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
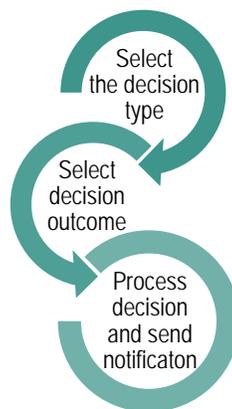
Approval decisions available in REGIS

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:

- ❖ a homepage tile
- ❖ 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

Under the Decisions title, select 'Add

Decisions'. The Decisions wizard will appear.

Step 4

Do not add a 'Current Due Date'.

Select the 3 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)

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) click the three dots ••• at the end of the 'User' cell to search for the person who is completing the task in the system.
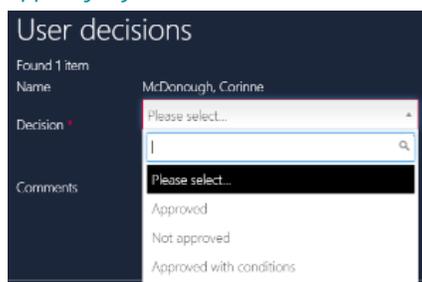
Step 7

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

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

Step 8

Click 👥 to view and manage the decision.

NOTE: Click where your name appears to finalise the decision. The below screen will appear for you to select a decision.

User decisions

Found 1 item
Name   McDonough, Corinne

Decision *   Please select...

              Please select...
              Approved
Comments   Not approved
              Approved with conditions

Decision outcomes are described on page 1.

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

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

✏️ 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 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

When the decision has been made and saved, select 'Decision Pending generation' from the right-hand side of the screen.

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

Step 2 Manage approved documents (appearing on email)

The documents selected/deleted here will be recognised by the system 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.

Click on the 'Decision Pending generation' icon to go to the 'Process decision page.

The list of documents will that appear are the documents associated with the application version that is being approved.

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 9 August 2021

Remove any document that should not be 'approved' by using the delete icon.

If you would like to add any documents that are not listed use the '+Add application documents' button'.

Step 3 Create email

Select 'Send Email' at the top of the screen. An email template will appear for review and completion.

Update the email template as required.

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

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'.

Step 4

Once you hit 'send', two more options appear at the top of the screen, '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, select 'Edit' from the right-hand side of the screen.

Step 2

Update the 'Approval date' and 'Expiry date' and then click 'Save' on the right-hand side of the screen.

Approval date   dd/mm/yyyy

Expiry date   dd/mm/yyyy