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 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 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/STE/s in REGIS for faster and easier completion. 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.

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 on the three vertical dots next to the application and then selecting 'Invite user to register or share application'.

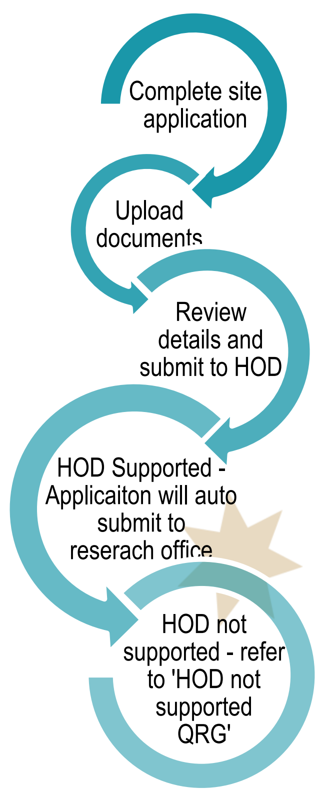
Share with View Access: User can only view the application and/or forms, but not make changes.

Share with Edit Access: User can view the application and/or forms and make changes.

Share with Edit & Submit Access: User can view the application and/or forms, make changes, and submit on behalf of the CPI.

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 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.

Note: You should speak to any Head of Department(s) whose support you will be seeking for your research, ***before*** *completing the application.*

Completing a Site-Specific Assessment (SSA) in REGIS

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

Step 1: Navigate to the application
If you are completing the STE directly after completing the HREA, see step 2.

Access the STE from the home page. Click the 'Projects' icon. Projects

Select the project from the list. The Project Details page will open.

Step 2. Open the SSA application
The status In Progress indicates the STE can be edited/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.

Step 3: Complete the SSA application
Mandatory questions and fields are marked with an asterisk * and must be completed before you can move on.

The following details will only describe where there are system requirements to be aware of to complete the form.

Part A: Project-Wide Information
Details here should match the Ethics details.

Part B: Project Team
This section relates to the PI and any other site personnel.

B2 will show the PI as listed at Project Registration.

B7 Admin contacts added during Project Registration will appear here. If no admin contacts were added, select 'Yes' to add up to two admin contacts with 'Submit' access here.

B8 Add members of the project team who are specific to the site including Associate Investigators (AI), other researchers and external researchers.

Study team members added during Project Registration will appear here. Depending on their roles, they may have been delegated 'Submit' access. For clinical trials, if no AI has been added during Project Registration, they can be added here with 'Submit' access.

Note: For clinical trials, you can add up to two 'admin' contacts and one AI. For non-clinical trials, you can add up to two admin contacts.

Part C: Departments and services
Head of Department (HOD) for the PI and any AI(s) must be listed here.

HOD for any supporting departments must be listed here. E.g., medical records, imaging.

If you or one of the named applicants is also a HOD, you should contact your local Research Office for guidance.

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

Tip: Want to get your study signed off by the HOD quickly? Discussing your study directly with any HOD before submitting the application tends to get the application signed off faster.

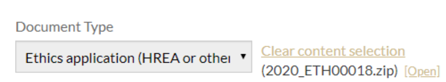
C4: Include detailed advice here regarding resources, this will help inform the HOD when they review the STE.

Use the plus sign at the bottom of the page to add additional departments and their Heads.

Part D: Recruitment, Records, Tissue & 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 a .zip file **DO NOT** clear content selection!



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

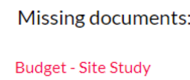
Document Type: Select from dropdown.

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.

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

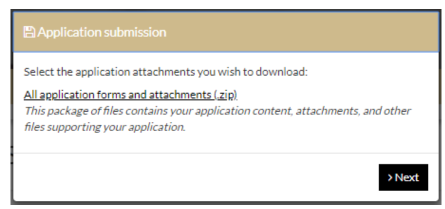
Depending on earlier responses in Part A-E, REGIS will indicate required documents that have not yet been uploaded.



Part G: Declaration and request Head of Department Decision
The PI or their delegate(s) can now submit the application. If you do not have access to submit, save the form, and notify the PI it is ready for submission.

Once submitted, the application will have the status of 'Completed Pending HOD'. 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 for your own records.



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

Supported = Submitted

When all HODs have reviewed the application and supported with either:

- able to undertake the investigations/services (OR)
- 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 then begin their review of your 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 HOD directly to discuss. It is the research applicant's responsibility to follow up outstanding HOD declarations.

How to View Completed & Outstanding Declarations

Step 1: Navigate to the application

If you are accessing the SSA from the homepage, Projects select the 'Projects' icon from the top of the page to view a list of Projects you have access to.

Select the project from the list by clicking on the STE identifier 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 Application information option to open the Application Details page

Step 4. View Individual decision outcomes and comments

Decisions Select 'Decisions' from 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 and then 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 HOD directly. Click 'Cancel' to close the Decision pop up.

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

See QRG – Site application HOD Not supported

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 relevant Research Office.

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

Acronyms

PI: Principal Investigator
AI: Associate Investigator
HoD: Head of Department