

Reviewing SSA applications and requesting information

Research projects to be conducted at sites under the control of SA Health will undergo site specific assessment/s (SSA) before authorisation can be granted by the Chief Executive or their delegate.

Eligible vs. Valid

- **Eligible:** Application has received ethics approval.
- **Valid:** Application is pending ethics approval.

How does it work in Research GEMS?

Note: This user guide assumes you have already set up your homepage tiles. See user guide – [Setting up home page tiles](#)



Review the SSA in GEMS

A Site application with a status of ‘Valid’ or ‘Eligible’ can progress to RGO review.

Step 1 Select Application

Select the application, from the homepage tile, that you want to begin review.


Note: Unless specified, all actions are in the Management menu. Access the menu option by clicking on the ‘Management’ Tile from the left-hand menu.

Step 2 View Documents

View the following documents in this section:

- ❖ Site Application form
- ❖ Site Specific documents
- ❖ Initial Ethics application and documents (.zip)
- ❖ Approved Ethics application and documents (if/when available)
- ❖ Project Registration

↔ This document in ‘Inherited from...’ a related application. E.g. Ethics application and is the approved document.

 **Bulk download**

Bulk download by selecting the checkbox next to the documents and then ‘Bulk download’.

Step 3 Reviewing HOD Decisions

Decisions

Click on ‘Decisions’

If the application has multiple HOD they can all be seen and managed within this line.

Where all Head of Department/s (HODs) have indicated they are “Able to undertake the investigations/services”.

Decisions

Found 1 item

| Identifier | Type | Outcome |
|------------|---------------------------------|-------------------------------------|
| 69 | Head of Department Support f... | able to undertake the investigat... |

The overall Outcome of the decision will show as “able to undertake the investigations”.

The RGO may wish to review each individual decision to see if any additional comments have been made.

Where one or more Decision is ‘Unable’

Decisions

Found 1 item

| Identifier | Type | Outcome |
|------------|--------------------------------|----------------------------------|
| 69 | Head of Department Support ... | unable to undertake the inves... |

or ‘Assistance required’ the overall outcome will show as ‘Unable to undertake’ to indicate the RGO may need to investigate further.

The RGO should review each individual decision to see what the decision were and if any additional comments have been made.

Found 1 item

| Type |
|---|
| Head of Department Support for Site Specific Assessment |



View and manage each individual user decision. A black panel will appear. Click on the decision to manage. (override)



Quick View all user decisions. But no edit.



Edit/Override overall (All) outcome.



Permanently Delete all decisions.

Individual Head of Department/s (HODs) outcome will be:

- ❖ **Able to undertake the investigations/ services**, indicating support for the project to go ahead. There are no conditions on this decision.

- ❖ **Able to perform the investigations/services indicated, if the following financial assistance is provided**, the application should show that the PI has addressed any listed requirements.

- ❖ **Unable to undertake the investigations/services indicated, on the following grounds**, in this instance the PI should have discussed this decision with the HOD and/or the nominated RGO.

Overriding a HOD decision Overall

Select 'Edit' from the right-hand side and click the 'Edit' icon on the HOD decision row.

Select Override outcome, select the new overall outcome and add comments to clarify why the decision has been

overridden.

Individual



View and manage each individual user decision.

A black panel will appear. Click on the decision to manage. (override). The override action will appear. Select the new individual outcome and add comments to clarify why the decision has been overridden.

Changing individual decisions will not change the overall decision.

Request More Information

After completing the review, a Decision needs to be made. Request for Information or RGO Recommendation.

For details on how to make the RGO Recommendation and CE/Delegate Decision see user guide - Approvals not associated with meetings.

More Information Required - SSA

- ❖ **Recommendation pending further information** – this option will create the 'more information' form. This option is selected when the RGO

requires information before the recommendation but no changes to the application or documents.

The status of the application will change to "Information Requested"

- ❖ **Decision pending further information** – select this option if changes to the application or documents are required. This option will create a new version of the site application and enable the applicant to edit it.

The status of the application will change to "In Progress"

Step 1

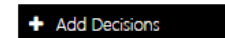
Decisions Click on 'Decisions'



Click 'Edit' on the right-hand side of the screen

Step 2

Select the hamburger next to the Decisions tile, then 'Add Decisions'



The Decisions wizard will appear.

Step 3

- ... Select the 3 dots at the end of the 'Type' cell to search for the decision type.

A black panel will appear.

Step 4

Select 'More Information Required – SSA'

Click on the checkbox next to the Decision and then on the tick icon at the bottom of the panel.

Do not change the entity.

Select

Click select the end of the 'User' cell to search for the person requesting information (RGO).

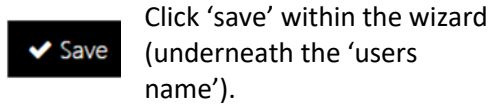
A black panel will appear.

Step 5



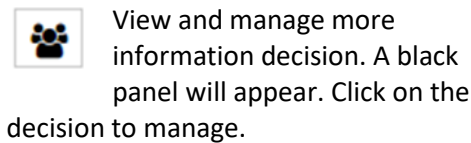
Search for the User by typing in their first or last name or email address.

Click on the checkbox next to the Decision and then on the tick icon at the bottom of the panel.



Click 'save' within the wizard (underneath the 'users name').

Step 6



View and manage more information decision. A black panel will appear. Click on the decision to manage.

Select the Decision outcome 'recommendation pending' or 'decision pending' as discussed above.

Click 'save' in the panel.

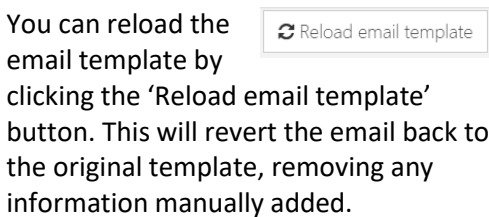
Step 7



A 'Send email' icon will now appear on the decision line. Click on the icon for the more information email to appear.

Step 8

Edit the template as necessary.



You can reload the email template by clicking the 'Reload email template' button. This will revert the email back to the original template, removing any information manually added.

If you add any information and navigate away from the page, the information will be saved.

Click 'Send'.

The email sent notification will show at the bottom of the screen and the 'Email sent' icon will appear on the decision line.



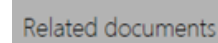
Depending on the decision selection the status of the application will now show as "Information Requested" or "In Progress".

Saving and editing a review/brief document

If you use a review document/brief that is submitted to the CE with the application the final document will need to be uploaded at RGO decision.

You can choose to save an in progress/draft version of the brief in 'Related Documents'

Step 1



Click on 'Related Documents' on the left-hand menu.



Select 'Edit' on the right-hand menu

Step 2

Click on the hamburger next to the Related Document page heading and selecting 'Add external document'.

The Wizard will appear.

Step 3

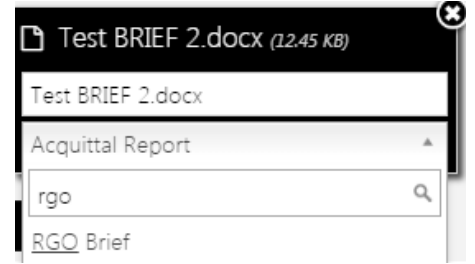


Click on the wizard for a browsing window to open or drag and drop the file.

Step 4

To change the title of the document, click in the first cell and manually change the title of the document e.g. Brief v1.

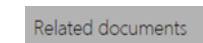
Select the category of the document, RGO Brief.



When in aggregate view the document will appear as 'RGO Brief'

Step 5

To work on the document again:



Click on 'Related Documents' on the left-hand menu Click Expand (if in aggregate view) and then download.

The document will open for editing.

To save an updated version of the document keep same electronic file name, for version management, save to your computer and then save in GEMS using Step 1 – 4 'Saving and editing a review/brief document'.



View previous versions



Document is NOT available in External Portal (to Applicant)



Document IS available in External Portal (to Applicant).