



Completing Site Assessment

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANT

Completing Site Specific Assessment

What is a Site Specific Assessment (SSA)?

Site Specific Assessment is the site governance process (separate to ethical review) completed at any time after the ethics application has been submitted in REGIS. The process is facilitated by the completion of a Site Specific Assessment (SSA) application for each site where the research will be conducted.

The assessment helps each site decide if there are resources available to effectively conduct a research project at a nominated site. It considers risks, impacts and practices at each research location.

Resources may include staff, equipment and human participant considerations. Evidence of adequate indemnity and contract arrangements (where applicable) is also reviewed.

Information provided during Project Registration will pre-populate relevant fields in SSA/s for faster and easier completion.

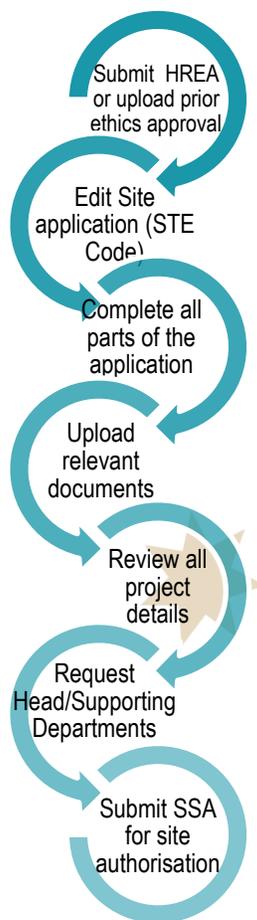
SSAs can be completed and submitted prior to ethics approval being granted but cannot be considered for final authorisation by the Chief Executive/Delegate until the Human Research Ethics Application (HREA) has been approved by the nominated Human Research Ethics Committee - see **Quick Reference Guide: Completing an Ethics Application** for further information.

How does it work in REGIS?

The Principal Investigator (PI), as the person responsible for the research conducted at their nominated site, is required to complete and submit the SSA for their site.

PI contact details for each site are entered at Project Registration. SSAs for each site are generated by REGIS only after the HREA has been submitted by the Coordinating Principal Investigator (CPI).

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



- ❖ Your REGIS username and password
- ❖ Completion of your HREA or prior ethics approval uploaded
- ❖ Site specific checklist of any additional documents required for the SSA.
- ❖ The names and contact details of anyone involved in the research project for that site who will be conducting research activity. IMPORTANT NOTE: those who are conducting research activity must have a REGIS account before you can complete the SSA.

Remember! You should speak all those endorsing your research prior to submitting the application.

If the project is a clinical trial, you may also need:

- ❖ Documentation on insurance and indemnity arrangements to upload to REGIS.
- ❖ A copy of the [Clinical Trial Research Agreement](#) (CTRA) to the local Research Office. You may submit this ahead of submission of the SSA. Speak to your [local Research Office](#) for guidance.

How to complete a Site Specific Assessment (SSA) application in REGIS?

Step 1

When you log in to REGIS, your home page will have a top right gold menu bar with some icons.



Click 'Projects' icon

This icon will take you to the **Projects Home View** where you can view all projects. A list of all application will appear by Title and Identifier (PID). Select the Project from the list.

Note: this guide assumes you have registered

What information is needed?

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

your project – see **Quick Reference Guide: Creating Project Registration** and either uploaded prior ethics approval – see **Quick Reference Guide: Uploading Prior Ethics Approval** – or completed and submitted a Human Research Ethics Application (HREA) – see **Quick Reference Guide: Completing an Ethics Application**.

Step 2

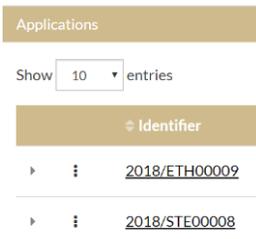
The **Project Details** View will appear showing a list of the applications associated with the Project.



Click 'Applications' to view applications for this project. Site applications are indicated with the STE code.

Step 3

A list of the applications associated with the research project will appear – both the ethics (ETH) and each SSA (STE). You will only be able to access the SSA (STE) associated with your site.



Click the 'Identifier' of the relevant SSA application (denoted by 'STE')

The SSA application will open and is ready for your completion.

Step 4

There are seven (7) sections of the SSA that will appear in the left panel. Questions and fields that must be completed to move to the next screen are marked with an asterisk *.

Step 5

Part A: Project Wide Information

All information that has been completed in Project Registration will be auto-populated into the SSA form. Do not amend the information as it will not be reflected in the HREA. If you would like to make any amendments to this text, you may need to submit an Amendment to the approving

HREC – see **Quick Reference Guide: Submitting an Amendment to an approved Project**.

Step 6

Part B: Project Team

This section relates to the Principal Investigator 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. You will need to complete these.

REMEMBER! You can save your SSA at any time and either complete another section or return late to add further information or complete and submit.

Step 7

Part C: Departments and Services

In this section, select the department from the dropdown, the department head email address will appear automatically. You can add further information as required.

Step 8

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.

Step 9

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.

Step 10

Part F: Attachments – Site Specific Documents

Attach any relevant documents associated with your application, based on the site checklist available from the Research Office.

Use the dropdown filter to specify the Document Type.



Use the plus/minus signs at the bottom to add additional documents

Upload New

Click 'Upload New' button to locate the file on your computer and upload it

Step 11

Part G: Declaration prior to Head of Department Decision

It must be completed by the PI. Carefully read each point to ensure that you have complied with the requirements of the SSA.

Complete SSA

Click 'Complete SSA'

Step 12

Head of Department Decision

Each listed Head of Department is sent notification that a SSA is ready for their decision.

● Submission Pending

In the Project View the STE will appear as Submission Pending

You will be notified by email once each Head of Department has made their decision.

Step 13

Part G: Declaration for submission to Research Office

The application is now required to be submitted for site review. Do this by repeating the following steps:

Step 1, Step 2, Step 3 and Step 11

● Submitted

In the Project View the STE will appear as Submitted

Once Site Specific Application has been submitted:

- ❖ Your application will be assessed for eligibility to be reviewed by the Research Governance Officer for the relevant site. If you have any questions throughout this process, you should contact the Research Office at the site to which you have applied.
- ❖ If your ethics application is yet to be approved after you have submitted your SSA/s, the final decision made by the PHO Chief Executive/Delegate, can only be made once ethics approval for the project has been received from the nominated Human Research Ethics Committee (HREC).

support.f1solutions.com.au
1300 073 447