



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

What is a site-specific assessment (SSA)?

SSA 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 applications are required for each site (e.g. location, service or facility) where the research will be conducted within a Centre (e.g. LHD or Network). SSAs can be completed and submitted before ethics approval has been decided but cannot be authorised until ethics approval has been obtained.

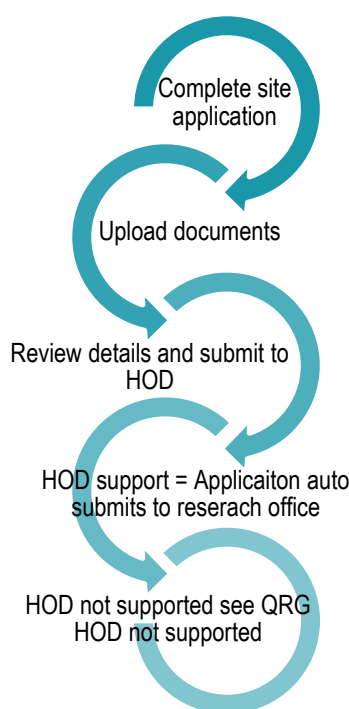
How does it work in REGIS?

A NSW Health SSA application can be completed in REGIS after Project Registration and, if required, the ethics application has been submitted. Information provided during project registration will pre-populate relevant fields in SSA/s in REGIS for faster and easier completion. Only 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. The following diagram highlights key aspects of how the SSA process works in REGIS.

Sharing the application to view or edit

The Principal Investigator (PI) can give view and edit rights to the SSA 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'.



- Health guidelines [here](#)) or providing departmental support
- Any site specific documents that were not submitted during project registration or ethics application.

Remember! You should speak to any Head of Department 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 SSA directly after completing the HREA, REGIS will automatically display 'Applications View' listing the ethics and site application/s within the Registered Project. See step 2.

If you are accessing the SSA from the home page, select the 'Projects' icon from the top right-hand gold menu bar to view a list of Projects you have access to.



What information is needed?


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

- Your REGIS user name and password
- Completion of your ethics application or prior ethics approval
- The names and contact details of anyone involved in the research project for that site who will be conducting research (refer to NSW

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

NOTE: If you are completing the SSA directly after completing the HREA you will start here.

A list of all the applications associated with the project is displayed on the **Project Details** page. The  **In Progress** status indicates the SSA can be edited or completed.

Select the 'Identifier' of the SSA to open the application – the STE code e.g. 2018/STE00067

NOTE: You will only be able to access the SSA associated with your site.

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

Step 3: Complete the SSA application

There are 7 sections of the SSA that will appear in the left-hand panel. Questions and fields that must be completed before you can move to the next screen are marked with an asterisk *

Part A: Project-wide information

Details that has been entered during Project Registration will be auto-populated into the SSA form. **Do not amend or delete any information in Part A. Errors/changes in this section will need to be completed in the HREA first. You should speak to the Coordinating Principal Investigator or the Research Office.**

Part B: Project team

This section relates to the PI and any other site personnel. Here you can add members of the project team who are specific to the site including Associate Investigators, other researchers or contact personnel who will be on site undertaking study activities or who have access to site participants. Some details will be pre-populated from Project Registration, with some additional questions for completion.

Part C: Departments and services

Select the department from the drop down menu, and the Head of Department's (HoD's) email address will appear

If you or one of the named applicants is also the 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.

C4: Include detailed advice here regarding resources as this will help inform the Head of Department when they review the SSA.

Use the plus signs at the bottom to add additional departments.



It is advised that you contact each HOD directly about your study before listing them in the application.

Part D: Recruitment, records, tissue and data

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

Part E: Site costing and funding

Here you can enter budgets and financial information. If you answer 'yes' to the questions you will be prompted for further information.

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

Part F: Attachments, site specific documents

Directly below the page heading you will see a Document Title which is the Ethics Identifier (20xx/ETHxxxx). The system has automatically attached a .zip file of the ethics application with all its attachments. **DO NOT** clear content selection!

You need to upload any relevant site specific documents associated with your application.

Document Type: Select from dropdown.

Document Descriptor: Enter in the following format: <short description of doc type><site acronym><brief unique descriptor> (PISCF-RNSH-Intervention)

20 characters max

Document version: as listed on document. If the document does not have a version entre o.

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

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



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 read each point to ensure that you have complied with the requirements of the SSA, then select

Complete SSA

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

REGIS HELP DESK

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

support@risolutions.com.au

1300 073 447

The application will now show a status of

● Completed pending HOD

REGIS will send an initial notification email to each listed HOD and 2 reminders with declarations pending.

Supported = Submitted

When all department heads 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.

The status of your application will change to.

● Submitted

The research office will 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 Head/s of Department.

It is the research applicant's responsibility to follow up outstanding HOD declarations. However, if you are unable to reach a HOD in a reasonable timeframe you should seek the advice of the local research office.

How to view completed and outstanding declarations

Step 1: Navigate to the application

If you are accessing the SSA from the home page, select the 'Projects' icon from the top right-hand gold menu bar to view a list of Projects you have access to.



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

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

Select the 'Decisions' option on the left-hand menu



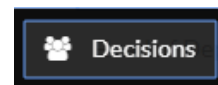
Note: all HOD declarations are grouped under the one decision type Head of Department Support for Site Specific Assessment.

◆ Title
Head of Department Support for Site Specific Assessment

Click the 'Options' (3 vertical dots) icon located next to the Title



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 person.

Click 'Cancel' to close the Decision pop up

If you have any questions about your application, contact your 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 after you have submitted your site application, the final decision made by the Chief Executive/Delegate can only be made once ethics approval for the project has been received from the nominated Human Research Ethics Committee.

For technical assistance, contact
REGIS HELP DESK

support@f1solutions.com.au
1300 073 447