Responding to a request for information – ethics applications

What is a request for information?

Upon submission, your ethics application (HREA) will be reviewed by a Human Research Ethics Committee (HREC) or an Executive Officer (EO).

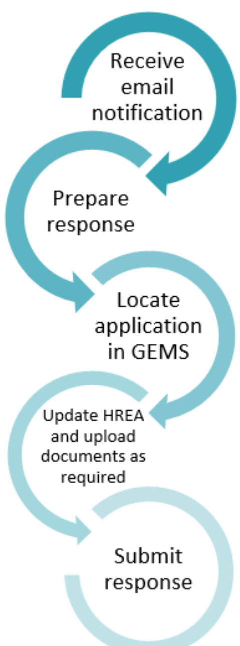
Once your application has been reviewed, you may be asked to provide more information.

What information is needed?

You should have the following information ready to respond to a request for more information:

- your Research GEMS username and password
- the email sent from GEMS describing the decision type and details required
- updated project documentation to upload, if required.

The following diagram illustrates the process of resubmitting an application in GEMS.

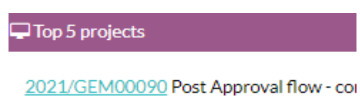


How to respond to a request for information

Step 1. Update documents
If you have been asked to make changes or update documents, this should be completed outside of GEMS and new versions of the documents created.

Research offices require a tracked version of any updated documents. Keep the filename and description the same but add 'tracked' at the end.

Step 2. Locate your application
When you log into GEMS, your home page should show your top 5 projects.



If you can see the project here, open it by clicking on the project identifier or the title.

If the project is not listed in your top 5 projects, use the 'Projects' icon to take you to Project View.

A list of projects will appear. Click on the title or identifier to be taken to the project details home page. You will see the associated ethics and SSA applications.

For information on sharing applications and permissions, see user guide [Sharing access to an application/project.]

Step 3. Update the application form
Click on the ethics application identifier (HRExxxx) and select 'new version' to open an editable version of the application. The status of the application will change to 'In Progress'

Carefully review the HREA and update any sections as required. GEMS will automatically generate a tracked version of the HREA which will be submitted with your response.

Step 3. Update, add or remove documents
On the left-hand side menu of the form select the ***HREA: Upload*** tab.

For information on documents and descriptors, see the File Naming Conventions user guide.

Step 3A. To update a document
If you have been asked to update the protocol this is located at question 4.1 in the HREA. All other project wide/master documents are located at question 4.2.

Document type: Do not change unless specifically directed to.
Description of attachment: Enter a clear and descriptive document descriptor.

Note: How you describe your documents are how they will be listed on the approval notification so ensure you are clear and descriptive i.e. Participant Consent Form, Master R44-001 Arm 1.

Document version: As listed on document.
Document date: As listed on document.

Any tracked documents should have 'tracked' in the electronic filename and in the description.

Step 3B. To add a new document

If you have been asked to respond to specific items that are in addition to changes to the form or other documents, the researcher can create a response/cover letter and upload here.

Tracked copies of documents should be uploaded as a new document.

- Click on the ‘Add row’ button at the bottom of the document table. A new document row will appear.

- Click ‘Browse’ to locate the file and upload it.

Document type: Select from dropdown list.
Description of attachment: Enter a clear and descriptive document descriptor.

Document version: As listed on document.
Document date: As listed on document.
- Click ‘Browse’ to locate the file and upload it.

Step 3C. To remove a document
The following instructions assist in removing a document that is not required. To update an existing document, follow steps 3A.

- Select the document to be removed by ticking the red x next to the document title.

Step 4. Submit the application
Once you have completed all the changes to the application form and the documents, finalise the response by moving to the end of the form ***HREA: Generate HREA Document*** for re-submission. The status of the application will then change to ‘Information Provided’

Information provided

If you have any questions, contact the relevant research office.

Remember: You cannot start your research until you receive both the ethics approval and governance authorisation letters/emails.