

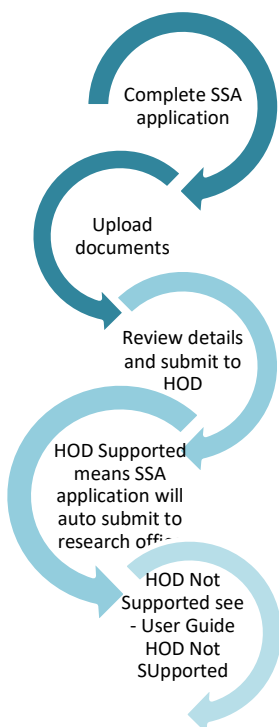
Completing a site application

What is a site application?

Site Specific Assessments (SSAs) are part of the site governance process adopted across SA Health, whereby potential research sites consider authorisation of a project to access and/or utilise its resources. SSA applications are required for each site where the research will be conducted within a Centre (e.g. hospital/Local Health 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 Research GEMS?

The overall process of completing the SSA in GEMS is shown here.



Who can view, edit and submit the application?

The principal investigator (PI) and any administration contacts nominated in the project registration are given automatic access to the SSA.

The SSA can be shared with view, edit and submit access to assist in the management of the application.

For further information on sharing and permissions, [click here](#).

Completing a site application

Step 1: Locate the SSA application

Directly after project registration, select the SSA via its identifier.



Alternatively, from the GEMS home page select the 'Projects' icon to view a list of projects you have access to.



You will only be able to access the SSA associated with your site.

Tip: You can save your application at any time and return later to complete.

Step 2: Complete the SSA application

Mandatory questions and fields are marked with an asterisk * and must be completed before submission.

The following details describe system requirements to be aware of in completing the form.

Part A: Project-Wide Information

Details here will pre-populate from the Project Registration and should remain consistent with the ethics application.

Part B: Site Team

This section relates to the PI and any other site team members.

B2 Will show the PI as listed at Project Registration.

B7 Select yes to add admin. contact/s and give submission rights for the SSA application and other project related forms.

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

Note: If the PI is not the person submitting the SSA application, upon submission an email will be sent to the PI to approve any users added requesting submit permission.

Part C: Departments and Services

Specify all departments where resources (staff, services and/or investigations) will be required.

The head of department (HOD) for any supporting departments must also be listed here - e.g. medical records, imaging.

- ❖ If the applicant is also a HOD, contact the local research office for guidance.
- ❖ **C1** If the department you require is not visible, contact the local research office for guidance.

Tip: Discussing your study directly with any HOD before submitting the application generally gets the application signed off faster.

C4: Include detailed advice here regarding resources. This will help the HOD make an informed decision when reviewing the SSA application.

Add additional departments using the '+Add row' button.



Part E: Site Costing and Funding

If you answer 'Yes', provide details of local study costs associated with the site.

Note: local research offices may have a standard budget template to be used.

Part F: Attachments - Site Specific Documents

The ethics application has been automatically identified as a document type to upload.

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

Document type: Select from dropdown list.

Document descriptor: Provide a clear and descriptive document descriptor.

Note: How your document is described is how it will appear on the approval notification so ensure it is clear and descriptive. Think about how you would want it to appear on the approval notification.

Document version: As listed on document. If the document does not have a version, enter 0.

Document date: As listed on document. If the document does not have a version enter today's date.

Use the '+Add row' button to add or the trashcan button to delete documents.



Depending on earlier responses, GEMS will indicate required documents that have not yet been uploaded, for example:

Missing documents:

Budget - Site Study

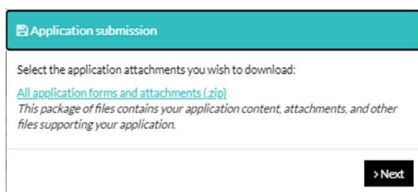
Part G: Declaration

This section must be completed by the PI or an authorised delegate.

Person/s with edit access can save the form and notify the PI or an authorised delegate that it is ready to submit.

For further information on sharing and permissions, [click here](#).

Once the SSA has been submitted, a pop-up message will appear on your screen to download a .zip file of the application form and attachments. You may wish to download this .zip file for your own records.



The status of the application will now appear as 'Completed pending HOD'.

Important! The application has NOT been submitted to the research office until **all HOD decisions have been registered.**

Head of department decisions

GEMS will notify each head of department (HOD) listed in Part C that their support has been requested.

For further information on the HOD approval process, [click here](#).

There are three outcomes from a HOD decision:

- ❖ Able to undertake the investigation/ services
- ❖ Able to perform the investigation/ services indicated, if the following financial assistance is provided
- ❖ Unable to undertake the investigation/ services indicated, on the following grounds

Once **all** decisions have been recorded by the nominated HODs, the SSA application will show a status of 'Submitted'.

If any HOD recorded a decision of 'unable to undertake the investigation/ services' the application will still be submitted, however you will be contacted by the reviewing research office to discuss this further.

Viewing Application decisions

Decisions for applications can be viewed via the GEMS portal. Find the SSA application, click 'Application Information' and click the 'Decisions' tab from the top menu.



Click the Title in the list of decisions which will display the outcome along with any comments made by the delegate.



Decisions that are blank have not yet been

made.

If you have any questions about your SSA application, contact the reviewing research office.

No status change?

If after some time your SSA application status has not changed from 'Completed pending HOD', it is recommended that you contact the HOD directly to discuss.

It is the applicant's responsibility to follow up outstanding HOD decisions.

What next?

Once the SSA application has been submitted, your application will be assessed for eligibility to be reviewed by the research governance officer. If you have any questions, contact the research office at the site relevant to the application.

If your ethics application is yet to be approved, the Chief Executive/Delegate decision cannot be made until the ethics approval has been granted by the human research ethics committee (HREC).