Reviewing Eligibility of an Ethics Application

What is Eligibility?

Before an ethics application is reviewed by the HREC the Executive Officer (EO) or Research Administrator is required to review the application to confirm its eligibility. The EO will view the application and supporting documents in GEMS and assign 'eligibility' to the application so that the application will proceed to ethics review.

Eligible is the default.

For an ethics application to be submitted in GEMS the system requires the following to have occurred:

❖ Project Registration completed
❖ Protocol/Project Plan uploaded
❖ HREA completed

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

The EO/research administrator should only mark an application as ineligible for the following reasons:

❖ The HREA appears to have dummy responses.
❖ The submitted documents do not match the description. e.g. incomplete template.
❖ The application cannot yet be reviewed by the committee due to quality.

Before an Ineligible decision.

It is recommended that the RO contact the applicant to discuss prior to marking the application as Ineligible.

How does it work in GEMS?

System requirements

Project Registration: Confirm that sites have been selected at project registration.

If sites are listed under 'SA sites' on the project registration, the site specific applications (SSAs) were created when the HREA was submitted.

If the project registration form shows no SA sites, the applicant may need to use the manual process to add new sites in GEMS.

This needs to be done before the application is approved. Ideally this should be done before the application is assigned to a meeting or review.

HREA: During Project Registration a Coordinating Principal Investigator (CPI) was selected. Is this the same person in the Project Registration and HREA? If no, you may wish to clarify.

In the HREA **the CPI MUST**:

❖ Q1.9.10 be "Coordinating Principal Investigator/Researcher" only
❖ Q1.9.11 have "Yes" selected

Q4.5 should match the risk pathway (LNR/Greater than). This information is found on the HREA output form on page one as a statement, e.g. "The applicant has requested that this ethics application be considered under the Greater than low risk review pathway."

These items are not a reason to mark an application as ineligible, but an application **cannot** be approved if these answers are not correct. It is important to consider these early in the process.

Note: There are serious consequences if these items are not correct when the application is approved.

Completing eligibility in GEMS

A new Ethics application will have a status of 'Submitted'.
Note: this user guide assumes you have already set up your homepage tiles. See Research GEMS User guide – Research Offices – Setting up a Homepage and Research GEMS User guide – Homepage tiles

Step 1
Select the new application from the homepage tile.

Step 2
Click on the Eligibility icon on the far right-hand side of the screen and the eligibility review will open.

Note: If a previous eligibility has been completed, please go to 'Completing an eligibility on a resubmitted application' on page 3.

Step 3
Download the application and attachments by clicking the 'Download' button at the bottom of the screen.

The documents will download in a temporary zip folder.

This will allow you to assess the eligibility of the application taking into consideration the examples on page 1 'Eligible is the default.'

Step 4
Eligibility Review - Criterion 1, 2 and 3

Criterion 1 and 2 specifically ask the research office to consider HREA system requirements.

Criterion 3 is a broad question that allows the research office to consider if their own review of an application is acceptable for review.

To respond to each criterion, select Yes or No from the dropdown menu. Comments added into these fields are not seen by the applicant.
Click the red arrow on the right-hand side of the page to progress.

Step 5
Eligibility step 4 - Review.

If the application is deemed ineligible by the research office, add the comments into the free text field that you want the applicant to see. The comments will
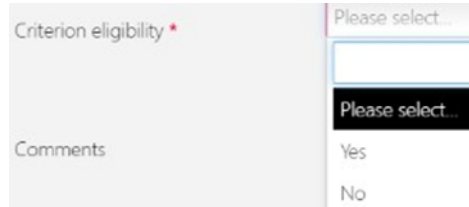
appear exactly as they are typed. If eligible, no comments are required.

Step 6
Use the toggle switch to indicate the eligibility status of the application.

The Review eligibility toggle determines the overall status of the application.
Note: Request approval is only used when Eligibility Approver B is used - see page 3

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

Step 7
The email template will automatically load based on the outcome of the eligibility review.

Step 8
Edit the email or add any attachments as required.

Add attachments by clicking or dropping the files in the section indicated.

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 the green tick to finish the eligibility assessment.

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

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

'Eligible' applications can be assigned to a meeting or review. See user guide 'Creating and Preparing HREC Meetings' and user guide 'Creating and managing a review'. 'Ineligible' applications will require another eligibility review once resubmitted. See page 4.

Requesting Eligibility Approver B

An internal second review can be requested for a dual eligibly process e.g. the admin team complete the initial eligibility but require confirmation from the EO.
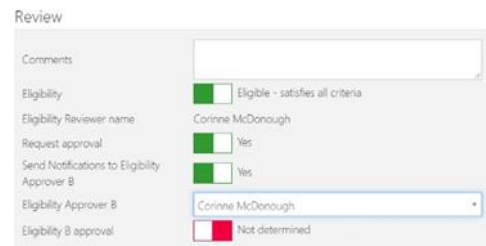
Initial Approver
During **Step 6,** before selecting the red arrow, select the option that suggests the application will be reviewed (Eligible or Ineligible) by Approver B.

'Request approval' and 'Send Notification' should be answered Yes.

Add the name of the person to complete the Eligibility 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.

The eligibility will show as 'Pending' and a task will be created against the application. You can view this 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 following **Step 2.**

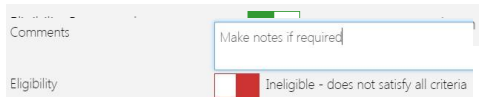On the same row as the Pending eligibility select the 'Assess eligibility' icon

To download the application and supporting documents follow **Step 5**

Review any comments made at criteria 1, 2 and 3.

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 at **Step 8** 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 page advising 'Eligibility created successfully'.
- The PI will receive the email notifying them of the outcome of the eligibility review.

To clear the task

- Locate the task from either the homepage tile or via the application, Management →Tasks
- Locate the Task 'Eligibility Approver B required'
- Click Edit and then 'Edit item' The task wizard will appear.
- Add the day the task was completed in 'Date completed' to clear the task.
- The Active toggle at the bottom of the page will change to No. Click 'Ok' and then 'Save'.

How do I know if an application has had a previous Eligibility Review?

After completing **Steps 1 -2 on page 2** you will see a previously completed Eligibility Review.

To complete the eligibility, the reviewer should focus on the outstanding items only.

Completing an eligibility on a resubmitted application

Step 1

Download the application and attachments from the 'Related Documents' tab and by selecting all the attachments and clicking 'Bulk download.

The system has now generated a tracked changes version of the HREA which can be downloaded. This document will download as a PDF.

This will allow you to assess eligibility of the application taking into consideration the comments of the previous eligibility review.

Note that the previous eligibility review will be downloaded as a .pdf.
Note the 'Overall Review and Comments'.

Step 2
Create a new Eligibility by selecting 'Management' from within the application and then 'Eligibility'.

Click 'Edit' on the right-hand side and then select '+Add eligibility assessment'.

Step 3
You can now complete this eligibility check using **Steps 4-8 on page 2.**

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

'Eligible' applications can be assigned to a meeting or review. See User Guide – Research GEMS Creating and Preparing HREC Meetings and User Guide– Creating Reviews. **'Ineligible' applications will require another eligibility review once resubmitted.**