

## Submitting a progress report or final report

### What is a progress or final report?

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

In Research GEMS, progress and final reports are processed using milestones.

### Who should submit the progress report?

The Coordinating Principal Investigator (CPI) can submit the progress and final reports, and is able to share access to team members to assist in the completion of these milestones. However, the overall responsibility **remains with the CPI.**

See [Sharing access to applications and projects](#) for further information.

### Top 5 milestones

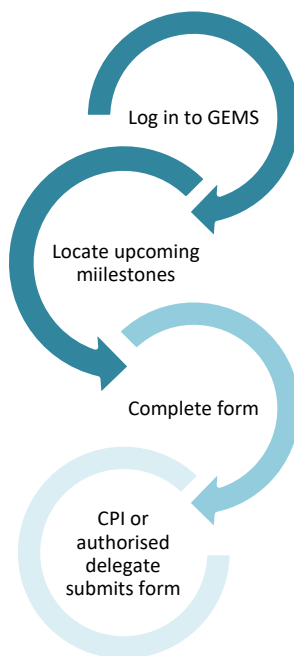
The 5 most pressing milestones and the number of days remaining before their due date is located on the right-hand side of the GEMS homepage. When the milestone has been processed/noted it will no longer appear in this list.

#### 📍 Top 5 milestones due

*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 GEMS?



### 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.
- ❖ 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, and participant activities have concluded, 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. This status reflects discontinuation of a research study by the investigator or sponsor. Possible reasons include ethical, safety, financial or other grounds.

### Progress report submission

**If the progress report is visible in the 'Top 5 milestones due' table:**

#### Step 1a.

From the home page and within the 'Top 5 milestones due' table, select the milestone you wish to complete by clicking the purple hyperlinked 'Progress report'.

This will open the report for completion.

**If the progress report is NOT visible in the 'Top 5 milestones due' table:**

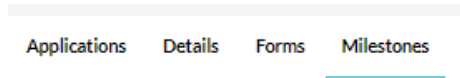
#### Step 1b.

To locate the project, click on the 'Projects' icon to see all projects.



Click the hyperlinked Project 'Title' in the list. This will take you to the project details page.

Click on the ethics (HRE) identifier. This will take you to the ethics details page. Select the 'Milestones' tab from the top toolbar.



The progress reports will be listed on this page. Click on the purple 'milestone title' or 'detail' hyperlink to enter the form.

MILESTONE TITLE	DETAIL
<a href="#">Progress Report</a>	<a href="#">Progress Report</a>

## Step 2. 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 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.

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

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

Please 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. Study status definitions are described under each status, once selected.

By selecting Closed (post analysis), Abandoned or Terminated a final report is required. Refer below for instructions on how to complete a final report submission.

## Step 4. Recruitment/data/samples

If the questions 'Does the study involve recruitment of participants?' and 'Does the study involve the collection of data or tissues samples only?' are both answered 'No' then the below warning message will appear.

It is assumed that research will involve either recruitment of participants or data/tissue samples. Please contact the research office to clarify your study type.

It is assumed that research will involve either recruitment of participants or the collection of data/tissue samples. You are advised to contact the research office to clarify the study type.

Selecting 'Yes' on either of these questions will display additional questions and sections.

Clinical trials progress reports will show additional questions.

This section also includes SA Site Specific Recruitment questions. All questions should be answered.

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.

## 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 additional question/s.

### Study Status

In progress

Definition: Clinical or study activities have commenced.

Single case AEs, SAE/SARs, SUSARs, device/non-therapeutic good trial equivalents or six monthly line listings are no longer reviewed by the HREC. If any of the events above resulted in an SSI then this should be reported to the HREC using the appropriate safety reporting form.

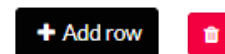
If the study is not a clinical trial, there is a single safety question.

## Step 7. Compliance, confidentiality and storage

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

## Step 8. Document upload

Upload documents using the 'Add row' button and remove documents using the 'rubbish bin' button.



## Step 9. Declaration

If you are the CPI or an authorised delegate with submit permission, you will be able to submit the report by clicking submit.

**Submit**

Person/s with edit access can save the form and notify the CPI or an authorised delegate that the progress report is now ready to submit.

**Step 10.**

The progress report has been submitted to the HREC when the status of the milestone changes to 'Received'.

● Received

**Final report submission****Step 1.**

Follow progress report submission steps 1-6.

**Step 2. Compliance, confidentiality and 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 (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.

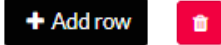
Data/Samples collected for this study can not be used for any other research without HREC approval.\*

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. Use 'Add row' and 'rubbish bin' button 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 'Add row' button and remove documents using the 'rubbish bin' button.

**Step 5. Declaration**

If you are the CPI or an authorised delegate with submit permission, you will be able to submit the report by clicking submit.

**Submit**

Person/s with edit access can save the form and notify the CPI or an authorised delegate that the progress report is ready to submit.

**Step. 6**

The project report has been submitted to the HREC when the status of the milestone changes to 'Received'.

● 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.