



REGIS
Eligibility of Ethics

FOR RESEARCH OFFICES

QUICK REFERENCE GUIDE

Reviewing Eligibility of an Ethics Application

What is Eligibility?

Before an ethics application is reviewed by the HREC or HREC executive, by being assigned to a meeting and/or review the EO or research administrator may review the application to confirm its eligibility. The EO will view the application and supporting documents in REGIS and assign 'eligibility' to the application, that is, that the application will proceed to ethics review.

Eligible is the default.

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

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

If an application has been successful in being submitted in REGIS it has met the minimum system requirements to be 'Eligible'.

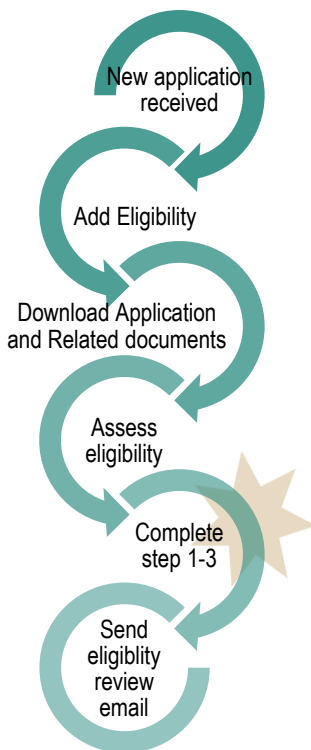
The EO/research administrator should only mark an application as ineligible for the following reasons:

- ❖ 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 REGIS?



NSW sites indicates the site applications that were created when the HREA was submitted.

Sites	
NSW Site	Principal Investigator

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

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 was selected. Is this the same person in 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

System requirements

Project Registration

Confirm that sites have been selected at project registration.

not correct. So it is important to consider these early.



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

Completing eligibility in REGIS.

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

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](#)

Step 1

Select the new application, from the homepage tile, that you want to complete the eligibility.

Step 2

Click on the Eligibility icon on the far right-hand side of the screen.

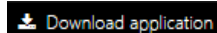
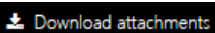


The eligibility review will open

If a previous eligibility has been completed, please go to "Reviewing Eligibility of a Resubmitted Ethics Application" page 4

Step 3

Download the Application and Attachments by clicking the download buttons at the bottom of the screen.

The application will download as a Word document and the documents will download as a temporary zip folder.

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

Step 4

Eligibility Review - Criterion 1/3

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 their own review of an application acceptable for review.

To respond to each criterion, click to select Yes or No from the dropdown menu.

Criterion eligibility	Please select
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Comments added into these fields are not seen by the applicant.



Click the large blue arrow on the right side of the pages to progress to the next step

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

After you have completed the comments in the review section use the toggle switch to indicate the eligibility status of the application.

The Review eligibility toggle determines the overall status of the application.

Review

Comments	When eligible this comment does not go to applicant
Eligibility	<input checked="" type="checkbox"/> Eligible - satisfies all criteria
Eligibility Reviewer name	Kylie Becker
Request approval	<input type="checkbox"/> No

Request approval is only used when Eligibility approver B is used - see page 3.



Click the large blue arrow on the right side of the page to progress to the next step
Or

Step 7

Depending on the outcome of the eligibility review you will need to manually select the email template at the top of the page.

Do this by clicking on the Email template cell and selecting the appropriate template.

Eligibility Review - Email

Email template	Application HREA Eligible Notification
Email template	Application HREA Ineligible Notification

Step 8

Edit the email as required.

The system defaults the Reply To: to no_reply@regis.health.nsw.gov.au.

You can add your own or a generic office email address here.

Reply To	Kylie.becker@health.nsw.gov.au
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Add attachments by clicking or dropping the files in the section above the body of the email.

Click or drop your files here



Click the big green tick to finish the eligibility assessment.



An alert will come up at the bottom right of the screen

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

'Eligible' applications can be assigned to a meeting or review. See [QRG– Creating and Preparing HREC Meetings and QRG– Creating Reviews](#). 'Ineligible' applications will require another eligibility review once resubmitted. See page 4.

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).

Using the Eligibility approved B functionality

Requesting Eligibility Approver B

If the Research Office uses 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 blue arrow:

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

Request approval and Send Notification: should be Yes.

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

Review	
Comments	this is a yes decision. Requesting <u>approver B</u> to confirm eligibility
Eligibility	<input checked="" type="checkbox"/> Eligible - satisfies all criteria
Eligibility Reviewer name	Kylie Becker
Request approval	<input checked="" type="checkbox"/> Yes
Send Notifications to Eligibility Approver B	<input checked="" type="checkbox"/> Yes
Approver	Pamela Hughes
Eligibility B approval	<input type="checkbox"/> Not determined



Click the blue arrow on the right 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

Pending

The eligibility approval will show as Pending

Office Tasks

Eligibility Approver B rec

REGIS will also create a task against the application. This can be seen in a Task Homepage tile.

Eligibility Approver B confirmation

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

Locate the pending eligibility by repeating **Step 2**



Next to the Pending eligibility select 'Assess eligibility'

To download the application and supporting documents repeat **Step 3**

Review the comments made at Criterion 1



Click the blue arrow on the right side of the page to progress

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

Eligibility B approval Approve recommendation

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

Comments

Eligibility Ineligible - does not satisfy all criteria

Eligibility B approval Approve recommendation



Click the blue arrow on the right side of the page to progress

Follow instructions for **Step 7** 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

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



Click Edit item

The task wizard will appear.

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

Date due



The Active toggle will change to No



Click Ok



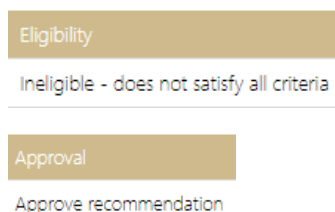
Click Save

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Reviewing Eligibility of a Resubmitted Ethics Application

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

After completing **Step 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 a .pdf of the previous eligibility review



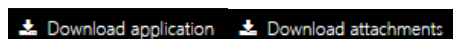
Note the "Overall Review and Comments"

Step 2

Create new Eligibility by completing **Step 2 on page 2**.

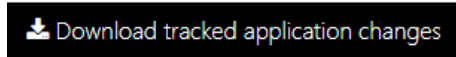
Step 3

Download the Application and Attachments by clicking the download buttons at the bottom of the screen.



The application will download as a Word document and the documents will download as a temporary zip folder.

The system has now generated a tracked changes version of the HREA



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.

Step 4

You can now complete this eligibility using **Step 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 **QRG– Creating and Preparing HREC Meetings and QRG– Creating Reviews**.

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

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).