

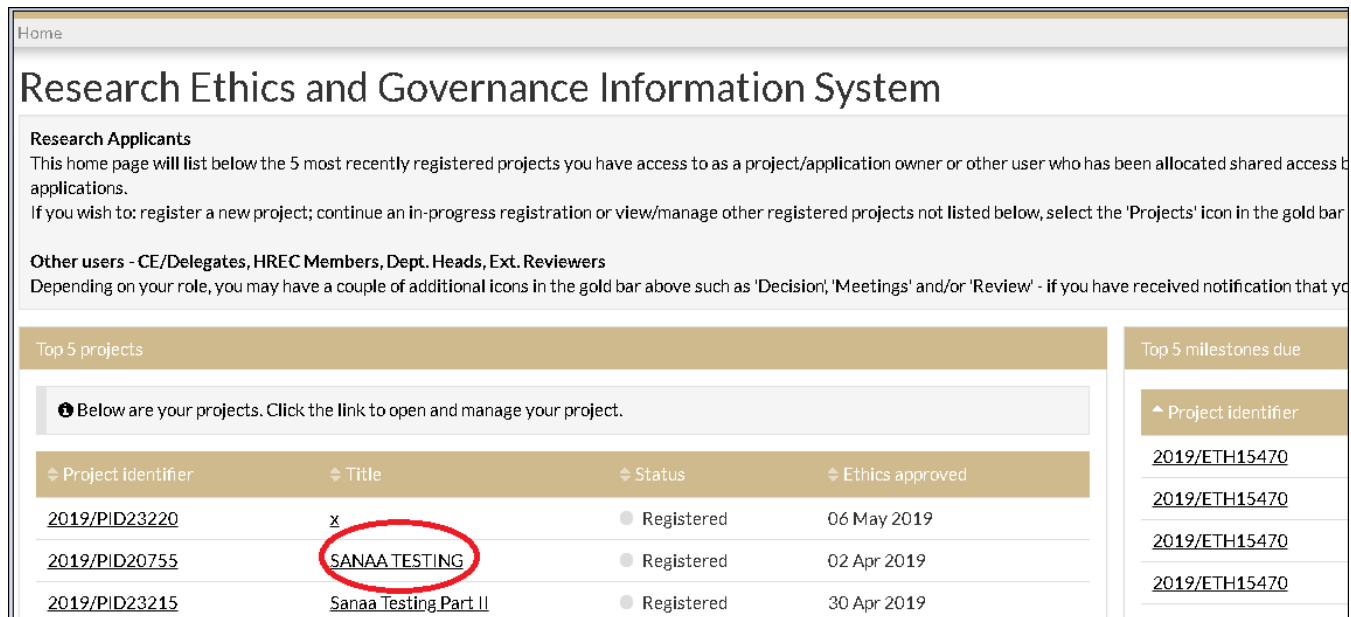
## How to create an SSA in REGIS

This needs to be submitted as an amendment to add a new site

NB: Only the CPI can submit this from their REGIS login

**Step 1:** Once you have logged into REGIS, find your study in your list of Projects.

Click on the study title:



Home

### Research Ethics and Governance Information System

**Research Applicants**  
This home page will list below the 5 most recently registered projects you have access to as a project/application owner or other user who has been allocated shared access to applications.  
If you wish to: register a new project; continue an in-progress registration or view/manage other registered projects not listed below, select the 'Projects' icon in the gold bar

**Other users - CE/Delegates, HREC Members, Dept. Heads, Ext. Reviewers**  
Depending on your role, you may have a couple of additional icons in the gold bar above such as 'Decision', 'Meetings' and/or 'Review' - if you have received notification that you

Top 5 projects

Below are your projects. Click the link to open and manage your project.

Project identifier	Title	Status	Ethics approved
<a href="#">2019/PID23220</a>	x	Registered	06 May 2019
<a href="#">2019/PID20755</a>	<b>SANAA TESTING</b>	Registered	02 Apr 2019
<a href="#">2019/PID23215</a>	Sanaa Testing Part II	Registered	30 Apr 2019

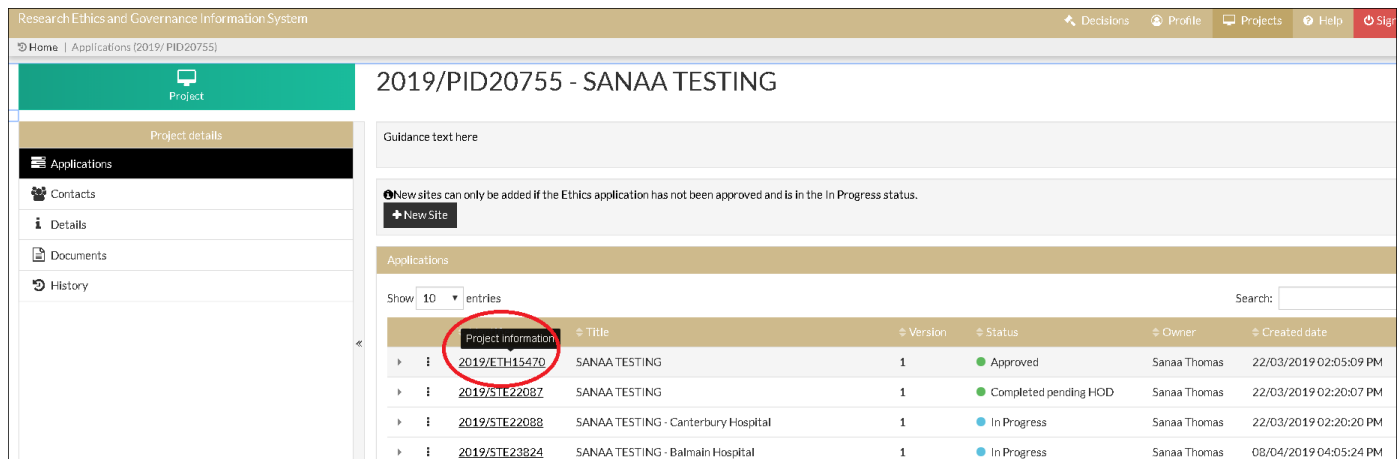
Top 5 milestones due

Project identifier

- [2019/ETH15470](#)
- [2019/ETH15470](#)
- [2019/ETH15470](#)
- [2019/ETH15470](#)

**Step 2:** This will open up the project. Click on the “ETH” number:

**Note:** Your study must be approved in order to submit amendments.



Research Ethics and Governance Information System

Home | Applications (2019/PID20755)

### 2019/PID20755 - SANAA TESTING

Guidance text here

New sites can only be added if the Ethics application has not been approved and is in the In Progress status.

New Site

Applications

Show 10 entries

Project information	Title	Version	Status	Owner	Created date
<a href="#">2019/ETH15470</a>	SANAA TESTING	1	Approved	Sanaa Thomas	22/03/2019 02:05:09 PM
<a href="#">2019/STE22087</a>	SANAA TESTING	1	Completed pending HOD	Sanaa Thomas	22/03/2019 02:20:07 PM
<a href="#">2019/STE22088</a>	SANAA TESTING - Canterbury Hospital	1	In Progress	Sanaa Thomas	22/03/2019 02:20:20 PM
<a href="#">2019/STE23824</a>	SANAA TESTING - Balmain Hospital	1	In Progress	Sanaa Thomas	08/04/2019 04:05:24 PM

**Step 3:** On the left-hand column, select “Forms” then “+New Form”:

Research Ethics and Governance Information System  
Home | Applications (2019/PID20755) | Project Details (2019/ETH15470) | Forms (2019/ETH15470)

## 2019/ETH15470 - SANAA TESTING

Project details are on this page.

Forms

Below are your forms. Click the link to open an existing form, use the 'new form' button below to start a new one.

**+ New form**

Show 10 entries

Title	Status	Created date
<a href="#">002349 - Significant Safety Issue Notification</a>	In Progress	24/05/2019 2:46:58 PM
<a href="#">002350 - Reporting Local Safety Events to the Institution</a>	In Progress	24/05/2019 2:48:13 PM
<a href="#">002165 - Notification of an amendment to a research study</a>	Submitted	2/04/2019 11:39:17 AM
<a href="#">002205 - Notification of an amendment to a research study</a>	Approved	8/04/2019 3:51:12 PM

**Step 4:** Select “Notification of an amendment to a research study”:

**+ New form**

Select the form you wish to fill out:

- Notification of an amendment to a research study**
- Reporting Local Safety Events to the Institution
- Serious Breach Notification form (third party)
- Significant Safety Issue Notification

**Cancel**

**Step 5:** Select “Addition of New Site”, then click the next page arrow:

**Amendment type\***

General amendments are those that impact on the conduct, the design, or the methodology of a trial and include:

- (a) Amendment to information previously given on the HREA
- (b) Amendments to the protocol *note: If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be provided.*
- (c) Amendment to the information sheet(s) and consent form/s for participants, or to any other supporting documentation for the study.

*Request for extension of HREC approval should be completed if a researcher/sponsor wishes to extend the project beyond the original period granted by the HREC*

- General Amendment
- Request for Extension of HREC Approval
- Addition of a New Site**
- Change in PI/CFI

**→**

**Step 6:** Click on the relevant state tab, then click the plus button.

**NB:** Only use this function to add NSW or ACT sites.

If adding a site from another state (or a private site), submit this as a “general amendment”.

Research Ethics and Governance Information System

Applications (2019/ PID20755) | Project Details (2019/ ETH15470) | Forms (2019/ ETH15470) | Forms (2019/ ETH15470) | New Form (Notification of an

Project Details and Amendment Type

**Addition of New Research Site/s**

Conflict of interests

Document upload

Coordinating Principal Investigator/Reporter's Declaration

### Addition of New Research Site/s

In the tabbed sections below, you will be required to nominate the sites at which you intend to undertake the activity.

You can **add** a site under the required tab/s by selecting the '+' icon. For locations with ACT Health or NSW Health, you either government organisation, you will provide details as indicated.

If you wish to **delete** a site that you have listed below, select the tick box next to the Project Centre label and then select the minus icon.

**Before proceeding, please note:**  
All PIs named in this section must have a REGIS user profile before you will be able to complete registration - a match will be found for you to select and their full name will be added below. If no match is found, leave the PI email blank and select 'Invite to Register'. This will open a dialogue box for you to enter the PI's REGIS email address. Once they can confirm they have registered their profile, come back to this page.

**Invite to register**

ACT Health **NSW Health** Other health jurisdictions or organisations

Select a Principal Investigator for each Site

+ -

**Step 7:** Work your way through the questions.

**NB:** If you are unsure whether your department is within RPAH or a “SLHD (site)”, please phone the Research Ethics and Governance Office to confirm before you proceed.

**NB:** The Principal Investigator must have a REGIS account, as only they will be able to access the SSA from under their login.

**Invite to register**

ACT Health **NSW Health** Other health jurisdictions or organisations

Select a Principal Investigator for each Site

Project Centre \*  
Sydney Local Health District

Project site \*  
Balmain Hospital  
Canterbury Hospital  
Concord Repatriation General Hospital  
**Royal Prince Alfred Hospital**  
Sydney Local Health District (Site)  
Z Pre REGIS SSA - Syd - Research Office, CRGH - Site  
Z Pre REGIS SSA - Syd - Research Office, RPAH - Site

Site Investigator details

Principal Investigator email address \* PI Name

Position \* Employer \*

Describe the person's expertise relevant to this research activity they will undertake at this site \*

**Step 8:** Work your way through the sections.

When you get to 'Document upload', upload the Principal Investigator's CV.

**NB:** If it is a migrated study and this is the first time the document has been uploaded into REGIS, click "No" to the question "Upload as new version":

**Step 9:** Click the submit button (only the CPI can submit amendments from their login):