

Respond to a request for information

FOR RESEARCH APPLICANTS

QUICK REFERENCE GUIDE

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.

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

- ❖ **Decision pending further information** – Changes to the application form or documents are required. This option creates a new version of the ethics or governance application for you to edit.
- ❖ **Approval (ETH)/Recommendation (STE) pending further information** – A 'More information' form is created for you to write a response, but no documents will be required to be uploaded.

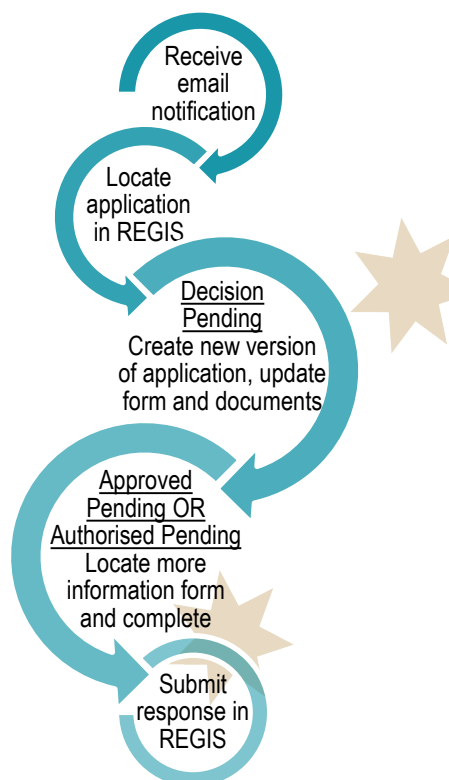
What information is needed?

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

- ❖ your REGIS username and password
- ❖ the email sent from REGIS 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 REGIS.



System Withdrawal after 30 days

Applicants will have 30 days from the date of the information request email to provide a response, after this time the application will be withdrawn by the system and a new application will be required.

You will have 30 days from the date of this email to provide a full response, after this time the application will be "Withdrawn" by the system and a new application will be required.

To request an additional 30 days, submit a response to the initial information request with a short cover letter/text response requesting this.

How to respond to a request for information in REGIS

Step 1. Locate your application

When you log in to REGIS, your home page will show your 'Top 5 projects'. If you can see the project here, open it by clicking on the project identifier (PID) or the title.



2021/PID01119 The New REGIS



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 in a table. Click on the title.

| TITLE |
|----------------------|
| <u>The New REGIS</u> |

The project title will appear at the top of the screen and you will see the ethics and governance applications associated with it.

Decision pending further information

Create new version of application

Step 1. Update documents

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

A tracked version of any updated documents will be required. Keep the filename and description similar but put tracked at the end.

Step 2. Update the application form

The status of the application will have changed to ● In Progress when the email notification was sent.

Click on the application identifier (ETH or STE) and an editable version of the application will open.

Step 3A. Update, add or remove documents ETH/HREA for STE/SSA go to 3B

Navigate to the Upload section on the left-hand side menu.

To Update a Document in the HREA

Q4.1 Protocol: To update the Protocol with a new version click on the ✕ to remove the old document

- Q4.1 Attach the [Project Description/Protocol](#) to your H
- It is recommended that you use one of the templates p
 - Individual attachments are limited to 10 MB in size.

| File Name |
|---------------------|
| ✕ Protocol_v 1.docx |

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

| |
|------------------------------------|
| ✕ Protocol_v2 dated 12 Jan 22.docx |
|------------------------------------|

Q4.2 Other Documents: To update study wide (master) documents with a new version click on the ✕ to remove the old document.

Q4.2.1 Upload attachment *

| File Name | Size |
|----------------------------|----------|
| ✕ Mater PIC v1 100122.docx | 18.24 kB |

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

Q4.2.1 Upload attachment *

| File Name | Size |
|----------------------------|----------|
| ✕ Mater PIC v2 120122.docx | 18.24 kB |

Then update the description of the attachment including the version and date

Q4.2.2 Description of attachment *

Master PICF version 2 dated 12 January 2022

Note: The document Type and Description is what the Research Office will see and how the document will appear on the approval notification.

| | |
|------------------------------|---|
| Document Type * | Q4.2.2 Description of attachment * |
| Participant Information ...x | Master PICF version 2 dated 12 January 2022 |

e.g. *Participant Information Sheet Master PICF version 2 dated 12 January 2022*

To add a new study wide document

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.

To remove a document



Only remove a document that is not required, to update an existing document follow the steps in *To Update a Document in the HREA.*

Step 3B. Update, add or remove documents SSA for ETH/HREA go to 3A

On the left-hand side menu of the form select: *Part F Attachments*

To Update a Document in the SSA form

Navigate to the **Part F Attachments**

To Update a Document

To update site documents with a new version, click on the ✕ to remove the old document.

| File Name | Size |
|---------------------------|----------|
| ✕ SS PISCF version 1.docx | 11.26 kB |

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

| File Name | Size |
|----------------------|----------|
| ✕ Site PICF v 2.docx | 16.40 kB |

Then update the description of the attachment including the version and date

Document Descriptor *

Site PICF version 2 dated 13 January 2022

To Add a New Document

To add a new site document

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.

To remove a document



Only remove a document that is not required by selecting the red bin delete icon to remove the document and entire document row. To update an existing document follow the steps in *To Update a Document in the SSA form*

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 and using the left-hand menu. Click on the following options as appropriate: *HREA: Generate HREA Document (for ethics application)* or *SSA: Part G Declaration (for governance application)*

The status of the application will be ● Information provided

For Site applications only

If a new Head of Department 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 REGIS that an SSA is ready for their decision.

You will receive an email from REGIS when all HODs have made their decision.

Approved/Recommendation pending further information

Respond to more information form

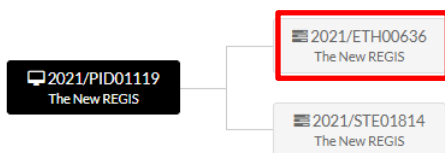
Currently only the Application Owner (CPI and PI) can access and submit this form.

Step 1.

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

Step 2. Locate the more information form

Click on the Application in the Hierarchy chart, to the right-hand side of the screen, to navigate to the Application Details.



Select the Forms tab along the top of the screen.

Application Details Decisions **Forms** Applications

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

Step 3. Open the More Information form

Click the more information required form link.

Copy the question(s) from the REGIS 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.

The status of the application will now show as ● Information provided

You have completed the request for information.

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.