



Creating a new Site Application

When do I use this guide?

This user guide is used when:

- ❖ Ethics is currently being reviewed by a SA Health HREC and a new site needs to be added/removed before the Ethics application has been approved. e.g. a site was missed or incorrectly selected during project registration, OR;
- ❖ When an amendment to add a new SA Health site has been approved through a non SA Health ethics committee under NMA and a SA Health site-governance form (SSA) is required in Research GEMS.

NOTE: Before you create a new site, contact the relevant Research Office to discuss. Depending on the status of the ethics application review (e.g. the application has already been assigned to a meeting or review) you may need to wait until you receive the request for information before adding a new site.

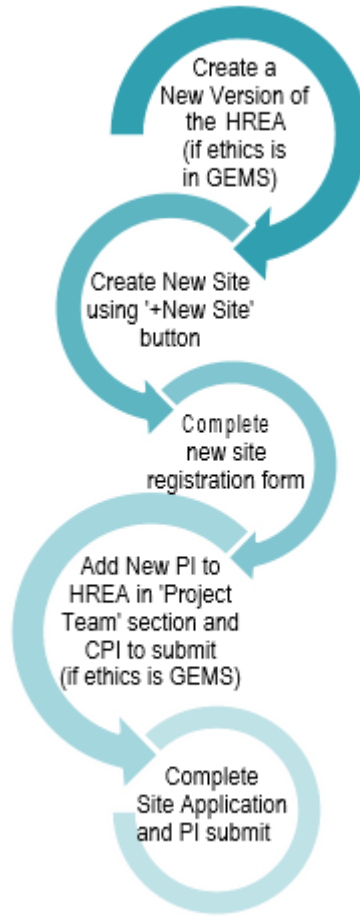
How does it work in GEMS?

Follow the steps below depending on the following circumstances:

If the HREA is currently being reviewed in GEMS and is not yet approved: go to **Part A** in this document.

If the Ethics application has already been approved in GEMS and the project is seeking to add a new site, an amendment is required. **See User Guide: [Completing and submitting and ethics amendment](#).**

If the HREA was approved external to GEMS, and one or more new SA Health site-governance applications are required, go to **Part B** in this document.



A list of projects will appear in a table. Click on the title or identifier to enter the Project Details home page.

The project title will appear at the top of the screen and you will see the associated ethics and governance applications.

Step 2. Create a 'New Site'

Click the  button.

Step 3. Complete the New Site registration form

This form is required to prefill the new Site application. Respond to each question.

NOTE: You must select at least one new site under one or more of the tabs 'SA Health' and/or 'Other jurisdictions and organisations'.

Step 4. Submit the New Site registration form

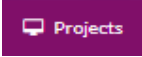
Click 'Submit' and the SSA form/s will be created. The new form will be in the status of 'In Progress'.

For guidance on completing the SSA, see the **User Guide: [Completing, requesting and submitting Head of Department Support](#).**

PART A: When the HREA is being reviewed in GEMS

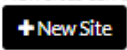
Step 1: Locate your application

When you log in to GEMS, your home page should show your top 5 projects. If you can see the project here, open it by clicking on the project identifier or the title.

If the project is not listed in your top 5 projects, click the  'Projects' icon at the top of the screen to take you to Project View.

PART B: When adding a new SA Health site to an externally approved application

Assuming the study has already been registered in GEMS (and has a GEM Identifier) a new site form can be created by the owner of the GEM Identifier and shared with the PI/Admin using the



+ New Site

following the above instructions from Step 2 OR can be added via a Site Amendment form.

See the User Guide: [Governance Amendment – Completing and Submitting a site amendment.](#)

For guidance on completing the SSA, **see the User Guide:** [Completing, Requesting and submitting Head of Department Support.](#)

If the study has not yet been registered this needs to be completed first.

See User Guide: [Project Registration](#)