

Responding to a request for information

What is a request for information?

A human research ethics committee (HREC), an executive officer (EO) or a research governance officer (RGO) will review your application, depending on whether it is:

- ❖ An ethics or governance application.
- ❖ Low risk or greater than low risk.

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

Research GEMS allows HRECs, EOs and RGOs to make 2 types of 'more information' requests:

- ❖ **Decision pending further information** – Changes to the application or documents are required. This option creates a new version of the ethics (HRE) or governance (site specific assessment – SSA) application for you to edit.
- ❖ **Approval (HRE)/Recommendation (SSA) pending further information** – A 'More information' form is created for you to complete. This option is selected when the HREC, EO or RGO requires information before the approval or recommendation but no changes to the application or documents is needed.

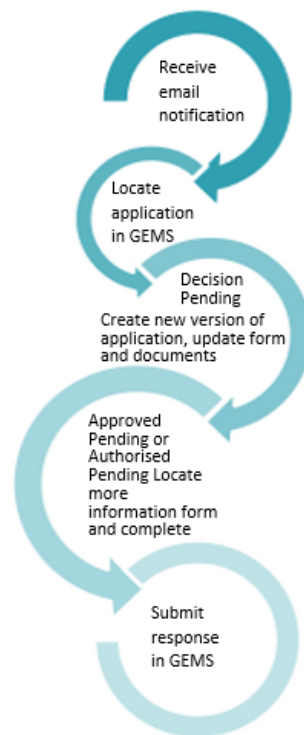
What information is needed?

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

- ❖ your 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 in GEMS



Step 1. Locate your application

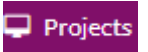
When you log into GEMS, your home page should show your top 5 projects.

 Top 5 projects

[2021/GEM00090](#) Post Approval flow - coi

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.

Decision pending further information

Create new version of application

The application owner (CPI and PI) and authorised delegates can access and submit this form.

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

Step 1. Update documents

If you have been asked to make changes to 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 similar but put tracked at the end.

Step 2. Update the application form

Click on the application identifier (HRE or SSA application) and select 'new version' to open an editable version of

the application. The status of the application will change to ● In Progress

Step 3. Update, add or remove documents

On the left-hand side menu of the form select: **HREA: Upload (ethics application) or SSA application: Part F Attachments – Sites Specific Documents (governance application).**

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.

In the SSA application, site specific documents are located at Part F: Attachments – Site Specific Documents.

Document type: Do not change unless specifically directed to.

Document descriptor: 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.

3B. To add a new document

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.

Document descriptor: 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.

3C. To remove a document

The following instructions is to remove 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.

❖ If the applicant has 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.

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 ethics application) or SSA application: Part G Declaration (for governance application)** for re-submission. The status of the application will then change to ● Information provided

For SSA applications only

If a new head of department (HOD) was included in the new version of the application the status will now be

● Completed pending HOD

The NEW HOD will receive a notification

from GEMS that an SSA application is ready for their decision.

The PI and relevant team members will receive an email from GEMS when all HODs have made their decision.

Approval/Recommendation pending further information Respond to more information form

The application owner (CPI and PI) and authorised delegates can access and submit this form.

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

Step 1.

The status of the application will have changed to when the request for information notification email was sent.

● Approved pending further information

Step 2. Locate the more information form

❖ Click the identifier of the application and the Application information menu will appear. Select 'Application information.'

Application information

❖ Select 'Forms' from the left-hand menu.

❖ This will bring up a 'More Information Required' form for you to action.

Step 3. Complete the More Information form

❖ Click the more information required form link.

❖ Copy the question/s from the GEMS email into the form and add your response/s and then click 'Submit'.

❖ The status of the form will now show as 'Submitted' and the modified date will show the date and time the form was submitted.

Once you have completed the request for information, depending on your response, there may be further requests for information, or the application will progress to the final decision which is:

- ❖ Approved, Approved with conditions or Not approved (for ethics applications).
- ❖ Authorised, Authorised with conditions or Not authorised (for governance applications).

If you have any questions, contact your research office.

Remember: You cannot start your research until you receive the ethics approval and governance authorisation letter/email.