

Create a New Site Application

When do I use this guide?

This quick reference guide is used when:

- ❖ Ethics is currently being reviewed by a NSW/ACT 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 NSW Health site has been approved through a non NSW/ACT ethics committee under NMA and a NSW Health site-governance form (STE) is required in REGIS.

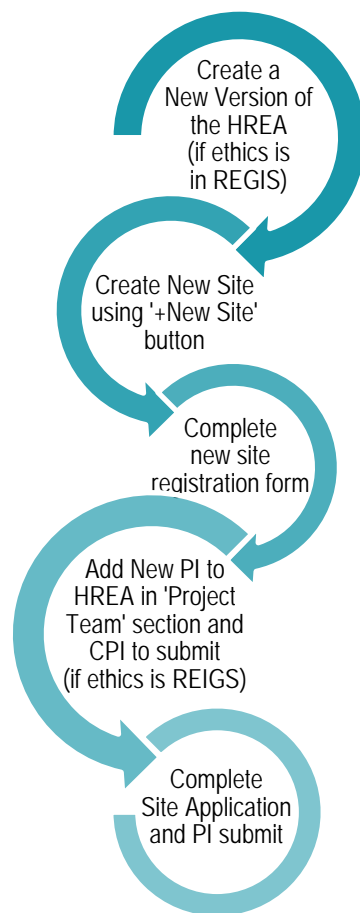
NOTE: Before you create a new site, contact the relevant Research Office to discuss. Depending on the status of the ethics application review (e.g. the application has already been assigned to a meeting or review) you may need to wait until you receive the request for information before adding a new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

How does it work in REGIS?

Follow the steps below depending on the following circumstances:
If the HREA is currently being reviewed in REGIS and is not yet approved: go to Part A in this document.

If the Ethics application has already been approved in REGIS and the project is seeking to add a new site, an amendment is required. See **Ethics Amendment - Completing and Submitting**

If the HREA was approved external to REGIS, and one or more new NSW Health site-governance application are required go to Part B in this document



PART A: When the HREA is being reviewed in REGIS

Step 1. Locate your application

When you log in to REGIS, 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 in the table on-screen.

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.



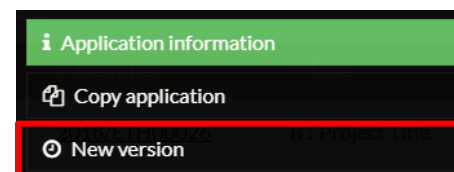
A list of projects will appear in a table. Click on the title or identifier to be taken to the Project Details home page.

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

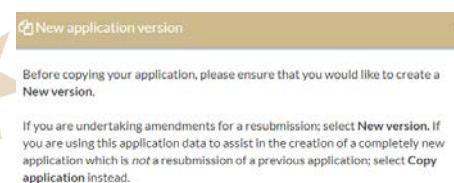
Step 2. Create a new version of the ethics application (HREA)

Click on the 3 dots next to the identifier of the ineligible application.

The Application information menu will appear. Select 'New version'.



A warning message titled 'New application version' will appear. Click on the 'New version' button.



A second message will appear. Unless you have been instructed, **do not** change the Application title.

In the application comments cell, add a note to describe why you are submitting a new version, e.g. Adding a new site prior to approval. Then click 'New version'.

New application version

You are about to create a new version of the selected application. If you would like to continue, click the 'New version' button below. If you would like to rename the application, please provide the new name below.

Application title
B1 Project Title

Application comments

< Back + New version Cancel

The status of the application will have changed to **In Progress**

Step 3. Create 'New Site Form'

Click the New Site button located under the PID.

+ New Site

Step 4. 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 'ACT Health', 'NSW Health' and/or 'Other jurisdictions and organisations'.

ACT Health

NSW Health

Step 5. Submit the New Site registration form

Click 'Submit' and the NSW STE form/s will be available to be completed. The new forms will be in the status of 'In Progress'.

For guidance on completing the SSA, see the QRG: [Site Application Completing, Requesting Head of Department Support and Submitting](#)

Step 6. Open the new HREA created at Step 2

From the Project applications table, open the Ethics application.

NOTE: Only the CPI or someone with editor access can complete the following steps

Step 7. Navigate to Project Team
Select 'Project Team' section on the left-hand, side menu.

Step 8. Add new Principal Investigator
Select the '+' add row icon and complete the new PI details.

The new project team member will now be available on the left-hand menu.

Step 9. Complete the new PI details
Select the name of the new PI displayed in the left-hand menu and complete questions 1.9.4-1.9.13.

Ensure the following are selected:

- 1.9.10 = Principal Investigator**
- 1.9.11 = No**

Step 10. Submit new version of HREA

Note: You MUST be the CPI of the project to complete this step.

Move to the end of the HREA by selecting 'Generate HREA document' on the left-hand menu. Select the 'Generate HREA document' button displayed on-screen.

A new version of the HREA will be submitted to the Research Office and confirmation emails sent to the CPI and other nominated contacts.

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

Assuming the study has already been registered in REGIS (has a PID) a new site form can be created by the owner of the PID and shared with the PI/Admin using the +New site button following the above instructions from Step 3 – 5 OR can be added via a Site Amendment form.

See the QRG: Governance Amendment – Completing and Submitting

For guidance on completing the SSA, see the QRG: [Site Application Completing, Requesting Head of Department Support and Submitting](#)

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

See QRG: Project Registration

For technical assistance, contact
REGIS HELP DESK

supportaf1solutions.com.au
1300 073 447