



Site Application, Completing, requesting Head of Department Support and Submitting

What is a site application (SSA/STE)?

SSA/STE is part of the site governance process adopted across NSW Health by which a potential research site considers authorisation of a project to access and/or utilise its resources. SSA/STE applications are required for each site where the research will be conducted within a Centre (e.g. LHD or Network). They can be completed and submitted before ethics approval has been made but cannot be authorised until ethics approval has been obtained.

How does it work in REGIS?

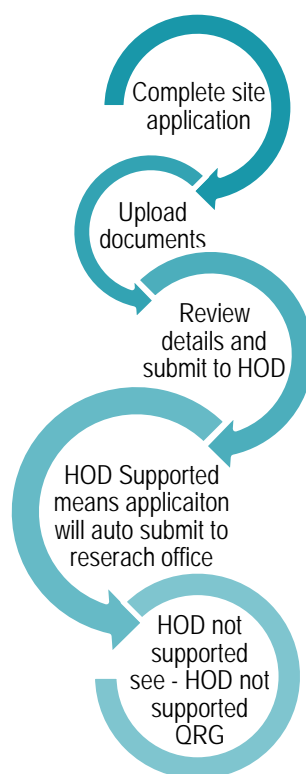
A NSW Health SSA/STE application can be completed in REGIS after Project Registration and, if required, the ethics application has been submitted. Information provided during project registration and HREA will pre-populate relevant fields in SSA/STE/s in REGIS for faster and easier completion. The Principle Investigator (PI), as the person responsible for the research conducted at their nominated site, can submit the SSA for HOD support. However, the PI can share access with others to assist completion of the application.

Sharing the application to view or edit

The PI can give view and edit rights to the SSA application to anyone with a REGIS account. This is done from the Project Details home page by clicking on the 3 vertical dots next to the application and then selecting 'Invite user to register or share application'.

How it works in REGIS The following

The following diagram highlights key aspects of how the SSA process works in REGIS.



- The names and contact details of anyone involved in the research project for that site who will be conducting research (refer to NSW Health guidelines [here](#)) or providing departmental support
- Any site specific documents that were not submitted during project registration or ethics application.

*Note: Remember! You should speak to any Head of Department/s you will be approaching to support your research **before** completing the application.*

Completing a Site-Specific Assessment (SSA) in REGIS

Step 1: Navigate to the application

If you are completing the STE directly after completing the HREA, see step 2.

Accessing the STE from the home page, select the 'Projects' icon



Select the project from the list by clicking on the identifier link and the Project Details page will open.

Step 2. Open the SSA application

The status ● In Progress indicates the STE can be edited or completed.

Select the STE identifier of the SSA to open the application, i.e. 2020/STE12345

You will only be able to access the STE associated with your site.

Tip: You can save your application at any time and return later to add more information.

What information is needed?

You should have the following information ready to complete and submit your SSA/STE:

- Your REGIS user name and password
- Completion of your ethics application or prior ethics approval

Step 3: Complete the SSA application

Mandatory questions and fields are marked with an asterisk * and must be completed before you can move to the next screen.

The following details will only describe where there are system requirements to be aware of to complete the form.

Part A: Project-wide information

Details here should match the Ethics details.

Part B: Project team

This section relates to the PI and any other site personnel.

B2 will show the PI as listed at Project Registration.

B7 select yes to add the admin contact.

B8 add members of the project team who are specific to the site including Associate Investigators (AI), other researchers and external researchers

Part C: Departments and services

Head of Department (HOD) for the PI and any AI's must be listed here.

HOD for any supporting departments must be listed here. E.g. medical records, imaging.

If you or one of the named applicants is also a HOD you should contact the local Research Office for guidance.

C1: If you do not see the Department you require, contact the Research Office for the site.

Tip: Want to get your study signed off by the HOD quickly? Discussing your study directly with any HOD before submitting the application tends to get the application signed off faster.

C4: Include detailed advice here regarding resources, this will help inform the HOD when they review the STE.

Use the plus sign at the bottom of the page to add additional departments.

Part D: Recruitment, Records, Tissue and Data

If you answer 'Yes' to any of the questions in this section, you will be prompted to answer some more questions and provide additional information.

Part E: Site costing and funding

E1.2: Answering 'Yes' to this question requires you to upload a budget document at Part F.

Part F: Attachments, site specific documents

The initial ethics application has been automatically attached a .zip file **DO NOT** clear content selection!

Document Type
 Ethics application (HREA or other) Clear content selection (2020_ETH00018.zip) [Open]

Upload any relevant site specific documents associated with your application.

Document Type: Select from dropdown.

Document Descriptor: Provide a clear and descriptive document descriptor.

Note: How your document is described is how it will appear on the approval notification so ensure it is clear and descriptive, think about how you would want it to appear on the approval notification.

Document version: As listed on document. If the document does not have a version enter 0.

Document date: As listed on document. If the document does not have a version enter today's date.

Use the plus and minus signs at the bottom to add additional documents or delete documents.

Depending on earlier responses in Part A-E, REGIS will indicate required documents that have not yet been uploaded.

Missing documents:
 Budget - Site Study

Part G: Declaration and request Head of Department Decision

This section must be completed by the **PI**. If you are not the PI listed at B2 you can save the application and let them know the application is ready to be submitted.

If you are the PI, you will be able to select the 'Complete SSA' button.

REGIS will now notify each Head of Department (HOD) listed in Part C that their support has been requested.

An announcement will pop up on your screen which allows you to download a .zip file of the application form and attachments. You may wish to download this .zip file for your own records.

Application submission

Select the application attachments you wish to download:

[All application forms and attachments \(.zip\)](#)
 This package of files contains your application content, attachments, and other files supporting your application.

> Next

NOTE: The application has NOT yet been submitted to the Research Office.

The application will now show a status of **Completed pending HOD** and REGIS will send an initial notification email to each listed HOD and two reminder emails with declarations pending.

Supported = Submitted

When all HODs have reviewed the application and supported with either:

- able to undertake the investigations/services
- able to undertake the investigations/services if the following financial assistance is provided

The system will automatically submit the application to the Research Office and the status of your application will change to **Submitted**

The research office will then begin the review of the application.

HOD not supported

If one or more of the HODs select:

- unable to undertake the investigations/services indicated

The status of the site application will show as ● **HOD Not Supported**

Use the next section of this document to view the decisions in REGIS.

You should discuss the decision directly with the HOD.

See QRG – Site application HOD Not supported

No status change?

If after one week your application status has not changed from 'Completed pending HOD', it is recommended that you contact the HOD directly to discuss.

It is the research applicant's responsibility to follow up outstanding HOD declarations.

How to view completed and outstanding declarations

Step 1: Navigate to the application

If you are accessing the SSA from the homepage, select the 'Projects' icon from the top of the page to view a list of Projects you have access to.



Select the project from the list by clicking on the STE identifier and the **Project Details** page will open.

Step 2. Open the SSA application

A list of all the applications associated with the project is displayed on the **Project Details** page.

Step 3. Locate HOD declaration(s)

Click the 'Options' (3 vertical dots) icon located next to the application identifier to view the application information menu.

Click the i Application information option to open the Application Details page

Step 4. View Individual decision outcomes and comments

Decisions Select 'Decisions' from the left-hand menu

Note: All HOD declarations are grouped under the one decision type 'Head of Department Support for Site Specific Assessment'.

Title	
⋮	Head of Department Support for Site Specific Assessment

Click the 'Options' (3 vertical dots) icon located next to the Title and then click the 'Decisions' icon to view individual decisions and comments.

A decisions pop up will appear listing each individual decision:

- ❖ User: HOD
- ❖ Decision: Outcome
- ❖ Comment

User	Decision
Weninger, Wolfgang	able to undertake the investigations/services
Loblay, Robert	able to undertake the investigations/services
Twigg, Stephen	able to undertake the investigations/services

Decisions that are blank have not yet been made. You should contact this HOD directly.

Click 'Cancel' to close the Decision pop up.

If you have any questions about your application, contact your reviewing Research Office.

See QRG – Site application HOD Not supported

Once your site application has been submitted, your application will be assessed for eligibility to be reviewed by the Research Governance Officer. If you have any questions, contact the Research Office at the site relevant to the application.

If your ethics application is yet to be approved, the final decision made by the Chief Executive/Delegate cannot be made until the ethics approval for the study has been received from the nominated Human Research Ethics Committee (HREC).