REGIS

Site Specific Assessment Part 1

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANT

SSA Part 1: Completing the Application & Requesting Head of Department Support

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.

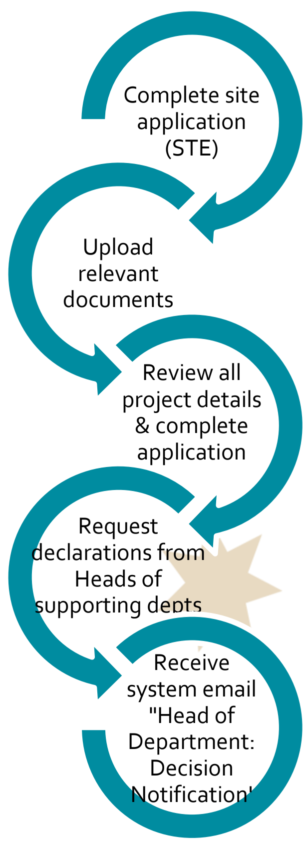
How does it work in REGIS?

A NSW Health SSA application can be completed in REGIS after Project Registration and, if required, the ethics application has been submitted.

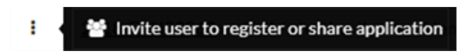
Information provided during project registration will pre-populate relevant fields in SSA/s in REGIS for faster and easier completion.

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'.



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 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.

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

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

Information that has been completed in 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

In this section, select the department/s from the drop down menu, and the Head of Department's (HoD's) email address will appear automatically. You can add further information as required.

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

C5: Include detailed advice here regarding resources as this will help inform the Head of Department when they review the SSA.

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.

E3: 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 it's attachments. **DO NOT** clear content selection!

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

Depending on the responses in Part A-E REGIS will indicate required documents that have not yet been uploaded e.g. Missing documents:

Budget - Site Study

1. Complete the Document Title. Do not add any version or dates here. E.g. Main Information Sheet
2. Use the drop down filter to specify the Document Type. E.g. Participant Information Sheet
3. Click Upload New to locate the file on your computer and upload it. Keep your electronic filenames as short as possible when asked to enter

The order of the steps 1-3 is VITAL to allow the system to manage document versions.

The system will create a system filename. e.g. Participant Information Sheet_Main Information Sheet_Site Name.docx

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

Part G: Declaration and request Head of Department Decision

This section must be completed by the PI.

Carefully read each point to ensure that you have complied with the requirements of the SSA, then select Complete SSA for REGIS to notify each Head of Department (HOD) listed in Part C that their support declaration has been requested.

The application will now show a status of

● Completed pending HOD

NOTE: The application has NOT been submitted to the Research Office at this stage.

What Next?

Once all HODs have provided a support declarations you will receive a system generated email.

The status of the site application will show as either:

- HOD Not Supported

OR

- Pending Submission

The application is now ready to be submitted to the Research Office.

See – SSA Part 2: Submitting SSA after HOD Declaration

What if I don't get the system notification?

The system will send reminder emails to any HOD who have declaration pending.

If after one week your application status has not changed from:

- Completed pending HOD

It is recommended that you contact the Head of Department directly to discuss.

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.

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

How to view outstanding declarations:

Useful when an application has multiple HODs

Step 1: Navigate to the application

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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 Identifier

2018/STE00067

to open the application information menu.

Click the Application information option to open the Application Details page

Step 2. 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

Decisions

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

For technical assistance, contact
REGIS HELP DESK

support@f1solutions.com.au
1300 073 447