



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 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 the request for information is provided before adding a new site.

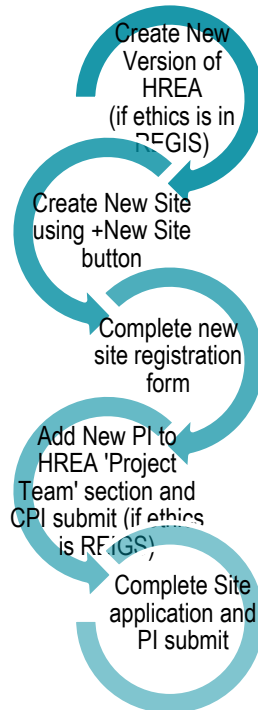
How does it work in REGIS?

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

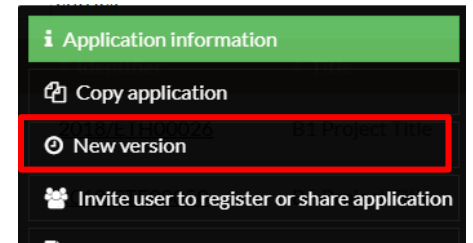


The project title will appear at the top of the screen and you will see the ethics and governance applications associated with it.

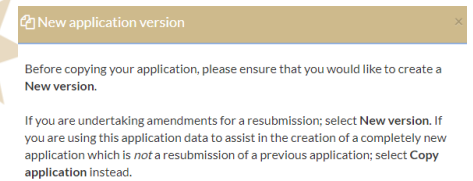
Step 2. Create a new version of the ethics application (HREA)

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'.

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 in the top right gold menu bar 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.

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

NSW STE/SSA forms will be available to be completed. The new forms will show a status of ● In Progress

For guidance on completing the SSA, see the QRG: [Site Specific Application Part 1: Completing Application & Requesting Head of Department Support](#)

Step 6. Open the new HREA created at Step 2

NOTE: to complete the following steps you will to either be the CPI or, have been granted shared edit access to the application.

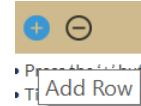
From the Project applications table, open the Ethics application.

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

Generate HREA document

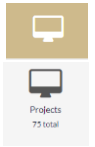
confirmation emails sent to the CPI and other nominated contacts.

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

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.

If the project is not listed in your top 5 projects, click the 'Projects' icon.



A list of projects will appear in a table. Select the project that a new site is being added.

Step 2. Create 'New Site Form'

Click

+ New Site

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

ACT Health

NSW Health

Step 4. Submit the New Site registration form

Click:

Submit

New site-governance application forms will now be available to be completed by the relevant PI for any NSW Health site added. The new forms will show a status of ● In Progress

For guidance on completing the SSA, see the QRG: [Site Specific Application Part 1: Completing Application & Requesting Head of Department Support](#)

For technical assistance, contact
REGIS HELP DESK

supportaf1solutions.com.au

1300 073 447