

Processing an Ethics Amendment

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



Note: this user guide assumes you have already set up your homepage tiles. See [Research GEMS User guide – Setting up Home page tiles](#).

Accessing the Related Form

Step 1

Select the amendment for processing from the homepage tile.

Step 2

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

Identifier: Each related form is given a unique identifier.



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: 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 the form only to assess the review pathway according to your office procedures.



Manually note the Identifier.



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: [Research GEMS Offices - Creating and Preparing HREC Meetings](#)

Step 1

From the Start menu on the left-hand side, select 'Meetings'



Step 2 Search for the existing meeting

Search by Title and/or Meeting status. Add other filters by dragging and dropping any filters from the left-hand side of the screen.



Select the meeting by clicking the edit icon.

Step 3

Select 'Forms' heading 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 search.

Step 5

New forms will show as 'Not grouped', see below grouping options:

You can edit the display order of multiple forms



within a group by selecting the 'Move up' or 'Move down' arrow icons.

Step 6

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 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-hand side of the form in the table listing and add comments. Click 'Save'.

Notes can be added before, during or after a meeting. This information will feed through to the draft minutes created in GEMS.

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
- ❖ Acknowledged

Comments added in the 'Reason' cell will feed through to email template. Click Save.

Step 3

When all notes and decisions have been entered, click save from the right-hand menu.



Step 4

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



The email template generated is based on the decision. Edit as required.

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. If you navigate away from the page, any information added will save.



Click the green tick to send.

The amendment will automatically un-submit. If 'Decision Pending – More Information Required' was selected, the status will now appear as 'Information Required'.

Note: 'PIs (All Other)' are no longer required to have GEMS accounts. PI details need to be manually added to outgoing correspondence. 'Other health jurisdiction or organisation' site details also need to be manually added to outgoing correspondence.

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



Processing amendment from the Project

Note: This option can only be used when the chair has been delegated authority to undertake review of HREC Executive Committee business.

It can not be used for 'addition of a site' amendments as the site does not get created when approved via decision.

Other amendment types can be approved through the 'decision' feature, however any changes to the study will need to be manually entered eg. Extension amendments, change to CPI.

From 'Related forms' download the Form and attachments (if required) by using the download form and attachments buttons



A temporary zip file will download. Review as per your local 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

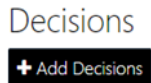
If the amendment is for change in 'PI (All Other)' you will need to manually add the PI as a contact in the HRE Project 'Contacts' section once their credentials have been validated, per your local office policy.

Step 2

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

Step 3

Under the Decisions title select '+ Add Decisions' and 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 drop-down menu will appear.

Step 5

Select the Decision Type: This is the type of 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 click the 'Apply' tick icon at the bottom of the panel.

Step 6

After selecting the Type you will need to complete the following questions as indicated;

Entity: Project related form

Current due date: Not required

Project related form: Select the form you are processing using the identifier previously noted.

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

For General Amendments, you need to select the documents as you are creating the decision against these documents. These documents will be listed on the approval decision notification.

Use the 'Select Documents' icon to choose the documents related to that amendment. Most recently submitted documents are identifiable by the * next to the System Version number. You can



also use the Form ID which appears in the 'Filename' i.e.030047.

Click the tick at the bottom of the page and click 'Save' on the right-hand side of the screen.

Step 9

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

Step 10

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

Step 11

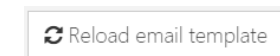
Click on 'Choose' to select the decision:

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

A comment is required then click 'Save'.

Step 12

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.



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.

Click 'send'. The ✓ next to the 'Type' of amendment indicates that an email has been sent.

If 'Decision Pending – More Information Required' was selected, the status will now appear as 'Information Required' and the amendment will automatically un-submit.

Note: 'PIs (All Other)' are no longer required to have GEMS accounts meaning PI details will need to be added manually to outgoing correspondence. 'Other health jurisdiction or organisation' site details also need to be manually added to outgoing correspondence.

Sharing Approved General Amendments

The Research Office will need to go in to 'Related Documents' and share the General Amendment approved documents with related sites in GEMS.

Select 'Edit' from the right-hand side and click the below icons (*not visible) to make them visible in the external portal and visible to other sites in the internal portal.

**Not visible*

Visible

