REGIS

Respond to a request for information

QUICK REFERENCE GUIDE FOR RESEARCH APPLICANTS

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 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 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.

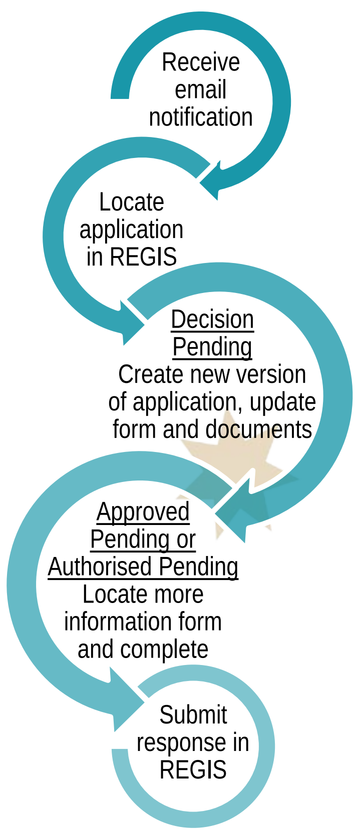
What information is needed?

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.

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 '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

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.

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

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 3. Update, add or remove documents

On the left-hand side menu of the form select: *HREA: Upload (ethics application)* or *SSA: 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 Site 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

Select document and click 'Clear content selection' and then click 'Upload New' to locate the file on your computer and upload it.

Click on 'Choose File', select the document and click 'Start upload'.

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 icon '+' at the bottom of the document table. A new document row will appear.

Click 'Upload New' to locate the file and upload it

Document Type: Select from dropdown menu.

Document Descriptor: Enter a clear and descriptive document descriptor

Document version: As listed on document

Document date: As listed on document

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

3C. To remove a document

Only use the following instructions if you are removing a document that is not required, to update an existing document follow the steps in **3A. To Update a Document**.

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

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 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.

Approval/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 options icon (3 dots) next to the identifier of the application and the Application information menu will appear.

Select 'Application information'.

ℹ Application information

Select 'Forms' from 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 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.