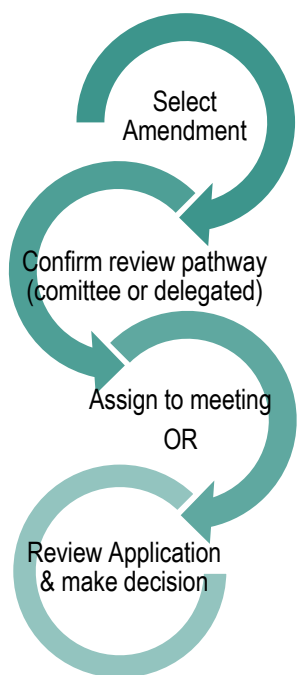


QUICK REFERENCE GUIDE

# Processing an ethics amendment

The following diagram is an overview of the HREC meeting process in REGIS.



**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](#)

## Accessing the Related Form

### Step 1

Select the amendment from the homepage tile that you want to process.

### Step 2

You will be taken to the 'Related forms' section of the Ethics Project (post-approval).

**Identifier:** each related form is given a unique identifier.

Identifier  
014884

**Title:** Title of the form e.g. Notification of an amendment to a research study.



**Submitted date:** date and time the form was submitted.

**Status:** the status of the form. In Progress, Submitted, or Approved.

**Tags:** System generated tags to identify the type of amendment e.g. General Amendment, Request for extension, Addition of a New Site, Change in PI-CPI

**Owner:** Application/Project owner or CPI.

### Step 3

Download the form and attachments or   download the form only to assess the review pathway according to your established office procedures.

- ❖ Full Committee review
- ❖ Executive Committee review
- ❖ Delegated to EO by Chair.


Manually note the Identifier (e.g. 014884)

## Assigning a Related Form to an existing meeting

For full committee review or executive committee review

*For instructions on how to create a meeting please see: [QRG - Research Offices - Creating and Preparing HREC Meetings](#)*


### Step 1

From the Start menu select the 'Meetings' 

*Hint: Right click your mouse on this icon to select open a new tab.*

### Step 2

**Search for the existing meeting**  
Search by Title and/or Meeting status. Add other filters by dragging and dropping any filters on the left-hand side of the screen.

 Select the meeting by clicking the edit icon

### Step 3

Select 'Forms' at the top of the Meeting page. Forms in meetings relates to amendments and safety reporting.

**Step 4**

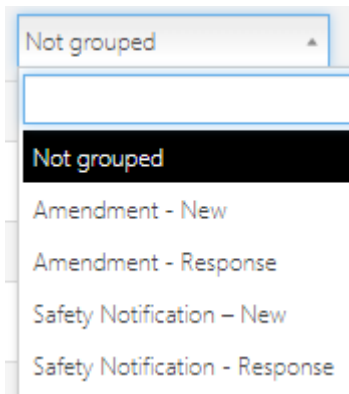
Click '+ Add form' and Use the Search function in the pop out panel to find the forms.



*Hint: Filter by Form, Status or text search for the form identifier number, then click save.*

**Step 6**

New forms will show as "not grouped", you can select to group forms as:



Where multiple forms are available within a group you can edit the display order within the group by selecting the "Move up" or "Move down" icons.



**Step 7**

All supporting documents submitted with the form (e.g. amendment) will be made available to view in the external portal.

To review and manage the documents click on the 'Select Document' icon.



**Adding notes and recording the decision - in the meeting.**

*Hint: You need to be in edit mode to make notes and decisions against forms.*

**Step 1**

Click the 'Add note' icon on the right side of the form in the table listing and add comments. Click 'Save'.



The notes can added before, during or after a meeting, this information will feed through to the draft minutes created in REGIS.

Complete the same step for all Forms.

**Step 2 Record a decision.**

The 'Manage Decision' gavel icon records the decision.



Select the Decision Type and Decision.

Decision Type: This is the type of form;

- ❖ Amendment form
- ❖ Amendment form with contact change for PI/CPI
- ❖ Request for extension of ethics approval
- ❖ Amendment form with Addition of new Site
- ❖ Project Incident report
- ❖ Safety Notification

Decision: Depending on the form there are different decisions available;

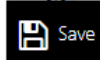
- ❖ Approved
- ❖ Decision pending – Request for further information
- ❖ Decision pending – More Information required
- ❖ Not approved
- ❖ Noted
- ❖ Rejected

Comments added in the Reason cell will feed through to email templates.

Click Save.

**Step 3**

When all notes and decisions have been entered make sure all details all saved by clicking save on the right hand menu.



**Step 4**

Click on the 'Send email' icon for the email wizard to appear.



The email template generated is based off the decision. Edit as required and click the green tick to send.



The 'Email Sent' icon will appear when you refresh the page.



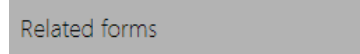
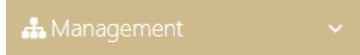
**Unsubmit the form (if more info requested)**

The Related form will need to be unsubmitted to allow the applicant to make changes to the form or documents.

You can return to the Ethics Project by using the "view project" icon.



Select 'Management' from the left hand menu and then 'Related forms'



Click the edit button and then the 'Unsubmit' icon



The Related form is now showing in a status of 'In Progress' and the applicant can make changes.

For technical assistance, contact  
REGIS HELP DESK  
support.f1solutions.com.au  
**1300 073 447**

## Processing amendment from the Project

**Note:** When the chair has delegated authority to undertake review of HREC Executive Committee business. e.g. EO

From Related forms download the Form and attachments (if required) by using the icons to the right of the screen.

Related forms

Download form



Download form and attachments



Download form and attachments

A temporary zip file will download. Review as per office procedure.

### Step 1

Manually note the Related Form Identifier (e.g. 014884) and the type of form being processed. e.g. General Amendment, Request for extension, Addition of a New Site, Change in PI-CPI

### Step 2

Select Decisions on the left hand menu and then select 'Edit' on the far right-hand side of the screen.

### Step 3

On the page, under the Decisions title select '+ 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 type.

- ❖ Amendment form
- ❖ Amendment form with contact change for PI/CPI
- ❖ Request for extension of ethics approval
- ❖ Amendment form with Addition of new Site

- ❖ Progress Report with status change
- ❖ Annual Progress Report
- ❖ Project Incident report
- ❖ First Patient In Report
- ❖ Safety Notification

Select the decision and then click the 'Apply' tick icon at the bottom of the panel.

### Step 6

After selecting the Type

**Entity:** Project related form

**Current due date:** Not required

**Project related form:** Select the form you are processing using the identifier noted down earlier.

**User:** Click the three dots at the end of the 'User' cell to search for the person who will or has made the decision.

### Step 7

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

Click on the checkbox next to the user and then on the 'Add user/s' tick icon at the bottom of the panel. This is the person who has been delegated authority to undertake review of HREC Executive Committee business e.g. EO.

Click 'Save' within the wizard.

### Step 8

Now select the 'View user decision' icon next to the form you are processing.

View user decision

### Step 9

Click on the available user decision and the management panel will appear

User decisions

Found 1 item

Name McDonough, Corinne

Decision Please select...  
This field is required.

Comments

Save Cancel

### Step 10

Click on 'Choose' to select the decision:

- ❖ Approved
- ❖ Not approved
- ❖ Decision Pending – Request for more information

A comment is required then click 'Save'.

**Step 11** Click on the 'Send email' icon which has generated, triggering the email wizard to appear. The email template will load based off your decision.

Edit as required and click 'send'. You will see a ✓ next to the 'Type' of amendment, indicating that an email has been sent.

**Decision Pending – More information required.**

### Step 12A – Unsubmit the form

The Related Form will need to be un-submitted to allow the applicant to make changes to the form or documents.

Select 'Management' from the left hand menu and then 'Related forms'

Management

Related forms

Click the edit button and then the 'Unsubmit' icon



The Related form is now showing in a status of 'In Progress' and the applicant can make changes.

Then click Save.

The Related form is now showing in a status of 'In Progress' and the applicant can make changes.

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