



Eligibility of Ethics

QUICK REFERENCE GUIDE

FOR RESEARCH OFFICES

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 Executive Officer (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'.

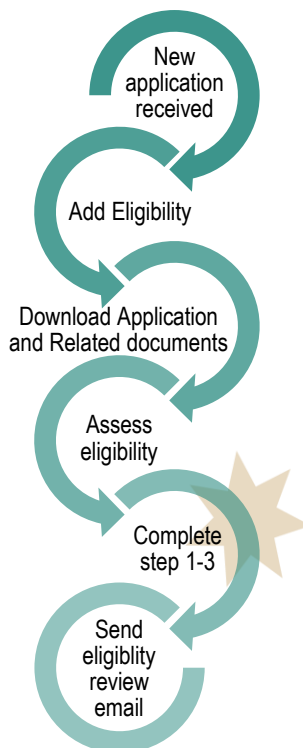
The executive officer/research administrator should only mark an application as ineligible for the following reasons:

- ❖ 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/ACT sites indicates the site applications that were created when the HREA was submitted.


Part C - Sites

Centre / Jurisdiction	Site	Principal Investigator
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If the project registration form shows no NSW/ACT 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'.

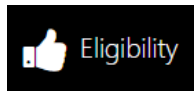
Note: this QRG assumes you have already set up your homepage tiles. See [QRG – Research Offices – Setting up a Homepage and REGIS User Manual guide – Homepage tiles](#)

Step 1

Select the new application from the homepage tile.

Step 2

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

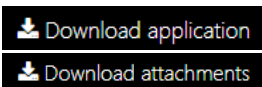


The eligibility review will open

Note: 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.

Comments added into these fields are not seen by the applicant.



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

Step 7

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

Step 8

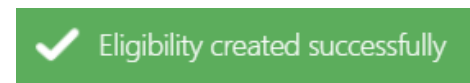
Edit the email or add any attachments as required.

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

Click or drop your files here

Click the green tick to finish the eligibility assessment.

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



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

Using the Eligibility approved B functionality

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

'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.

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 red arrow:

Select the outcome to 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.

Review

Comments	<input type="text"/>
Eligibility	<input checked="" type="checkbox"/> Eligible - satisfies all criteria
Eligibility Reviewer name	Corinne McDonough
Request approval	<input checked="" type="checkbox"/> Yes
Send Notifications to Eligibility Approver B	<input checked="" type="checkbox"/> Yes
Eligibility Approver B	Corinne McDonough
Eligibility B approval	<input type="checkbox"/> Not determined

Click the red 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

The eligibility approval will show as **Pending**

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

Task

Name	Task type	Due date
! Eligibility App...	Eligibility - Appro...	07/03/2020

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**

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 side of the page to progress

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

Eligibility B approval 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.

Comments	<input type="text"/>
Eligibility	<input type="checkbox"/> Ineligible - does not satisfy all criteria
Eligibility B approval	<input checked="" type="checkbox"/> Approve recommendation

Click the red arrow on the right 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

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



Management

Tasks

Locate the Task 'Eligibility Approve B required'

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

Reviewing Eligibility of a Resubmitted Ethics Application

Click Edit  → Edit item 

The task wizard will appear.

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

Date completed

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

Click Ok  and then Save 

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.

Eligibility	Approval
Eligible - satisfies all criteria	Approve recommendation

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.

 Download application

 Download attachments

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

 Download tracked application changes

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*.

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