✳ 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.

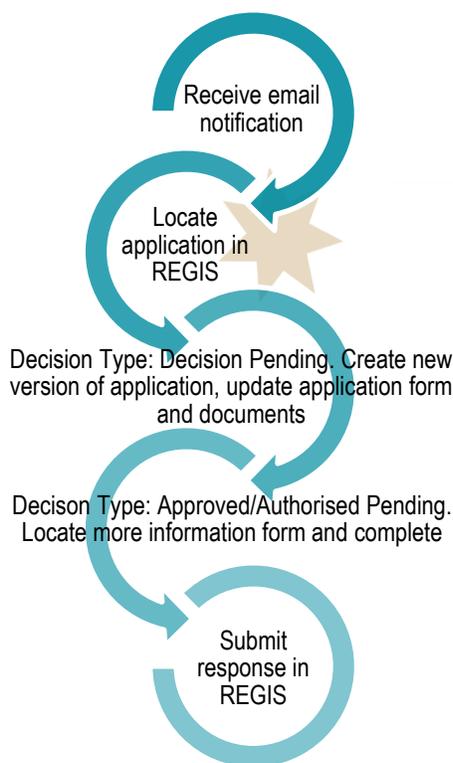REGIS allows HRECs, EOs and RGOs to make 2 types of 'more information' requests:

❖ **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.

Receive email notification

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Locate application in REGIS

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Decision Type: Decision Pending. Create new version of application, update application form and documents

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Decison Type: Approved/Authorised Pending. Locate more information form and complete

↓

Submit response 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

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.

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.

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.

Clear content selection
(KCTP_Protocol_REGIS.docx) [Open]

Upload New   Click 'Upload New' to locate the file.

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.   Upload New

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

Select Attachment file
Choose File No file chosen

Start upload   Close

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

For example:

PIS-Mas-Intervention-11 30-JAN-2018

The document description should remain in the following format
<Document type>-<Title>-<Version>-<Date DD-MMM-YYYY>.

Tracked Documents

All tracked documents should be included at section 4.2 including the tracked Protocol.

Tracked should appear in the electronic filename and in the description.

3A. To update a document on the Site application
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.

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

Document Type: DO NOT change, unless specifically requested

Document Descriptor: Should be in the following format: <short description of doc type><site acronym><brief unique descriptor>
Document Descriptor *

PIC-RNS-Intervention

For further assistance if needed, contact your local research office at these links – NSW or ACT.

Document version: update inline with any new document versioning in the document

Document date:. update inline with any new document versioning in the document

Tracked Documents

All tracked documents should be included at this section.

Tracked should appear in the electronic filename and in the description.

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
Document descriptor should be in the following format
<short description of doc type>-<brief unique descriptor>
(**PISCF-Intervention, IB-DrugName**)

 Add the document version and date in the specific cell.

Following the format described will speed up approval letter processing and reduce errors.

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

Tracked Documents

All tracked documents should be included at section 4.2 including the tracked Protocol. Tracked should appear in the electronic filename and in the description.

Response Letter/Coverletter

If the HREC has asked the applicant to respond to specific items that are in addition to changes to the form or other documents the researcher can create a response letter/cover letter and upload this at section.

For Site application
Document Type: Select from dropdown

Document Descriptor: Should be in the following format: <short description of doc type><site acronym><brief unique descriptor>

Document Descriptor *

PIC-RNS-Intervention

Document version: update inline with any new document versioning in the document

Document date:. update inline with any new document versioning in the document

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

Tracked Documents

All tracked documents should be included here.

Tracked should appear in the electronic filename and in the description.

Response Letter/Coverletter

If the RGO has asked the applicant to respond to specific items that are in addition to changes to the form or other documents the researcher can create a response letter/cover letter and upload this at section.

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.

Document Title
Master PISCF

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.

For Site applications only: If a new Head of Department was included in the new version of the application the status of the application will change from 'In Progress' to: 🔵 Completed pending HOD

The NEW HOD will receive a notification from REGIS that a SSA is ready for their decision.

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

See- Site Specific Application Part 2: Submitting Site Application after Head of Department Declaration

Approval/Recommendation pending further information.

Respond to more information form

Currently only the Application Owner (CPI/HREA, PI/Site) can access and submit this form.
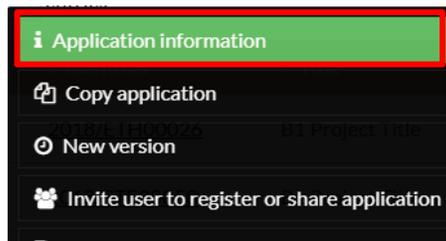
Step 1.
The status of the application will have changed to 'Information Requested' when the email notification was sent advising of the request for information.
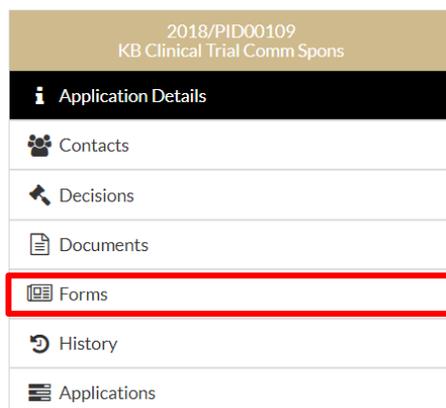
● Information Requested

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'.

i Application information
⧉ Copy application
◷ New version
👥 Invite user to register or share application

Select 'Forms' on the left-hand menu.

2018/PID00109
KB Clinical Trial Comm Spons

i Application Details
👥 Contacts
⚒ Decisions
📄 Documents
📖 Forms
↺ History
▥ Applications

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

For further assistance if needed, contact your local research office at these links – NSW or ACT.