

Review SSA & Requesting Info

FOR RESEARCH OFFICES

QUICK REFERENCE GUIDE

Review Site Application & Requesting Information

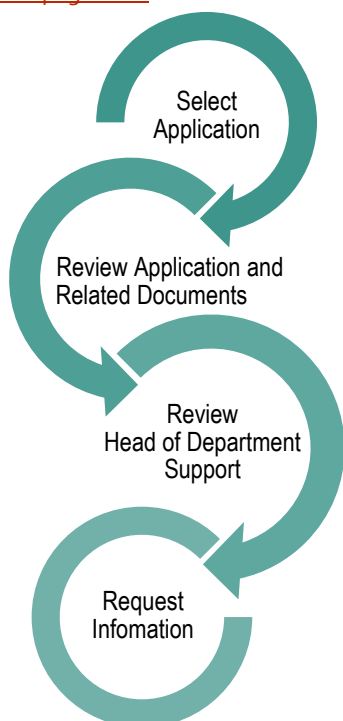
Research projects to be conducted at sites under the control of a Public Health Organisation (PHO) will undergo site specific assessment before authorisation can be granted by the Chief Executive or their delegate.

Eligible vs. Valid

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

How does it work in REGIS?

Note: this QRG assumes you have already set up your homepage tiles.
 See [QRG – Research Offices – Setting up a Homepage](#) and [REGIS User Manual guide – Homepage tiles](#).



Review the SSA in REGIS

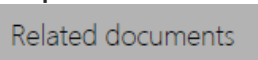
A Site application with a status of 'Valid or 'Eligible' can progress to RGO review.

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

Step 3 Reviewing HOD 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". The overall Outcome of the decision will show as "able to undertake the investigations".

Decisions

Found 1 item

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

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

Decisions

Found 1 item

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

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

Decisions

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 righthand 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.

Override outcome	<input checked="" type="checkbox"/> Yes
Description	Head of Department Support for Site Specific Assessment
Outcome	able to undertake the investigations/services
Comment	Confirmed that XX requirements have been met

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.

User decisions

Found 2 items

Name: Becker, Kylie

Decision: Choose...
This field is required.

Comments:
This field is required.

Save Cancel

Name: User410, Dummy
Decision: able to undertake the investigations/services
Reason: able to support
Assigned: 03/07/2018 7:08:15 PM
Submitted: 03/07/2018 7:09:23 PM

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 QRG - 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

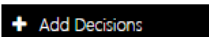
Decisions

 Edit

Click on 'Decisions' Click 'Edit' along the bottom of the screen.

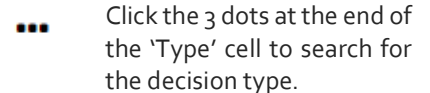
Step 2

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



The Decisions wizard will appear.

Step 3



Click 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 click 'Apply' at the bottom of the panel.

Do not change the entity.

Select  Click the 3 dots at the end of the 'User cell to search for the person requesting information (RGO)


A black panel will appear.

Step 5

Add Users

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

Click on the checkbox next to their name, then click 'Add User' at the bottom of the panel.

 Save

Click 'Save' within the wizard (under the 'notes' section).

Step 6**View and manage the 'More Information Required' decision**

Click on this decision icon 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.

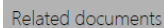
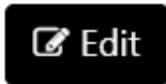


Depending on the decision selection the status of the application will now show as "Information Requested" or "In Progress".

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

Click 'Edit' along the bottom right corner of the page.

Step 2

Click on 'Add Document' on the left side under the Related Documents page heading. The Wizard will appear.

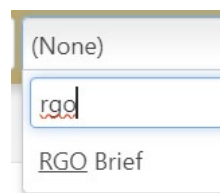
Step 3


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.

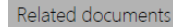
Select the category of the document, RGO Brief.




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 you need.

You can then access the document from the browser's downloaded folder.

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



View previous versions



Document is **NOT** available/visible in External Portal (for the Applicant)



Document **IS** available/visible in External Portal (for the Applicant).