

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:

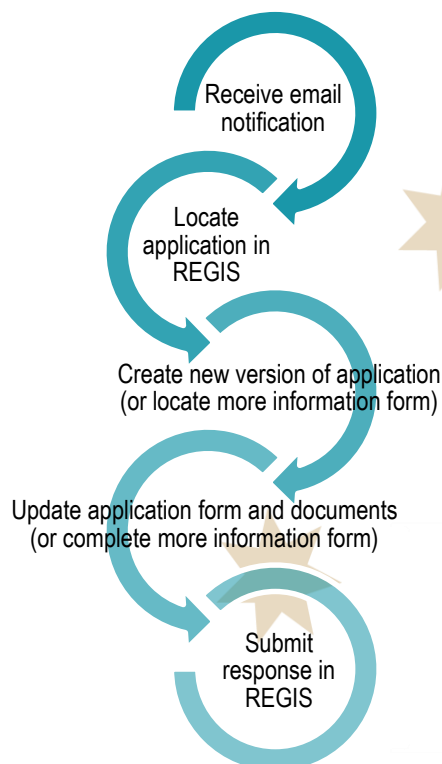
- ❖ **Approval (ETH)/Recommendation (STE) pending further information** – this option will create the 'more information' form for you to complete. This option is selected when the HREC, EO or RGO requires information before the approval/recommendation but no changes to the application or documents.
- ❖ **Decision pending further information** – this option is selected if any changes to the application or document are required. This option will create a new version of the ethics or governance application for you to edit.

What information is needed?

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

- ❖ your REGIS user name 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.




How to respond to a request for information in REGIS

Step 1. Locate your application

When you log in to REGIS, 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.

Project identifier	Title
2018/PID00061	B1 Project Title

If the project is not listed in your top 5 projects, use the top right gold menu bar.

 Click the 'Projects' icon to take you to Project View.

A list of projects will appear in a table. Click on the title or identifier to be taken to the Project Details home page.

Title	Identifier
B1 Project Title	2018/PID00061

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

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.

DO NOT change the electronic filename for any document to be uploaded to the HREA.

Step 2. Update the application form

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

● In Progress

Click on the application identifier

[2018/ETH00067](#) [2018/STE00151](#)

An editable version of the application will open to make any changes required.

Step 3. Update, add or remove documents

On the left-hand side menu of the form:

- ❖ HREA: Upload (ethics application)
- ❖ SSA: Part F Attachments – Sites Specific Documents (governance application)

3A. To update a document on the HREA

Do not change the electronic filename of any updated documents. The HREA requires the electronic filename to remain the same even when a new version of the document is uploaded.

The filename should not include any versioning or dates. This detail can be added to the description of attachment for the HREA.

REGIS manages document versioning for the HREA, meaning it will overwrite the old version of a document so only the most current version of a document is visible. Previous versions are not deleted and will remain in the system.

If you have been asked to update the Protocol this is located at question 4.1. All other project wide/master documents are located at question 4.2.

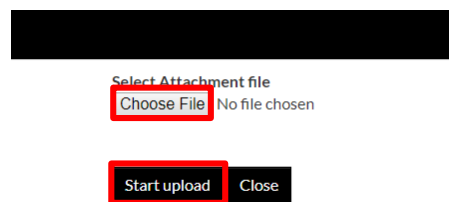
Select 'Clear content selection'.

[Clear content selection](#)
(Test PISCF KB.docx) [Open]

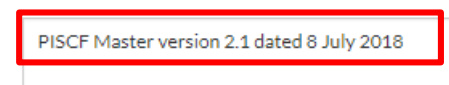
You can now select the 'Upload New'

button. The upload wizard will appear.

Click on 'Choose File' and browse for the document to be uploaded. Then click on the 'Start upload' button.



For any project wide/master documents listed at 4.2 update the Description of attachment with any new version and date.



3A. To update a document on the SSA

REGIS manages document versioning for the SSA, meaning it will overwrite the old version of a document so only the most current version of a document is visible. Previous versions are not deleted and will remain in the system.

The system uses inbuilt logic to create a unique filename based off the information added at Part F. Unlike HREA, versions and dates should not be included in the 'Document Title' when you reach Part F.

DO NOT change the Document Title.

DO NOT change the Document Type, unless specifically requested.

[Clear content selection](#)
(Participant Information Sheet_Master PISCF_WSLHD - Sexual Health Centre.docx) [Open]

Click 'Upload New' to locate the file on your computer and upload it.

[Upload New](#)

3B. To add a new document

Click on the 'Add' icon at the bottom left of the document table. A new document line will appear.



For HREA

Add the Title e.g. Master PISCF version 1.1 10 May 18.

Click 'Upload New' to locate the file on your computer and upload it.

[Upload New](#)

For SSA

Complete the Document Title. Do not add any version or dates here. E.g. Main Information Sheet.

Use the drop down filter to specify the Document Type. E.g. Participant Information Sheet

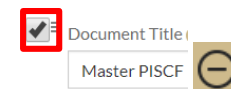
Click 'Upload New' to locate the file on your computer and upload it.

The order for uploading document in the SSA is VITAL to allow the system to manage document versions.

The system will create a system filename. e.g. Participant Information Sheet_Main Information Sheet_Site Name.docx

3C. To remove a document,

Select the document to be removed by ticking the check box next to 'Document Title', then clicking on the 'delete' icon on the bottom left of the document table.



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)
- ❖ SSA: Part G Declaration (for governance application)

● Information provided

The status of the application will now be 'Information provided'.

You have completed the request for information.

Approval/Recommendation pending further information.

Step 1.

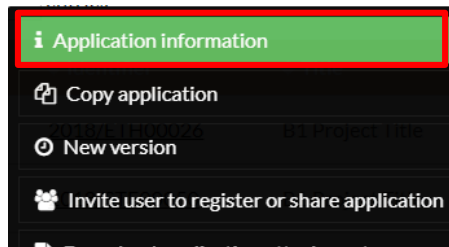
The status of the application will have changed to 'Information Requested' when the email notification was sent advising of the request for information.

● Information Requested

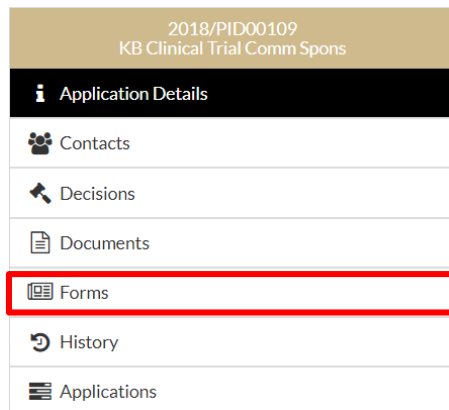
Step 2. Locate the more information form

- Click on options icon (3 dots) next to the identifier of the application.

The Application information menu will appear. Select 'Application information'.



Select 'Forms' on the left-hand menu.



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

Step 3. Open the More Information form

Click on the form link.

⋮ [More Information Required](#) ● In Progress

Copy the question(s) from the email sent to you by REGIS into the form.

Add your response(s).

Submit

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.

● Submitted

The status of the application will now show as 'Information provided'.

● 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 project until you receive the ethics approval and governance authorization letter/email.

For technical assistance, contact
REGIS HELP DESK

support.f1solutions.com.au

1300 073 447