RÊGIS



Approval or Authorisation not associated with a meeting

FOR RESEARCH OFFICES

Application approvals/authorisations processed outside of a meeting

The Research Office can approve applications in REGIS either via a Meeting (ethics) or by creating a Decisions in the application (ethics & site). An approval is either ethics-specific (i.e. approved) or site-specific (i.e. authorised).

Approvals in REGIS not associated with a meeting

For ethics applications, the Chairperson has the discretion to delegate to the Executive Officer (EO) the authority to review Human Research Ethics Committee (HREC) Executive Committee business that is considered administrative or within the capacity of the EO.

For site applications, site authorisation is granted by the Chief Executive (CE) or delegate of the Public Health Organisation. A site authorisation is made only after the Research Governance Officer (RGO) Recommendation.

The diagram in the next column provides an overview of how approvals that are not associated with a meeting can be made in REGIS.

NOTE: This document describes both ethics and governance processes. Unless a step specifies 'ethics' or 'site'/'governance'; the step is the same for both.



Approval decisions available in REGIS

Ethics approval/decision

Type of Decision: Application decision

Decision outcomes:

- approved the application has been approved, with standard conditions
- approved with conditions when the HREC or EO requires additional reporting or monitoring, not more information
- not approved the HREC will not approve this application.

Governance authorisation/decision

Type of Decision: RGO Recommendation Decision outcomes:

- ✤ is recommended
- is not recommended (RGO will provide reasons)
- requires consideration by the Chief Executive or delegate (RGO will provide reasons).

The RGO should add any project monitoring by the site, requested by the reviewing HREC.

Type of Decision: CE/Delegate Decision outcomes:

- authorised the application has been authorised, with standard conditions
- authorised with conditions when the CE requires additional reporting or monitoring, not more information
- not authorised this application will not be approved by the CE or delegate.

Creating an approval decision in REGIS

Step 1

Find the appropriate application in REGIS by using:

- a homepage tile
- the quick search at the top of the screen, or
- the Application tile from the Start hamburger.

APPROVAL OR AUTHORISATION NOT ASSOCIATED WITH A MEETING

Step 2

Select the application. Click on Management tab \rightarrow Decisions, then click 'Edit'.

Step 3

Use the hamburger next to the Decisions title to 'Add Decisions'

Decisions = + Add Decisions

The Decisions wizard will appear.

Step 4

Do not add a 'Current Due Date'.

Select ••• at the end of the 'Type' cell to search for the decision type. A black panel will appear.

Step 5

Select the approval/decision type.

- Application Decision (ethics)
- Recommendation by RGO (site)
- CE/Delegate Decision (site)

Clicking on the checkbox next to the Decision and then on the tick icon at the bottom of the panel.

Step 6

After selecting the Type 'Application Decision' (if ethics) or 'Recommendation by RGO' (if SSA):

- do not change the entity
- click •••• at the end of the 'User' cell to search for the person who is completing the task in the system.

A black panel will appear.

Step 7

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.

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

Clicking on the checkbox next to the User and then on the tick icon at the bottom of the panel. Click 'Save' within the wizard.



Step 8



View and manage the decision. A black panel will appear.

Click where your name appears to finalise the Decision.

Name Decision	Becker, Kylie
Assigned Submitted	26/04/2019 10:12:27 AM

Decision outcomes described on page 1.

Ethics applications can now progress to the next section of this document 'Process the Decision'.

RGO recommendation: to add a review document or brief upload by clicking on 'Choose Files'

Click 'save' in the wizard.

Site applications, the CE/Delegate Decision will appear automatically on completion of the RGO recommendation.

Add a User for the 'CE/Delegate Decision'



Select 'Edit item' and repeat **Step 7**. The User is the CE or delegate.

If you want the CE to see any notes on the front page of the decision make them in the notes section.

If you are the CE/Delegate repeat **Step 8** and progress to 'Processing the Decision'.

If you are not the CE/Delegate a system generated email will be sent to the selected user. After the CE has made a decision progress to 'Processing the Decision'.

Processing the Decision

In REGIS, 'processing the decision' means sending the formal approval/authorisation email to the research applicant.

Step 1



When the decision has been made and saved, the check mark icon will appear on the right-hand side of the screen.

Select it.

NOTE: if the check mark icon does not appear refresh your screen.

Step 2 Manage approved documents (appearing on email)



Select the 'Application Documents' tile.

A list of the Related Documents will appear.

Use the delete icon to remove the documents that should **NOT** appear in the link of approved documents or the list of approved documents.

These documents will also be automatically shared with related applications/projects and the applicant in the external portal



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Step 3 Create email

Use the hamburger next to the page heading 'Process Decision'. Select 'send email'.

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

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An email template will appear for review and completion.

Update the email template as required.

Ensure that the list of documents are in a format that would be recognisable to other research offices/jurisdictions.

The template includes a system generated link 'Application Documents' which also allows the recipient to access a copy of the approved documents for 14 days.

When the email is ready click 'send'.

Step 4

Once you hit 'send', two more options appear on the Process decision hamburger. Select the option that matched your office requirements.

Notification Acknowledged

P Not expecting Acknowledgement



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