

Amendments in GEMS

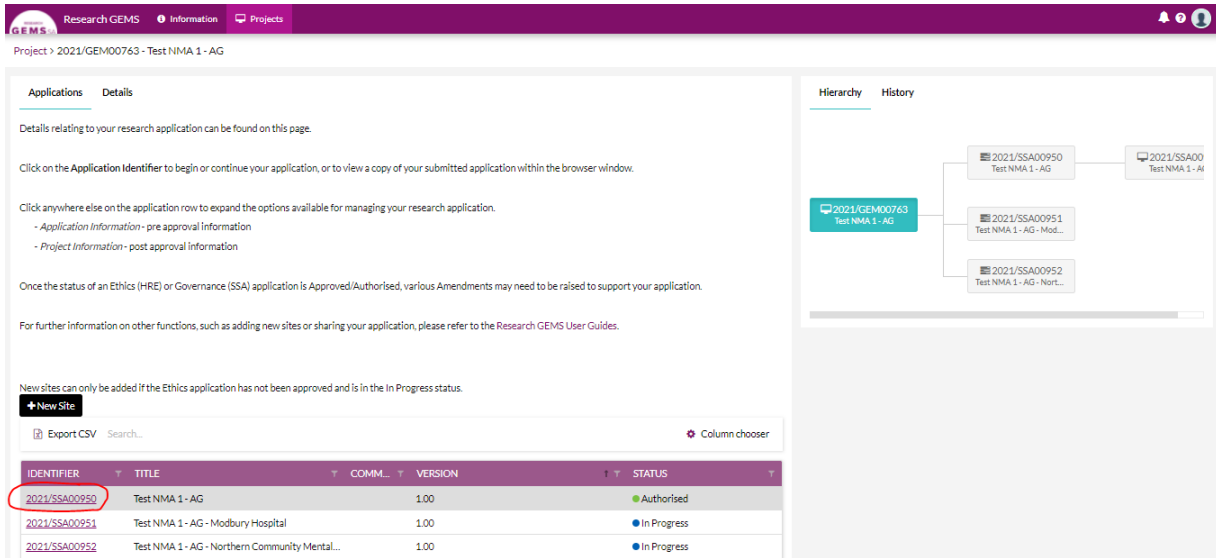
Please note: If the Ethics (HRE) for the project is in GEMS and the amendment requires HREC approval, please ensure you submit your amendment within the HRE (not the SSA). Once this is approved by the relevant Ethics committee, this amendment will then automatically flow through to all authorised SSAs in the project.

Please see instructions below for

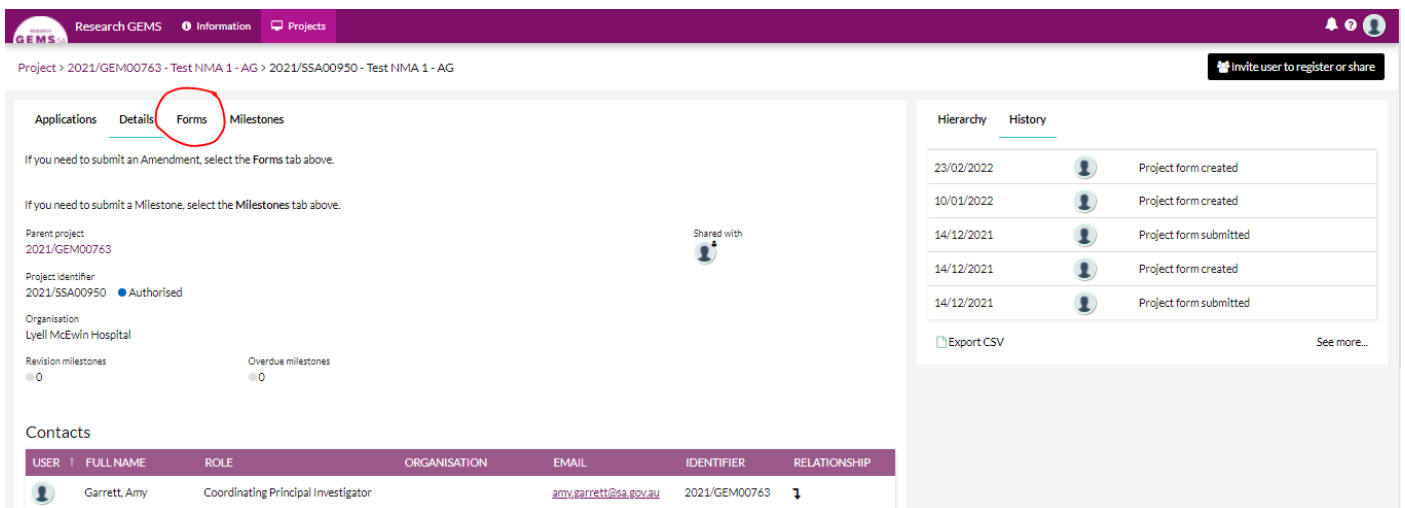
1. Amendments (when there is no HRE in GEMS) – Page 2
2. Amendments to the HREC (when there is HRE in GEMS) – Page 5

Site Amendments (when there is no HRE in GEMS)

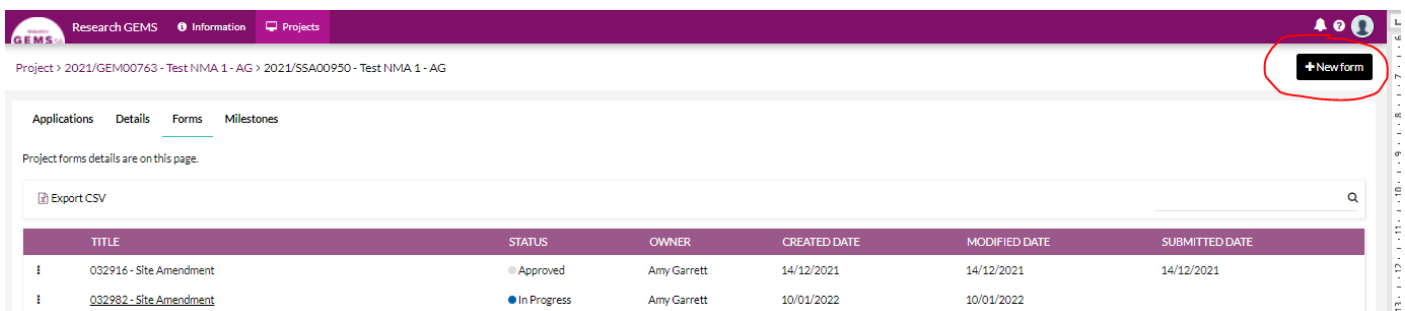
1. In your GEM project, click on the SSA you are submitting the amendment to



2. In the SSA, click on 'Forms'



3. Click the '+New Form' button



4. Select the 'Amendment Type'

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 delay the review of the form.

Site Details (which this form was created)

Principal Investigator
amy.garrett@sa.gov.au

Site Name
Lyell McEwin Hospital

Site Reference
2021/SSA00950

Select Amendment Type *

The types of amendment that can be submitted to the RGO are:

- General amendment
- Addition of a site
- CPI change notification
- PI change notification
- Extension of HREC approval notification
- Change site investigators or site administration contacts
- Change to contracts

Show Detailed Description of Amendment Types

General

Next →

5. Fill in all sections of the form, ensuring to upload any relevant Ethics approvals in the 'Ethics Approved Document Upload' section

Research GEMS Information Projects

Form > Site Amendment

Project Details and Site Amendment Type ✓

General Site Amendment

Ethics Approved Document Upload

Declaration

General Site Amendment

Previous

Preview Save

Next

Lyell McEwin Hospital

Does the amendment require changes to contracts? *

Contract amendments may be required, for example, when there are changes to the study visits (investigations/ frequency), or when any of the sponsor details are changing (address, invoicing information)

Yes No

Does the amendment require changes to study budgets? *

Budget amendments may be required, for example, when there are changes to the study visits (investigations/frequency), or when any of the sponsor details are changing (address, invoicing information).

Yes No

Summary of Site Implications

Site Specific Document Upload

Click 'Add Row' button below to upload files

+ Add row

General Amendment

Previous

Next

6. Once you have all green ticks, the Site PI will be able to 'Submit'

Research GEMS | Information | Projects

Form > Site Amendment

Project Details and Site Amendment Type ✓

General Site Amendment ✓

Ethics Approved Document Upload ✓

Declaration ✓

Declaration

← Previous

declare that:

- I am the CPI/PI of this study.
- The Information provided is true and accurate.

Clicking the SUBMIT button below will submit your completed Site Amendment form to the Research Office for consideration.

← Previous

Submit

Preview Save

If you are not the PI and therefore do not have the Submit button, ensure to 'Save' the form

Research GEMS | Information | Projects

Form > Site Amendment

Project Details and Site Amendment Type ✓

General Site Amendment ✓

Ethics Approved Document Upload ✓

Declaration ✓

Declaration

← Previous

I declare that:

- I am the CPI/PI of this study.
- The Information provided is true and accurate.

Clicking the SUBMIT button below will submit your completed Site Amendment form to the Research Office for consideration.

← Previous

Save

Preview Save

7. If you saved the form, the Site Amendment will have a status of 'In Progress'. You will need to contact the PI to log in and Submit

Research GEMS | Information | Projects

Project > 2021/GEM00763 - Test NMA 1 - AG > 2021/SSA00950 - Test NMA 1 - AG

Applications | Details | Forms | Milestones

Project forms details are on this page.

Export CSV

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|-------------------------|-------------|-------------|--------------|---------------|----------------|
| 033483 - Site Amendment | In Progress | Amy Garrett | 19/04/2022 | 19/04/2022 | |

New form

Once the PI has submitted the form, the Amendment will show a status of 'Submitted'

Research GEMS | Information | Projects

Project > 2021/GEM00763 - Test NMA 1 - AG > 2021/SSA00950 - Test NMA 1 - AG

Applications | Details | Forms | Milestones

Project forms details are on this page.

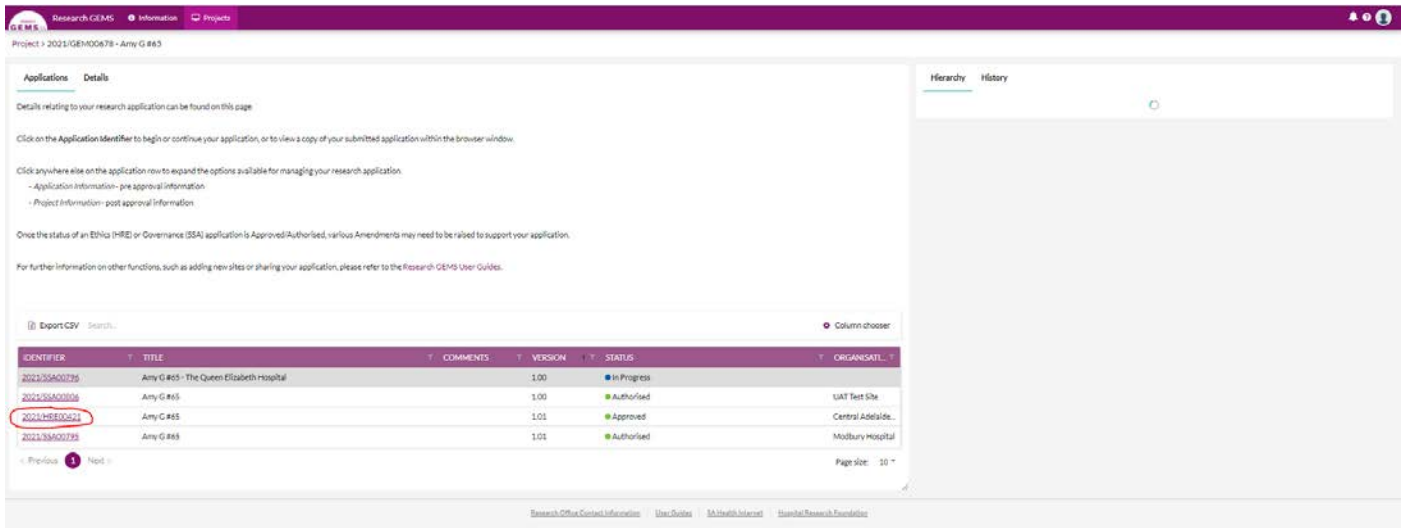
Export CSV

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|-------------------------|-----------|-------------|--------------|---------------|----------------|
| 033483 - Site Amendment | Submitted | Amy Garrett | 19/04/2022 | 19/04/2022 | 19/04/2022 |

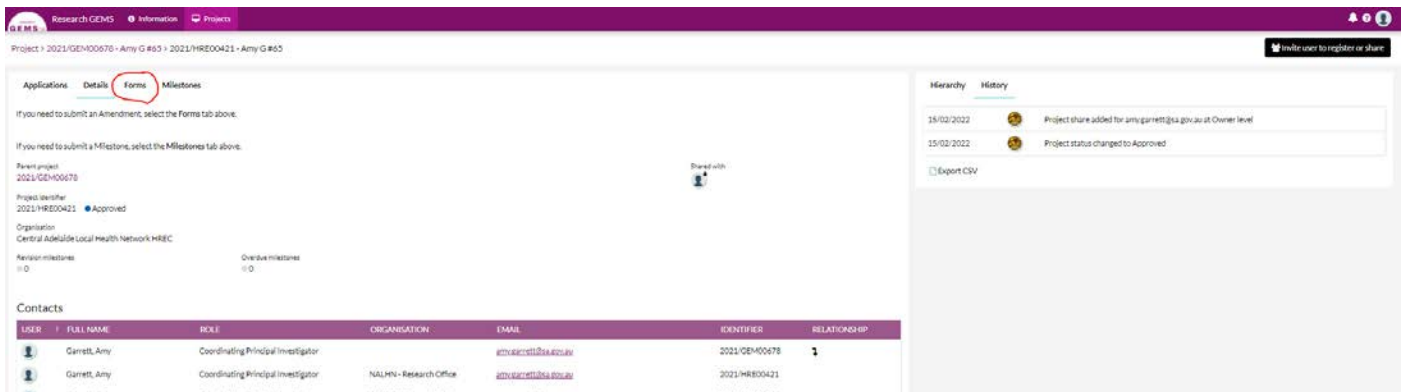
New form

Amendments that require Ethics approval (HRE exists in GEMS)

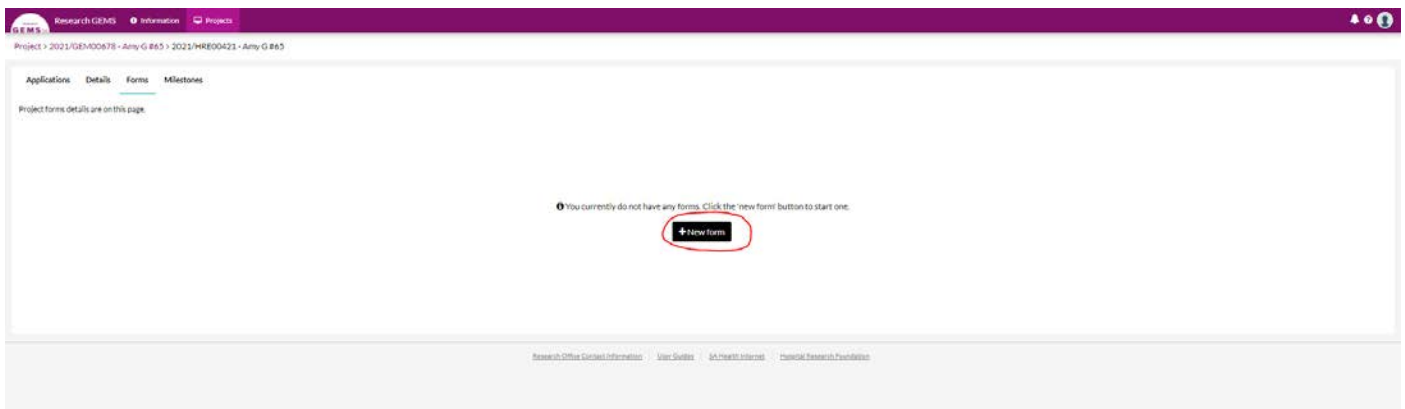
1. In the GEM Project, click on the HRE project



2. Go to the 'Forms' tab



3. Click new form button and select the type of amendment



4. Fill in the form

The screenshot shows the 'Project Details and Amendment Type' section of the Research GEMS form. The left sidebar contains a navigation menu with 'Project Details and Amendment Type' selected. The main content area includes instructions on how to use the form, a list of amendment types supported, and a 'What is an amendment?' section with a bulleted list of factors. Below this is the 'Project Details' section, which includes fields for 'Project Title' (Test Case NALHN AG), 'Ethics application no.' (2021/HRE00412), and 'Lead HREC' (Central Adelaide Local Health Network HREC). Navigation buttons for 'Preview', 'Save', and 'Next' are visible in the top right corner.

5. Check there are green ticks on all the sections. If you are the CPI, you can click the 'Submit' button

The screenshot shows the 'Coordinating Principal Investigator Declaration' section of the Research GEMS form. The left sidebar shows green checkmarks next to 'Project Details and Amendment Type', 'General Amendment', and 'Document upload', indicating they are completed. The main content area contains a declaration statement: 'I declare that: - I am the CPI of this study. - The information provided is true and accurate.' Below this is a 'Submit' button, which is circled in red. Navigation buttons for 'Previous' and 'Next' are also present.

If you are not CPI, use the 'Save' button to save the form

This screenshot is identical to the previous one, showing the 'Coordinating Principal Investigator Declaration' section. In this version, the 'Save' button in the top right corner is circled in red, indicating the action to take if the user is not the CPI. The 'Submit' button is no longer circled.

6. If you click save as above, the Form will have a status of 'In Progress', and the CPI will need to log in and press submit

The screenshot shows the 'Forms' tab of a project page in Research GEMS. A table lists project forms. The first row has a title '033487 - Notification of an amendment to a research study' and a status of 'In Progress'. The table columns are: TITLE, STATUS, OWNER, CREATED DATE, MODIFIED DATE, and SUBMITTED DATE.

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|---|-------------|-------------|--------------|---------------|----------------|
| 033487 - Notification of an amendment to a research study | In Progress | Amy Garrett | 26/04/2022 | 26/04/2022 | |

Once the form is submitted, the status will be updated to submitted

The screenshot shows the same project page as above, but the status of the form has been updated to 'Submitted'. The table columns are: TITLE, STATUS, OWNER, CREATED DATE, MODIFIED DATE, and SUBMITTED DATE.

| TITLE | STATUS | OWNER | CREATED DATE | MODIFIED DATE | SUBMITTED DATE |
|---|-----------|-------------|--------------|---------------|----------------|
| 033487 - Notification of an amendment to a research study | Submitted | Amy Garrett | 26/04/2022 | 26/04/2022 | 26/04/2022 |