

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. Researchers 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. The CPI can also delegate 'submit access' to anyone with a REGIS account. **This does not remove the overall responsibility from the CPI.** The CPI OR their delegate(s) can submit the progress report to the HREC.

Sharing Access to the Milestone

The CPI is the only person who can **share** the ETH Project. Clicking anywhere on the ETH row, (except the ETH identifier), will expand the row.

Click **'Invite user to register or share project'**. Click '+ Add another user' Enter their REGIS username and the level of access they require under 'Modify Access'. You can also use this option to modify an existing user's access from 'Edit' to 'Edit and Submit'.

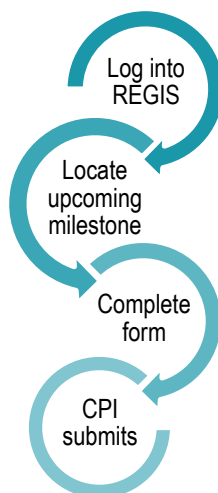
Sharing and Roles

Share with View access: User can only view the application and/or forms

Share with Edit access: User can view and edit the application and/or forms

Share with Edit and Submit access: User can view, edit, and submit forms and milestones.

How does it work in REGIS?



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. Such a study will never progress to "Complete" or "Closed (post analysis)".

Progress Report Submission

Step 1 Locate the milestone Top 5 Milestones

Top 5 milestones will show you the next 5 milestones due. Click the Milestone to be taken directly into milestone form.

Top 5 milestones due			
2022/STEO0094 Certificate of Currency	Pending	28/04/2022	166 days overdue
2021/ETH400771 Progress Report	Pending	18/08/2022	54 days overdue
2021/ETH400800 Progress Report	Pending	22/09/2022	19 days overdue
2022/STEO0031 First Patient In	Pending	17/10/2022	5 days
2022/STEO0139 First Patient In	Pending	24/10/2022	12 days

OR

Email Reminder

Select the link in the email reminder

OR

Homepage

When you log in to REGIS, your home page lists your 'Top 5 projects'. If you

Study Status Definitions

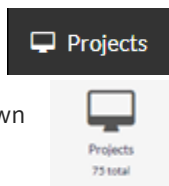
Not yet commenced: No clinical activities involving participants (including participant recruitment) have commenced.

In progress: Clinical or study activities have commenced.

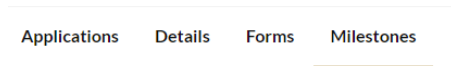
Completed: When the last participant has met the last study analysis endpoint. For both, single-site studies and the last site in a multi-site study, this is likely the

can see the project here, open it by clicking on the project identifier.

If the project is not listed in your 'Top 5 projects', use either of the Projects icons shown here to view all projects.



Select the ETH Identifier and then select Milestones



A list of all milestones for the study will appear. Select the milestone you wish to submit.

IDENTIFIER	MILESTONE TITLE	DETAIL
2021/ETH00589	2021/ETH00589 2022 Progress...	Progress Report
2021/ETH00589	Progress Report	Progress Report
2021/ETH00589	Progress Report	Progress Report
2021/ETH00589	Progress Report	Progress Report
2021/ETH00589	Progress Report	Progress Report

Step 2 - Complete Report

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 2a - Project Details

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

Any 'Sites External to REGIS', will need to be manually entered

IDENTIFIER	TITLE	STATUS
2021/ETH00589	For helptext for approval page	Approved

Sites External to REGIS

Sites external to REGIS include any other sites in states/jurisdictions approved under NMA (VIC, NSW, QLD, SA, WA, NT, ACT, TAS). You can add more rows by clicking on the

[+ Add Another](#)

Select + Add Another and follow the instructions on the page and when all details have been completed use the next page arrow to progress.

Step 3 - Study Status

Select the study status from the dropdown menu.

To view the study status definitions, select the radio button on the form.

[Click here for Progress Report Status definitions](#)

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

Step 4 - 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 5 - 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 all questions and progress to the next section.

Step 6 - 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.

If the study is not a clinical trial, there is a single safety question. Answer all questions and progress to the next section.

Step 7 - Compliance, Confidentiality & Storage

Selecting 'No' to any of these questions will produce a free text box where you can provide an explanation.

Step 8 - Document Upload

This section allows the applicant to submit documents directly related to the Annual/Progress or Final Report. This might include the annual safety report or audit report. Do not upload documents for amendment or noting.

To upload a document, click 'Add Another'

[+ Add Another](#)

Document Type: Select Audit/Other from the dropdown

Step 9 - Declaration

The CPI OR their delegate(s) can submit the report by clicking the 'Submit' button.

[Submit](#)

If you do not have access to submit, save the form, and notify the CPI or delegate that it is ready for submission.

[Save](#)

Step 10

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.

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.

Each authorised site in REGIS has been notified and will only contact you if they require more information. Please accept this notification on behalf of the HREC and NSW sites listed in the form.

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

Final Report Submission

Step 1

Follow Progress Report Submission Steps 2-6.

Step 2 - Compliance, Storage & Confidentiality

Selecting 'No' to any of these questions will produce a free text box where you can provide an explanation.

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 (e.g., 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.

[+ Add Another](#)

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

If the study is terminated early, you will be asked what the justification for early and are there any potential implications.

Step 4 - Document Upload

This section allows the applicant to submit documents directly related to the Annual/Progress or Final Report. This might include the annual safety report or audit report. Do not upload documents for amendment or noting.

To upload a document, click 'Add Another'.

[+ Add Another](#)

Document Type: Select Audit/Other from the dropdown. Drag and drop or search to attach the files.

Step 5 – Declaration

The CPI OR their delegate(s) can submit the report by clicking the 'Submit' button.

[Submit](#)

If you do not have access to submit, save the form, and notify the CPI or delegate that it is ready for submission.

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