REGIS

Site Application - Completing

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANTS

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, TAS & ACT 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?

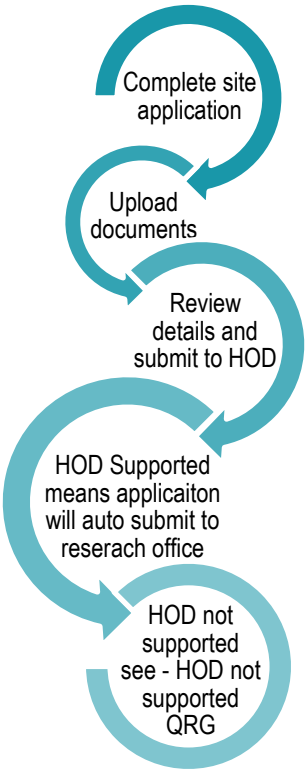
A NSW/TAS/ACT Health SSA/STE application can be completed in REGIS after Project Registration and if required, the ethics application has been submitted. Information provided during project registration and HREA will pre-populate relevant fields in SSA/STEs in REGIS for faster and easier completion. The Principal Investigator (PI), as the person responsible for the research conducted at their nominated site, can submit the SSA for HOD support. The PI can also 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 any blank space on the relevant row of the application to be shared. . The row will then expand, where you can click on 'Invite user to register or share application'.

How it works in REGIS

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



What information is needed?

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

- Your REGIS username & 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.

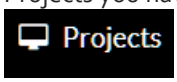
*Note: Please speak to the relevant Head of Department(s) you will be approaching to support your research **before** completing your application.*

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.

Click the 'Projects' icon at the top of your REGIS home page to view a list of Projects you have access to.



Select the project from the list by clicking on the Project Title.

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.

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.

Part A: Project-wide information
Details here should match the Ethics details.

If the responses provided during Project Registration indicated your study is a Clinical Trial, a warning message will appear at the top advising that the site application must be included in the NSW Health Statewide CTMS (or in the local SWSLHD CTMS for South Western Sydney sites).

A7a: Enter the NSW Health Statewide CTMS CCID here, if applicable.

Part B: Site 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
C1: Click the black 'Add Another' button to add the relevant department for your site. E.g. Emergency, Surgery, Records, Imaging, etc.

Once the department has been selected, the HoD is automatically populated. If you or one of the named applicants is also a HOD you should contact the local Research Office for guidance.

If you do not see the Department or HOD you require, contact the Research Office for the site.

*Note: Please speak to the relevant Head of Department(s) you will be approaching to support your research **before** completing your application.*

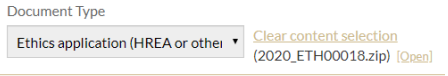
C4: Include detailed advice here regarding resources; this will help inform the HOD when they review the STE.

Click the black 'Add Another' button to add additional departments as needed.

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 as a .zip file; **DO NOT** clear content selection!



Upload any relevant site-specific documents associated with your application.

Document Type: Select from dropdown.

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Note: How your document is described is how it will appear on the approval notification.

Click the black 'Add Document' button to add additional documents or the red 'trash can' icon to delete documents.

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

Missing documents:

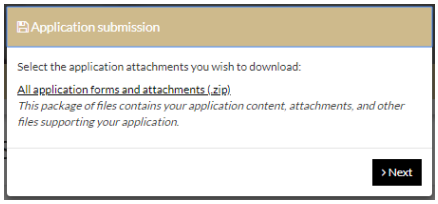
Budget - Site Study

Part G: Declaration and request Head of Department Decision
This section must be completed by the **PI** or their authorised delegates with submit access. If you are not the PI (or a submitter), save the application and let them know the application is ready to be submitted.

If you are the PI or a delegate with 'Submit' access, you will be able to click the 'Complete SSA' button.

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

A pop up will allow you to download a .zip file of the application form and attachments for your own records.



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

The application will now show a status of ● Completed pending HOD

REGIS will send an initial notification email to each listed HOD followed later by two reminder emails.

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

REGIS 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.

You should then discuss this decision directly with the HOD. Use the next section of this document to view the decisions in REGIS.

See QRG: Site Application HOD Not Supported

No status change?

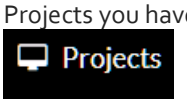
If after one week your application status has not changed from 'Completed Pending HOD', it is recommended that you contact the HOD directly to discuss.

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

Click the 'Projects' icon at the top of your REGIS home page to view a list of Projects you have access to.



Select the project from the list by clicking on the Project Title.

Step 2. Open the STE Application

The list of application(s) associated with the project are displayed on the **Project Details** page, on the left-hand side (LHS).

On the right side of the page, under the Hierarchy tab, click on the relevant STE Application that you want to check.

At the top of the page, click on the 'Decisions' tab.

Step 3. View Individual decision outcomes and comments

The 'Decisions' tab will show you the list of HODs along with their respective decisions.

Clicking on each row will expand the row, showing additional information about the decision. Putting your mouse over the Usernames will show the names of the relevant HoDs.

Decisions that are in the status of 'Pending' have not yet been made. You should contact this HOD directly.

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

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

If your ethics application is yet to be approved, the final decision 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).