Approval or Authorisation not associated with a meeting

✳ REGIS

QUICK REFERENCE GUIDE

FOR RESEARCH OFFICES

Application approvals/authorisations not associated with 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.
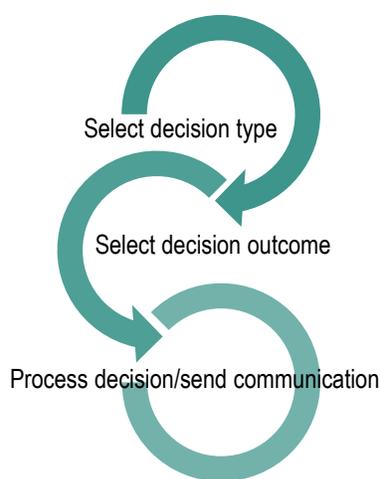
For site applications, site authorisation is granted by the Chief Executive (CE) or delegate of the Public Health Organisation.

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.

Select decision type

Select decision outcome

Process decision/send communication

Approval decisions available in REGIS

Ethics approval/decision

Type of Decision: Application decision Decision outcomes:

❖ **approved** – the application has been approved and REGIS will now process the decision
❖ **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 and REGIS will now process the decision
❖ **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.

Relevant icons

The following icons will be referred to throughout this document.

✏	Edit appear on the right-hand side of the screen
≡	Hamburger (more options)
✔	Tick to add selected
✔ Save	(wizard) Save
💾	(page) Save

Quick Reference Guide - Research Office - Approvals not associated with meetings - Version 1.2

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.

Step 2
Select the application.

Click on Management tab → 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
Select the 3 dots 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 'Select' at the end of the 'User' cell to search for the person who will or has made the decision.

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.

For ethics, this would be the HREC Chair or the person who has been delegated authority to undertake review of HREC Executive Committee business e.g. EO.

For governance, this would be the RGO.

Click 'Save' within the wizard.

Step 8

View and manage the decision. A black panel will appear. Click on the decision to manage.

Decision outcomes described on page 1.

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

Click 'save' in the wizard

Ethics applications can now progress to 'Process the Decision'.

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

To add a User for the 'CE/Delegate Decision'

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

Repeat **Step 8** and progress to 'Processing the Decision'.

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

An email template will appear for review and completion.

The templates meet the minimum requirements of the National Statement (5.2.22) to be used as a formal communication.

Edit as required and click 'send'.

The email will be sent to the Coordinating Principal Investigator, Principal Investigators and administration contacts as required.

REGIS extra

Once you hit 'send', 2 more options appear on the Process decision hamburger. Use this feature as required.

⚑ Notification Acknowledged
⚐ Not expecting Acknowledgement

**For technical assistance, contact
REGIS HELP DESK**

**support.f1solutions.com.au
1300 073 447**

NSW GOVERNMENT | Health

ACT Government