**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.
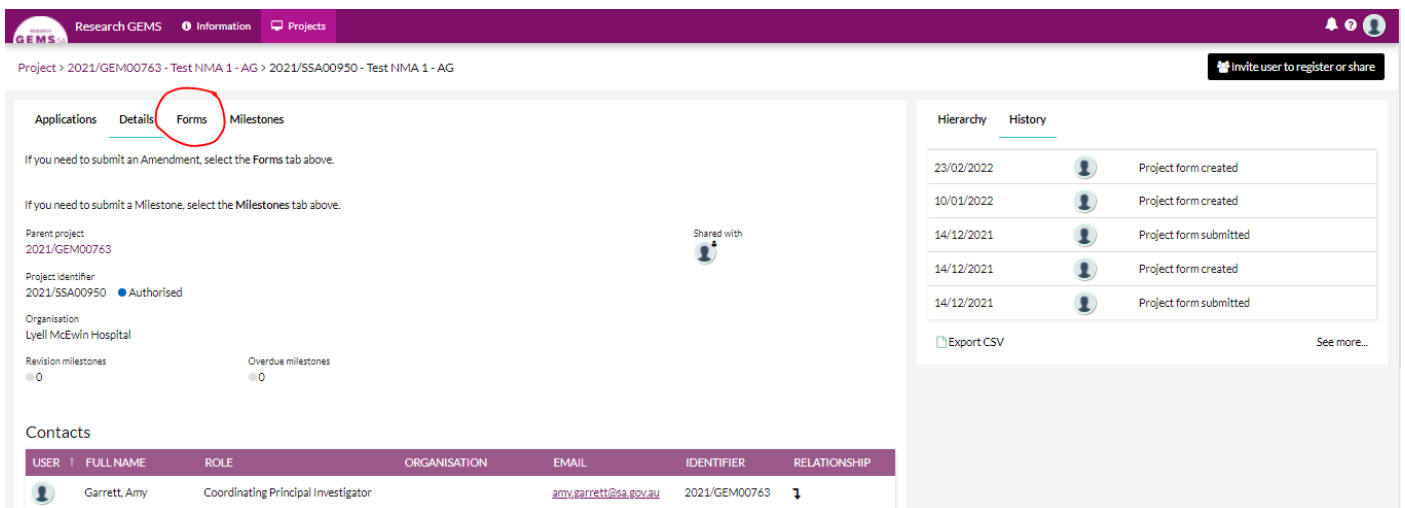
Please see instructions below for

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

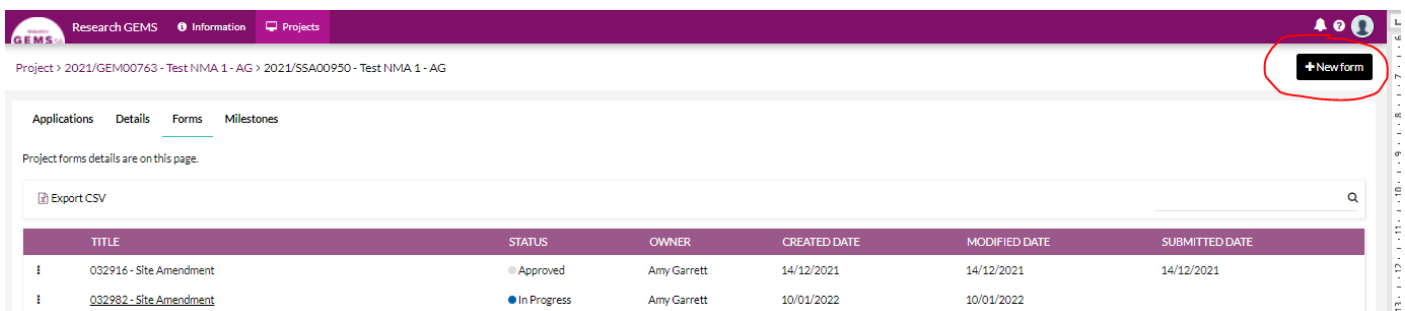# Site Amendments (when there is no HRE in GEMS)

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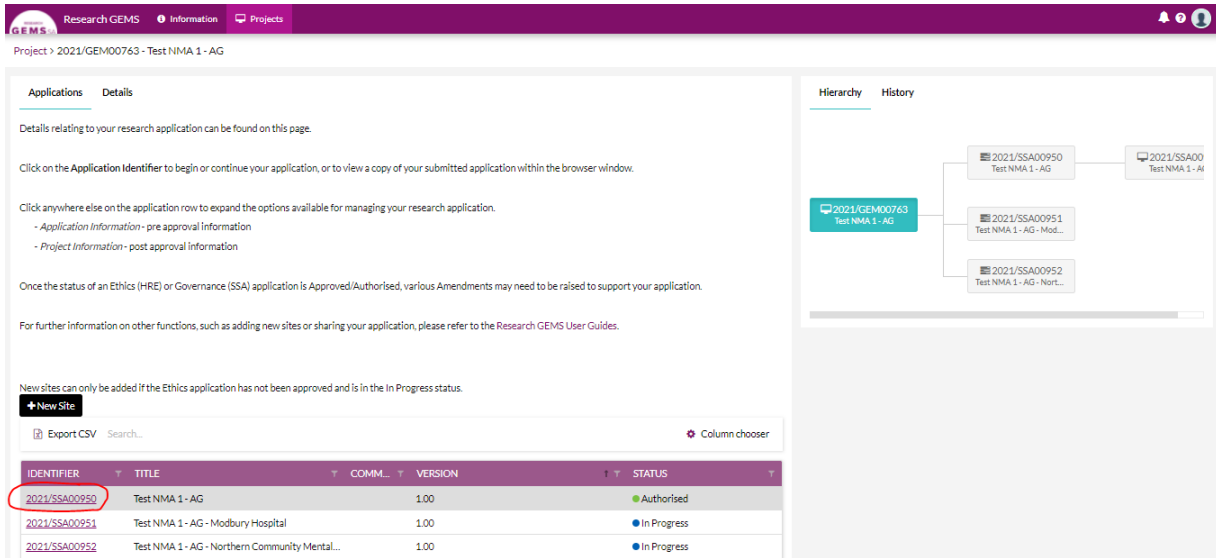
2. In the SSA, click on 'Forms'

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   ❶ Information   🖥 Projects

Form > Site Amendment

Project Details and Site Amendment Type ✔	**General Site Amendment**	🖹 Preview	💾 Save
General Site Amendment	← Previous		Next ➜
Ethics Approved Document Upload	▼ Lyell McEwin Hospital		
Declaration			

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'

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

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

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

Amendments that require Ethics approval (HRE exists in GEMS)

1. In the GEM Project, click on the HRE project
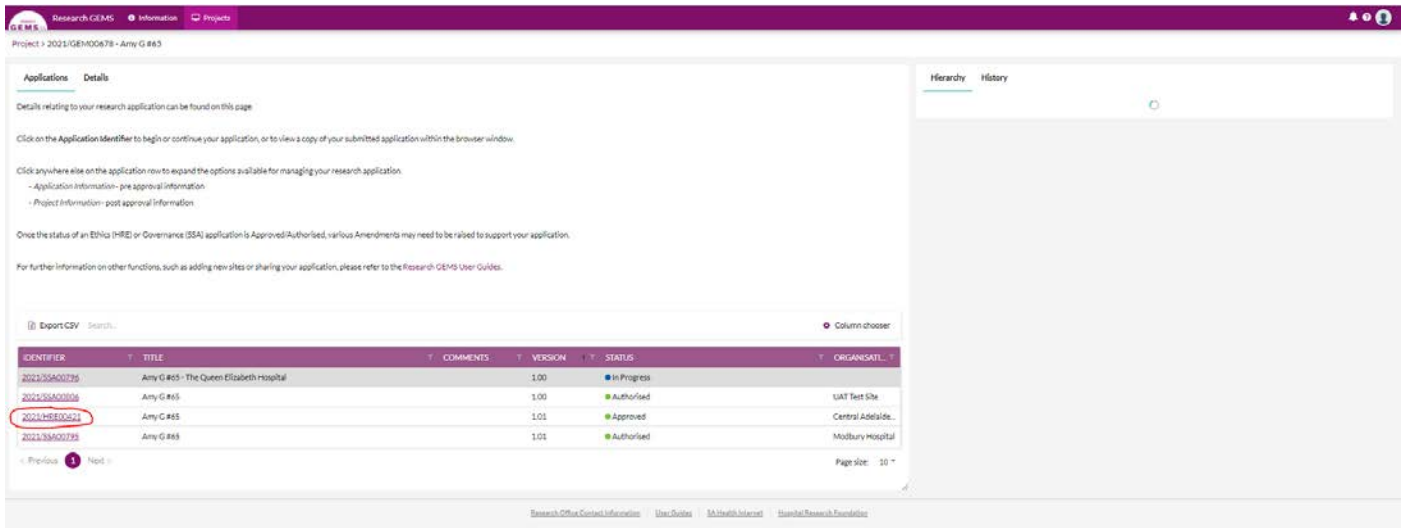
2. Go to the 'Forms' tab
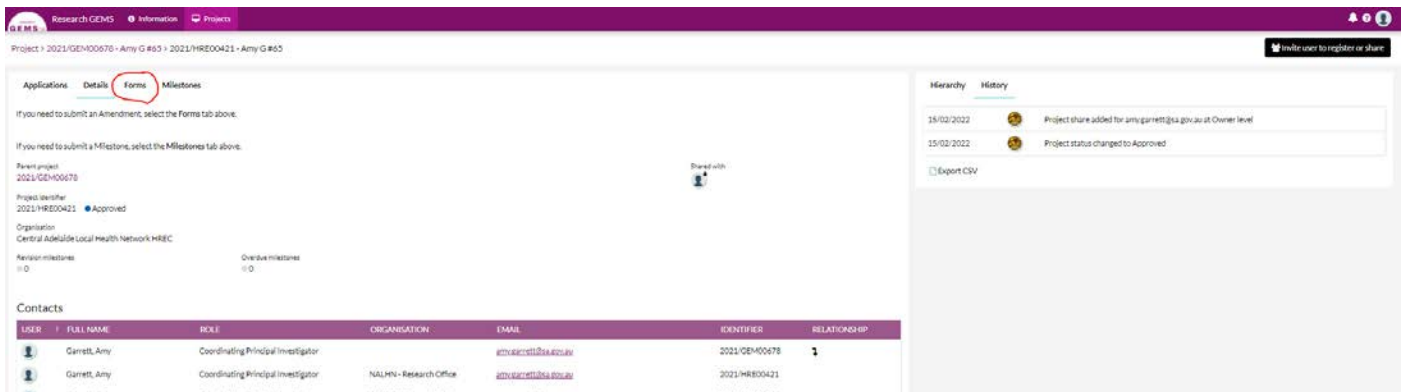
3. Click new form button and select the type of amendment

4. Fill in the form

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

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

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

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