

Ethics amendment – responding to an information request

How does it work in Research GEMS?

If you receive an email notification indicating an amendment requires changes before it can be approved, the form will have changed to the status

- Information Required

Submitting a response to a request for further information

Step 1. Update documents

If you have been asked to make changes to or update documents, this should be completed outside of GEMS first. Be sure to update the document version and date in the document footer.

Step 2. Locate ethics project

Accessing from email link

Click on the link from the system generated email. Progress to Step 3.

OR

Accessing from GEMS homepage

Click the 'Projects' icon to see all projects.



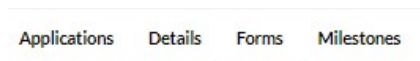
Click the hyperlinked Project 'Title' in the list. This will take you to the project details page.

Click the ethics identifier from the table at the bottom of the 'Applications' tab.

IDENTIFIER	STATUS
2022/HRE00046	● Approved

Step 3. Find the Forms page

Click on the 'Forms' tab within the top banner of the ethics project.



- ❖ Locate the relevant amendment form that has the status of 'Information Required'.
- ❖ Click the hyperlinked title to open the form.
- ❖ Make any changes to the form as required.

Step 3a. To update a document submitted with the amendment

Click on the 'Document upload' tab.

Under 'Upload as a new version' select Yes or No as appropriate.

Yes indicates that you are uploading a new version of an existing approved document in GEMS. Selecting **No** indicates that you are uploading a new document, one that has not previously been submitted.

When **Yes** is selected, the document will appear in the 'Document title/Descriptor' drop-down menu and once selected, the 'Document Filename' will auto-populate.

Update the **Document Version and Date** of the document being re-submitted (normally listed in footer).

Version*	Date*
2	12/08/2020

Select 'X' to remove the old version of the document.

✘ [103.1 appl](#)

Click 'Browse' and the upload wizard will appear. Select the document and then 'open'.

When **No** is selected, you will need to provide a 'Document Title/Descriptor'. Please ensure it is clear and detailed as this is what will appear on the approval decision notification. Select the document 'Type', provide the 'Version' and 'Date' and upload the document, as described above.

Step 4. Declaration

Only the CPI or an authorised delegate with submit permission can submit the updated amendment.

Person/s with edit access can save the form and notify the CPI or authorised delegate that it is ready to submit.

Once the amendment is submitted, you will be taken back to the forms page of the ethics project.

The status of the form will now have changed to:

- Information Provided

Created Date: identifies the date when the form was initially created.

Modified date: identifies the date when the form was submitted or resubmitted.

What next?

The amendment will be received by the research office managing the ethics project.

Once the amendment request has been reviewed, the CPI and relevant team member/s will receive an email. The amendment will either be approved, not approved or another request for information will be generated.