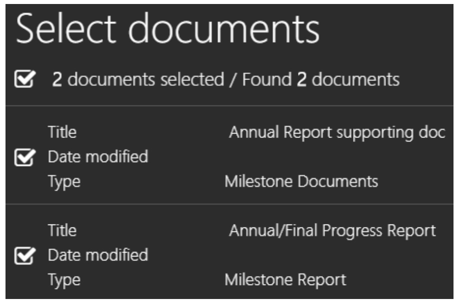
Step 8

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

To review and manage the documents click on the 'Select Document' icon.

Hint: if you don't see the following icons, click 'Edit'

Select Documents



Adding notes and recording the decision

Step 1

Select the Milestones tile on the left-hand side of the screen.

MILESTONES

Step 2

Click the note icon on the right side of the application in the table listing.

Step 3

Add comments from the meeting. Click save when you are finished.

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

Step 4 Record a decision.

The 'gavel' icon records the decision:

Decision Type:

- **Annual Progress Report**
- **Progress Report with Status Change (Completed, Terminated/Abandoned) – no auto status changes.**

Decision:

- **Decision Pending – Request for more information**
- **Noted**
- **Rejected**

Step 5

Click 'Save' in the wizard.

Repeat Step 2-5 for all milestones.

Step 6

Click page save to save all of the decisions and outcomes.

Click edit.

Step 7

Outcome

Noted

For all milestones with the outcome of 'Noted' click on the email icon, edit template as required and send email.

This will mark the annual report/milestone as achieved.

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

Step 8

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

MILESTONES

Received

Select the milestone to be processed.

See Accessing the Progress Report for the menu details.

For technical assistance, contact
REGIS HELP DESK

support.f1solutions.com.au
1300 073 447

Step 1

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

Move through the 'Process milestone `wizard'.

Step 2. Milestone Review
Currently not available functionality

When the milestone review functionality is available the list of completed reviews will appear here.

Click to go to milestone reviews

Click the blue next arrow.

Step 3. Process Milestone
Date received - is the date the milestone was initially submitted. This should not be changed.

Status - select the status from the dropdown menu.:

Achieved – milestone report noted and accepted by the HREC.

Revision – further information is required.
Complete the additional information required.
Select the date the milestone should be returned.
Click the toggle to update the milestone due date.

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

Effective Date – the date the decision was made

Click on the blue next arrow.

Step 4. Attach minutes

Functionality currently not used.

Click on the next blue arrow.

Step 5. Rate milestone

Functionality currently not used.

Click on the next blue arrow.

Step 6. Send milestone email

Edit as required and click 'send'.

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

Change the Status of the Project.

When a milestone of Completed, Closed (post analysis), Terminated/Abandoned is noted the RO should change the status of the Ethics Project.

Step 1.

Select the Management tile

and then Status

Step 2.

Select Edit

then select the hamburger and '+ Add Status'

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)"

Ok and then Save

How to share with governance?

When the milestone is "achieved" share the milestone form and system generated email with related entities.

Select the Management tile

and then Related documents.

Use aggregate view to easily identify the documents.

select Milestone Reports and locate the document then select System Generated Email and select the milestone email

Visible in related entity

For technical assistance, contact
REGIS HELP DESK

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