

Create a New Site Application

When do I use this guide?

This quick reference guide is used when:

- ❖ (Part A) **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;
- ❖ (Part B) **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.

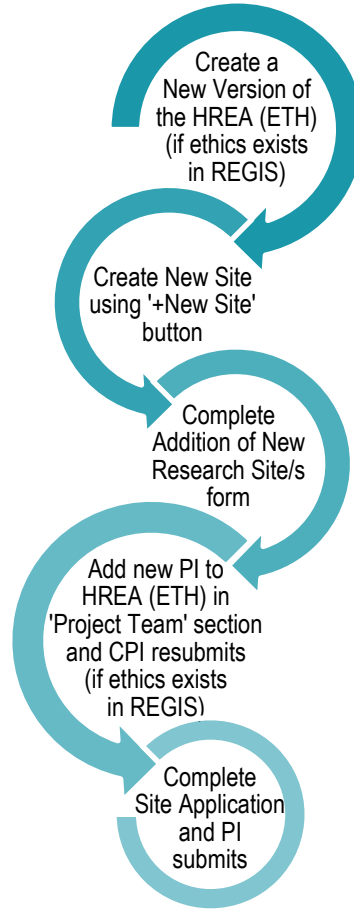
How does it work in REGIS?

Follow the steps below depending on the following circumstances:

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

If the HREA 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 applications are required, go to **Part B** in this document.

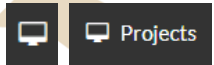


PART A: When the HREA is being reviewed in REGIS

Step 1. Locate your application

Select your project from your 'Top 5 projects' by clicking on the Project Identifier (PID).

If the project is not listed in your 'Top 5 projects', click the 'Projects' icon at the top of the page to view your full Projects list.

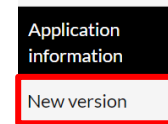


Click on the title to be taken to the Project Details page.

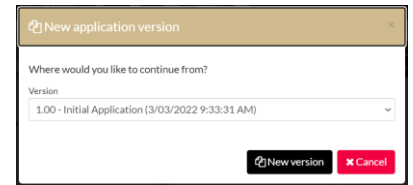
The project title will appear at the top of the screen, and you will see the associated Ethics and Governance applications.

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

2022/ETH00013 Click anywhere on the ETH study row and select 'New version'.

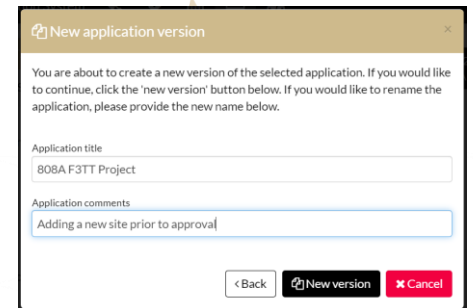


A pop-up will appear; this identifies the current version of the application. Click 'New application version'.



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

You can add a note in 'Application comments' to describe why you are submitting a new version, e.g., Adding a new site prior to approval. Then click 'New version'.

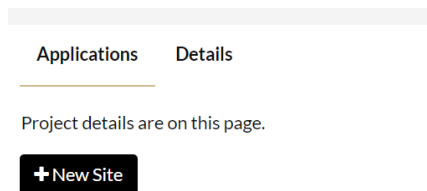


The status of the application will have changed to **In Progress**

Step 3. Create 'New Site Form'

Click the '+ New Site' button located under the Applications header.

Project > 2022/PID00022 - 808A F3TT Project

**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' or 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

Click on the ETH identifier to open the Ethics application.

NOTE: The CPI, anyone with edit or submit 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

+ Add Another

Select the '+ Add Another' button and complete the new PI details.

The new project team member will now be available in the 'Project Team Details' page.

Step 9. Complete the new PI details

Locate the new PI and complete questions 1.9.4-1.9.13.

Ensure the following are selected:

1.9.10 = Principal Investigator

Step 10. Submit new version of HREA

The CPI or their delegate(s) can now submit the amendment. If you do not have access to submit, save the form and notify the CPI and their delegate(s) that it is ready for submission.

Click 'Generate HREA document' from the left-hand menu. Click 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

If not already done, register the study in REGIS so that it has a PID. See QRG: Project Registration

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](#)

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).

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