

Submitting a Progress/Final Report

What is a Progress/Final Report?

It is a standard condition of HREC (Ethics) approval that an annual progress report is submitted for review by the approving HREC.

A HREC may request increased progress reporting as a special condition of the Ethics approval.

In REGIS progress reports are processed through Milestones.

Who should submit the progress report?

The Coordinating Principal Investigator has the overall responsibility of the study and they have the responsibility to submit the progress report to the HREC.

Top 5 Milestones.

Top 5 milestones due

On the right hand side of the REGIS homepage is where you locate the 5 upcoming milestones and the number of days remaining before the due date. When the milestone has been processed/noted it will no longer appear in this list.

* Project identifier	Title	Detail	Status	Days remaining
* 2018:ETH00002	Progress Report	Progress Report	External Review	63
* 2018:ETH00015	Progress Report	Progress Report	Pending	97
* 2018:ETH00025	Progress Report	Progress Report	External Review	93
* 2018:ETH00043	Progress Report	Progress Report	Pending	97

Symbols

	Download a .pdf of the form
	Save the milestone to complete late
	Navigate forward and back

Study Status Definitions

Not yet commenced: No clinical activities involving participants (including participant recruitment) have commenced. No research activities have commenced.

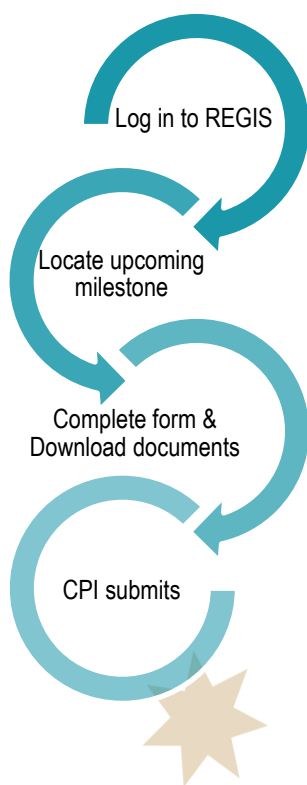
In progress: Clinical or study activities have commenced.

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.

Terminated/Abandoned: (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 does it work in REGIS




Submitting Progress Report

Step 1

Select the milestone you wish to process by clicking on the Project Identifier, Title or Detail.

Step 2

On the left hand side of the screen select Milestone details.

 Milestone details

Step 2

Now select Submit report.

Submit report

Step 3

A number of details regarding the Study have been prefilled at Project Details.

Each authorised site should be added in the table on this page by selecting the site from the drop down menu, to add another site click on the '+' icon.

Only authorised sites will appear in the dropdown.

Step 4

Select the study status from the dropdown. Study status definitions are described on page one of this document.

The definition of the study status will appear in the page when selected.

Step 5

Depending on the answers provided the form will display additional questions or sections.

Answer each question and progress to the next section.

Step 6

If you are the CPI you will be able to submit the report by clicking submit.

Submit

If you are not the CPI save the form by selecting the save icon.



Notify the CPI that the Progress Report can now be submitted.

Step 7

The Project Report has been submitted to the HREC when the status of the milestone changes to "Received".



What Next?

The Progress Report will be processed by the Research Office.

You will receive an email notification when the Progress Report has been noted or if further information is required.

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).