

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 <u>QRG – Research Offices – Setting up a</u> <u>Homepage</u> and REGIS User Manual guide - <u>Homepage tiles.</u>



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.

Unless specified all actions are in the Management menu. Access the menu option by clicking on the 'Management' Tile on the left-hand menu.

Step 2 View Documents

Related 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



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". The overall Outcome of the decision will show as "able to undertake the investigations". Decisions

Found 1 item

69

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

Head of Department Support f... able to undertake the investigat.

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 \equiv



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

REGIS REVIEW SSA & REQUESTING INFO

Decisions 🚍

Found **1** item

Head of Department Support for Site Specific Assessment



۲

Ø

m

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



Edit/Override overall (All) outcome.

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



outcome	Yes
on	Head of Department Support for Site Specific Assessment
	able to undertake the investigations/services
	o c 2
	Confirmed that XX requirements have been met.

Individual

Override

Descripti



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 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.

February 2018 © NSW Ministry of Health SHPN (OHMR) 180933

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



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' Decisions = + 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.

For further assistance if needed, contact your local research office at these links – <u>NSW</u> or <u>ACT.</u>



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 Add Users

Search...

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

The system will only display Users who fit the search criteria.

The User must have a REGIS account, and can be anyone with a REGIS account.

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 9

Edit the template and 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

a



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 or drop your files here

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.

Test BRIEF 2.docx (12.45 KB)	(
Test BRIEF 2.docx	
Acquittal Report	
rgo	Q
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 REGIS using Step 1 - 4 'Saving and editing a review/brief document'.



View previous versions

Document is <u>NOT</u> available in External Portal (to Applicant) Document <u>IS</u> available in External Portal (to Applicant).

For further assistance if needed, contact your local research office at these links – <u>NSW</u> or <u>ACT.</u>

February 2018 © NSW Ministry of Health SHPN (OHMR) 180933



3