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...
Submitting an Amendment to an approved HREA.

Information as it will not be reflected in the SSA form.

Project Registration will be auto-completed.

All information that has been completed in the SSA form.

Next screen are marked with an asterisk (*).

Questions and answers may be pre-populated from Project Registration.

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

You can add further information as required.

In this section, you can add members of the project team who are specified 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.

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

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 approval 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).