

CE/Delegate authorisation of site applications

All human research studies that take place within SA Health must undergo a site specific assessment (SSA) and be authorised by the Chief Executive (CE) or their delegate before the study can commence at the site.

Recommendation to CE/Delegate decision

Following the submission of a SSA application, the research governance officer (RGO) will conduct an assessment of the application, before making one of the following recommendations to the CE/Delegate for their review in Research GEMS:

- ❖ Is recommended.
- ❖ Is not recommended (RGO to provide reason/s).
- ❖ Requires consideration by CE/Delegate (RGO to provide reason/s).

RGOs can also upload a briefing document and any related site monitoring requirements requested by the reviewing human research ethics committee (HREC) for the CE/Delegate in GEMS.

CE/Delegate decision

The CE/Delegate should provide their authorisation of a SSA application in GEMS, which has replaced the former manual signatory collection process (wet signatures).

Authorisation of the application constitutes authorisation of the SSA.

The CE/Delegate can select one of the following decisions in GEMS.

Authorised (standard conditions) – the research project can occur at the site indicated in the application and there are no conditions on this decision.

Authorised, additional conditions required – the research project can occur at the site indicated in the application, subject to conditions e.g., PI must provide additional site reporting, in line with HREC additional requirements.

Note: This decision should not be selected if the CE/Delegate is seeking more information to authorise the application. See [requesting more information](#).

Not authorised – the research project cannot occur at the site indicated in the application. Reason/s for not granting the authorisation is to be provided by the CE/Delegate, and will be communicated to the SSA applicant in the outcome of their application.

How to provide the CE/Delegate decision

CE/Delegate can review and record their decision for SSA application/s without logging into GEMS.

This is done by using the links provided in the notification email sent by GEMS, which will take the CE/Delegate straight to the decisions page in GEMS.

The SSA application form, related documents and any other RGO provided documentation can be downloaded from the decisions page.

Note: This feature is assessable on mobile phones and other devices.

Step 1. Locate the email

The CE/Delegate will receive an email requesting authorisation for a SSA application.

Click on the link in the email to go directly into the decisions page of the SSA application or log into GEMS.



If logging into GEMS, locate the 'Decisions' icon at the top of the page or the approvals icon under 'Your activities' at the bottom of the page. Both will take you to the decisions page. Click on the SSA application you intend to review to see a quick view of the request or click 'Decision Details' for a more detailed view.

Step 2. Review the request

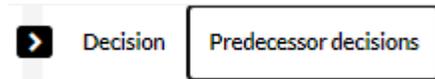
In 'Decisions Details' are the basic study details, including the application form and related documents available for download.

Click on the download icon to download a document individually or tick multiple boxes against the document title for a bulk download of files in a .zip file.

Step 3. Record CE/Delegate decision

On the right-hand side of the page is where you record the CE/Delegate decision.

To view the RGO recommendation, including RGO provided documentation e.g. briefs, select the 'Predecessor decisions' tab.



Select your CE/Delegate decision from the options available.

It is a requirement to provide comments in the text box field if the decision selected is:

- ❖ Authorised, additional conditions required, or
- ❖ Not authorised.

Click 'Save' and a system notification will appear confirming the decision has been saved.

Note: You are unable to edit the decision once it is saved.

Requesting more information

If the CE/Delegate requires more information before making their decision, they should contact the RGO listed in 'Predecessor decisions' e.g. via email, who will seek the further information from the principal

investigator (PI). **DO NOT SELECT AUTHORISED WITH CONDITIONS.**

The RGO will let the CE/Delegate know when the information is available in GEMS.

Once the information is available, the CE/Delegate can record their decision in GEMS.

When the RGO has delegated authority

In situations where the RGO can make the CE/Delegate decision, the CE/Delegate should provide in writing to the RGO the authorisation to do so.