

Ethics Amendment - Responding to an Information Request

Step 1. Update documents

This should be completed outside of REGIS. Ensure to update the 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: Access the Amendment Form**

OR

Accessing from REGIS homepage

Locate your project via your 'Top 5 projects' or the 'Projects' icon at the top of the page 

Click the Project Identifier (PID) or 'Title' in the list and select the ETH identifier.

Step 3. Access the Amendment Form

Select 'Forms', locate the 'Information Required' amendment form and click to open. Make any changes to the form as required.

3A. To update a document

To upload an updated document, click on the  to remove the old document.

Upload file *

File Name

 Master_PISCF v3 120122.doc

Then drag and drop or browse your local files for the new document.

Upload file *

File Name

 Master_PISCF v4 170122.doc

Ensure you update the description of the attachment to include the updated version and date

New Document Title *

Master PICF Version 4 dated 17 January 2022

Note: The New Document Title and Document Type is what the Research Office will see and how the document will appear on the approval notification e.g., Participant Information Sheet Master PICF version 4 dated 17 January 2022

3B. To Add a New Document

To add a new document to the amendment, select 'Yes' if it is a new version of an existing approved document or 'No' if it is a document that has not been approved by the reviewing research office.

Upload as a new version: Select Yes

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Upload attachment: Drag and drop or browse your local files for the new document.

For new documents, **Upload as a new version:** Select No

Document Type: Select from dropdown

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Upload attachment: Drag and drop or browse your local files for the new document.

3C. To remove a document

 **Only remove a document that is not required.** Use the red bin delete icon to remove the entire document and document row. To update an existing document, follow the steps in 3A.

Step 4. Declaration

The CPI (& their nominated delegates with submit access) can submit the updated amendment. If you do not have submit access, save the form, and notify the CPI or one of their delegates that it is ready for submission.

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 application.

Once the amendment request has been reviewed you will receive notification via a system generated email. The amendment will either be approved, not approved or there will be a request for further information.