Progress/Final Report

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.

REGIS jurisdictions have introduced streamlined annual reporting. Researcher are required to fill out a single annual report form to the HREC and NSW sites.

In REGIS progress and final reports are processed through Milestones.

Who should submit the progress report?

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

Sharing Access to the Milestone

The CPI is the only person who can share the ETH Project.

Select the 3 vertical dots against the ETH identifier and select 'Invite user to register or share project'. Select '+ Add another user', provide their REGIS username and the type of access under 'Modify access' and then select 'Share with edit access'. Click 'Save and send' and that person can now access the Milestone to edit it.

Top 5 Milestones.

♀ Top 5 milestones due

The 5 upcoming milestones and the number of days remaining before their due date is located on the right-hand side of the REGIS homepage.

When the milestone has been processed/noted it will no longer appear in this list.

NOTE: A red dot against a milestone indicates that it is overdue and needs immediate actioning.

● 09 Apr 2020 (54 days overdue)

How does it work in REGIS

Log in to REGIS

Locate upcoming milestone

Complete form

CPI submits
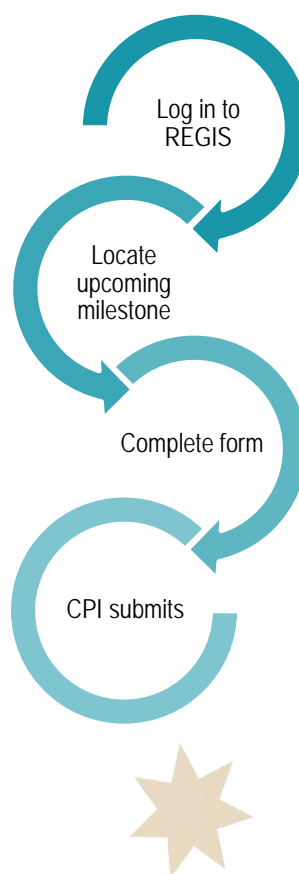
Study Status Definitions

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

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, wherein activity will not resume. Possible reasons include: Ethical, safety, financial or other grounds. Will never progress to "Complete" or "Closed (post analysis)".

Progress Report Submission

Step 1

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

Step 2

You will be automatically brought to the Progress Report page 'Milestone details' section. Select Submit report.

Submit report

Step 3 - Project Details

If the below message appears it is a warning only, you are still able to submit the form.

> HREC expiry within 6 months (or expired). Consider if you need to submit a Request for extension of HREC approval. For guidance please see: Completing and submitting a HREC/Ethics amendment
> **Seeing this message will not stop the submission of this form.**

Ensure that the study type is correct as additional questions are generated based off this. If the study type is incorrect then you will need to contact your local research office to have the study type classification changed.

Is the study type correct? ❓

> **Yes:** disregard message and progress
> **No:** please contact the research office and request the study type classification be changed. Click on the helptext icon above for a list of study types and definitions.
> Seeing this message will not stop the submission of this form, however forms submitted with incorrect study types may cause the form to be unsubmitted.

Step 3a

HREC approved sites for Table 1 and Table 2 will pre-fill all authorised and submitted NSW sites in REGIS.

For 'Sites External to REGIS', these will need to be manually entered

> **Sites External to REGIS**
> Sites external to REGIS include any other sites not listed in the above 2 tables. This includes sites form other states/jurisdictions approved under NMA (VIC, SA, QLD, WA), private sites, University sites or NSW sites not included in REGIS. You can add more rows by clicking on the "+" icon at the bottom of this table.
>
> | Site Identifier ❓ | Site ❓ | Status ❓ | Principal Investigator ❓ |
> |---|---|---|---|
> | | | ▼ | |
>
> ⊕ ⊖ ⊛

Follow the instructions on the page and when all details have been completed use the next page arrow to progress.

Step 4 - Study Status

Select the study status from the dropdown menu. Study status definitions are described under each status, once selected.

Study Status

In progress

Definition: Clinical or study activities have commenced.

By selecting Closed (post analysis), Abandoned or Terminated a final report is required. Click here to proceed to Final Report Submission.

Step 5 - Recruitment/Data/Samples

In addition to the study wide recruitment/data. This form includes NSW Site Specific Recruitment/Data questions.

Each authorised NSW site will be included in the form to be completed before being submitted to the HREC.

Answer each question and progress to the next section.

Step 6 - Progress Summary

The current approved version of the protocol recognised in the system is automatically listed. If incorrect, you will need to manually enter the correct details.

Answer each question and progress to the next section.

Step 7 - Safety Reporting

If the study is a clinical trial, you will be asked if you want to submit the annual safety report. Selecting 'Yes' will generate an additional question.

The below message advises CPI/Sponsors that they should no longer send Single case AEs, SAE/SARs, SUSARs, device/non-therapeutic good trial equivalents or six monthly line listings to the HREC as they will not be reviewed. If any of the events above resulted in an SSI then this should be reported to the HRECs using the form on the OHMR Safedty Reporting webpage.

> NSW/ACT Research Offices have adopted the NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016). In accordance with this document, CPI/Sponsors should no longer send to HRECs the following reports: • Single case AEs, SAE/SARs and SUSARs or device/non-therapeutic good trial equivalents or six monthly line listings. Any of these reports sent to HRECs will not be reviewed. If any of the events listed above result in a Signification Safety Issue then this should be reported to the HRECs using the form posted on the OHMR Safety Reporting Webpage.

If the study is not a clinical trial there is a single safety question.

Answer each question and progress to the next section.

Step 8 - Compliance, Confidentiality & Storage

Selecting 'No' to any of these questions will produce a free text box asking for an explanation as to why.

Step 9 - Document Upload

Upload documents using the plus sign ⊕ ⊖ and remove documents using the minus sign.

*TIP: You can duplicate rows by clicking the checkbox against a row and then selecting the duplicate sign*

Step 10 – Declaration

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 and notify the CPI that the Progress Report can now be submitted. **Save**

Step 11

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

Received Status
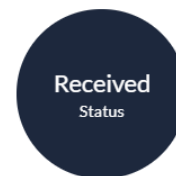
Final Report Submission

Step 1

Follow Progress Report Submission Steps 3-7.

Step 2 - Compliance, Confidentiality & Storage

Selecting 'No' to any of these questions will produce a free text box asking for an explanation as to why.

There are five data archival periods to choose from. Each provides further information once selected;

- ❖ Indefinite: Interventional TGA/CTN Scheme; Gene Therapy (after 2000)
- ❖ 15 years: Interventional/Clinical research
- ❖ 5 years: Non Interventional/Low Risk projects
- ❖ 3 years: Other (eg. Project never commenced, projects were not approved, no participants enrolled)
- ❖ 12 months: Short term/Student projects

Details on how the data/and or samples will be destroyed and the sites where the data will be stored on completion of the project need to be provided.

The question 'Data/Samples collected for this study cannot be used for any other research without HREC approval' is a required field and needs to be answered with the 'Yes' and 'No' options provided.

Data/Samples collected for this study can not be used for any other research without HREC approval. *

Yes, HREC approval will be sought if further research is required

No further research will be completed on this data

Step 3 - Final Report

List all publications to date and conferences, seminars etc. at which findings from the research project have been presented. Use the plus and minus signs to add/remove documents ⊕ ⊖

If you have indicated that the study involved recruitment of participants, then a question is generated based on that.

If the study terminated early you will be asked what the justification for early termination was and are there any potential implications.
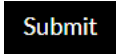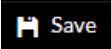
Step 4 - Document Upload

Upload documents using the plus sign ⊕ ⊖ and remove documents using the minus sign.

*TIP: You can duplicate rows by clicking the checkbox against a row and then selecting the duplicate sign*

Step 5 – Declaration

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 and notify the CPI that the Progress Report can now be submitted. **Save**

Step 6

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

Received
Status
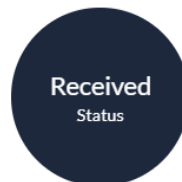
What Next?

The Progress Report will be processed by the Research Office.

Once the Progress report has been accepted by the HREC the system will share the report with all NSW authorised sites. You will not have to submit any further documents to any NSW sites.

The email notification now acts as a HREC and NSW RGO acknowledgment of annual reporting requirements being met.

NSW site RGO's will only contact you if they require further information.

Research Governance Office's (RGOs) in NSW have been provided with the progress rep
This email notification can be considered the HREC and RGO acknowledgement/noting

You may need to forward the annual report and HREC notification to sites at other jurisdictions.