Approval or Authorisation not associated with a meeting

REGIS

QUICK REFERENCE GUIDE   **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).
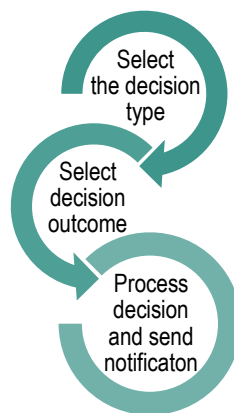
Approvals In REGIS Not Associated with a Meeting

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.

Select the decision type → Select decision outcome → Process decision and send notificaton

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:

- ❖ your homepage tiles
- ❖ the quick search at the top of the screen, or
- ❖ the Application tile from the Start menu.

Step 2

Select the application and click on Management tab, Decisions and then click 'Edit'.

Step 3

Click the black 'Add Decisions' button. The Decisions wizard will appear.

Step 4

Do not add a 'Current Due Date'.

Select the three horizontal 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)

Click the checkbox next to the relevant 'Decision' and then click 'Apply' at the bottom of the panel.

Step 6

After selecting the Type 'Application Decision' (if Ethics) or 'Recommendation by RGO' (if SSA), click in the 'User' box, (or the dots icon •••) to search for the person who will make the decision in REGIS.
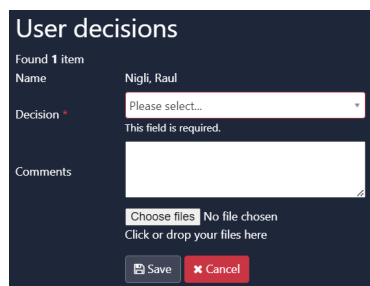
Step 7

Search for the User by typing in their name or email address.

Click the checkbox next to the User and then click on 'Add User(s)' at the bottom of the screen. Click the black 'Save' button below the Notes box within the wizard

Step 8

Click 👥 to view and manage the decision. A panel will open on the right-hand side (RHS).
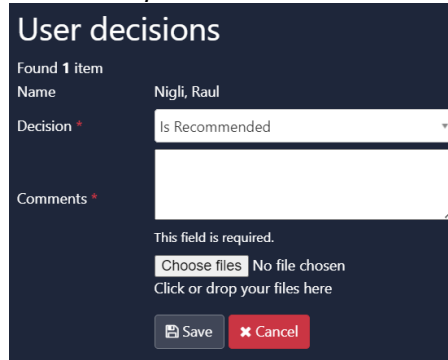
NOTE: Click where your name appears to finalise the decision. The following screen will appear for you to select a decision.

Decision outcomes are described on page 1

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

Recommendation by RGO: Upload documents by clicking on the 'Choose Files' button; then click 'Save'.

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

Add a User for the 'CE/Delegate Decision'

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

If you want the CE to see any notes on the front page of the decision, make them under 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, then a system generated email will be sent to the selected user. After the CE makes 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

Once the decision has been made and saved, along the bottom of the screen, click the newly available 'Decision' button. The Process Decision wizard will appear.

NOTE: If the button does not appear, please refresh REGIS

Step 2 Manage approved documents (appearing on email)

Review, add or remove any documents as applicable. Click the black 'Add Application Documents' button. On the panel that appears, select the relevant documents, then click the green 'Select Documents' button.
Remove any documents by clicking the red trash can/ delete icon.

These documents are associated with the application version that is being approved. They will be recognised by REGIS as the 'Approved' documents. They will be:
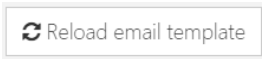
• Added to the automatically created .zip send to CPI/PI and admins.
• Automatically shared with related applications/projects (sites) in the internal portal
• Automatically made visible to the applicant in the external portal.

Note: The version and date, if they exist, are now included in the document title. This means that only the document title and document type will appear on the approval notification i.e., Participant Consent Form, HYDRA Trial version 1 dated 26 May 2024

Step 3 Create email

Click on the black 'Send Email' at the top left corner of the screen. You can choose an email template as appropriate from the drop-down box. An email template will then appear for review and completion.

Update the email template as required.

 You can revert the email back to the original template, removing any information manually added, by clicking the 'Reload email template' button.

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

When the email is ready, click 'Send'. Review the confirmation to ensure that everything has been actioned.

Step 4

Once you hit 'send', you will be taken back to the Overview page. At the bottom of the screen, click the Decision button.

At the top left corner of the screen, you will now have two more options: 'Notification acknowledged' and 'Not expecting acknowledgement'. Select the option that matches your office requirements.

HREC Approval and Expiry Dates – Ethics Outside REGIS

When Ethics is outside of REGIS, the RGO will need to manually enter the Ethics approval and expiry dates in the STE Application and Project, as listed on the HREC approval letter.

Step 1

On the STE the Summary page, click 'Edit' at the bottom right-hand side of the screen.

Step 2

Update the 'Approval date' and 'Expiry date'.

Approval date	dd/mm/yyyy
Expiry date	dd/mm/yyyy

Step 3

Click the green 'Save' button along the bottom right-hand side of the screen.