Reviewing eligibility of a Site Specific Assessment

For a site application to be submitted in Research GEMS the system requires the following to have occurred:

❖ Project Registration completed
❖ Protocol uploaded

If an application has been successfully submitted in GEMS, then it has met the minimum system requirements to be made 'Eligible'.

The Research Governance Officer (RGO) should only mark an application as ineligible for the following reasons:

❖ The site application appears to have dummy responses.
❖ The submitted documents do not match the description. e.g. incomplete template.
❖ The site application is submitted without the correct Head of Department support.

It is recommended that the Research Office contacts the applicant to discuss prior to marking the application Ineligible.

Ethics Approved Tag

A tag will automatically be added to submitted site applications that have Ethics approval in the system (ethics approved in GEMS or external ethics approval uploaded into GEMS).

The 'HRE Approved' tag is permanent and cannot be deleted.

Eligible and Valid

The RGO should begin the eligibility assessment process as soon as the application moves to the submitted status in GEMS. This is generally after the Head of Department has provided their decision.

Once the SSA is marked eligible, the application status will automatically update depending on whether the ethics approval has been received in GEMS.

An **eligible** status means that the ethics approval has been received and recorded within GEMS.

A **valid** status means that the ethics approval has not been received in the system (either via a SA Health HREC in GEMS, or an NMA HREC application).

After ethics approval is recorded in GEMS, the system will change the status of the application to 'Eligible'.

When an application is in the 'Valid' status the RGO can complete all actions up to RGO recommendation.

Completing eligibility in GEMS.

A new Site application will have a status of 'Submitted'.

Note: This guide assumes you have already set up your homepage tiles. See GEMS User guide – Setting up Homepage tiles

Step 1

Select the new application to complete the eligibility.

Step 2

In the Application, click on the 'Management' tile in the left-hand menu and then select 'Eligibility'.**Step 3**
Click 'Edit' on the right-hand menu to make the eligibility page editable.

Step 4
Select '+Add eligibility assessment' to be taken to the eligibility review.

Step 5
Download the application and attachments by clicking the 'Download application' and 'Download attachments' buttons at the bottom of the page.

The attachments will download as a temporary .zip folder and includes the application form.

Assess the eligibility of the application.

Step 6
Eligibility Review - Criterion 1/1

After completing the eligibility review, indicate the eligibility status of the application by selecting either 'Yes' or 'No' from the drop-down box.

Note: Comments added into this field are

recorded in the eligibility report but are not seen by the applicant.

Click the red arrow on the right-hand side of the page to progress.

Step 7
If ineligible add the comments into the free text field as they should appear to the applicant.

If eligible, comments made here will not be seen by the applicant.

Step 8
After completing any comments in the review section indicate the eligibility status of the application in section '2. Review'. This should be the same selection as indicated in '1. Eligibility review – Criterion 1'.

It is this second eligibility toggle in section '2. Review' that determines the overall status of the application.

Note: Request approval is only used when Eligibility Approver B is used – see section: Requesting Eligibility Approver B.

Click the red arrow on the right-hand side of the page to progress.

Step 9
The email template will load based off the decision. Edit the email as required. 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.

Add any attachments by clicking or dropping the files in the section indicated:

Click the green tick to finish the eligibility assessment.

A green alert will come up at the bottom of the screen indicating that the 'Eligibility created successfully'.

The status of the application will change to either 'Ineligible', 'Eligible' or 'Valid'.

Note: The status will also be changed in the external portal.

'Eligible' and 'Valid' applications can now progress to RGO review.

A 'Valid' application is able to progress up to RGO recommendation before Ethics approval is confirmed.

'Ineligible' applications will require another eligibility review once resubmitted.

Requesting Eligibility Approver B

A second reviewer can assess the application if the Research Office uses a dual eligibility process e.g. the admin

team complete the initial eligibility but require confirmation from the RGO.

Initial Approver - During Step 8, before selecting the red arrow.

Select the outcome to be reviewed (Eligible or Ineligible) by Approver B.

'Request approval' and 'Send Notifications to Eligibility Approver B' should be 'Yes'.

Add the name of the person to complete the Eligibly review.

Click the red arrow on the right-hand side of the page to progress.

Click the green tick to finish the eligibility assessment.

An email will be sent to the person listed as Approver B and the eligibility will show as 'Pending'.

A task will also be created against the application which is visible in a Task homepage tile.

Eligibility Approver B confirmation

On receiving the email or Task indicating you have been selected as the approver on an eligibility assessment, locate the application.

Locate the pending eligibility by repeating Step 2 or via the Task homepage tile, if you have it setup.

On the same row as the Pending eligibility select the 'Assess eligibility' icon

To download the application and supporting documents repeat **Step 5.**

Review the comments made at 1. Eligibility review - Criterion 1

Click the red arrow on the right-hand side of the page to progress.

If you agree with the eligibility review, select Eligibility B approval and Approve recommendation.

To change the eligibility outcome, change at the Eligibility toggle. If ineligible, add comments and then select Approve recommendation at Eligibility B approval.

Click the red arrow on the right-hand side of the page to progress.

Follow instructions for **Step 9** to manually select the email template at the top of the page.

Click the green tick to finish the eligibility assessment.

An alert will come up at the bottom of the screen, advising 'Eligibility created successfully'.

The PI will receive the email notifying them of the outcome of the eligibility review.

Clear Task

Locate the task from either the homepage tile or via the application, Management → Tasks

Locate the Task 'Eligibility Approve B required'

Click 'Edit' and then 'Edit item'. The task wizard will appear.

Add the day the task was completed to clear the task.

The Active toggle at the bottom of the page will change to No.

Click 'Ok' and then 'Save'.