



Resubmitting an application after an ineligible notification

What is an ineligible application?

After a new application (ethics or site-governance) is submitted to a research office, it is reviewed to assess if it is eligible to progress to the appropriate review process.

The research office is directed by guidelines provided by NSW Health or ACT Health on requirements for an eligible application.

If an application does not meet the requirements, the research office will send the applicant an email via REGIS, explaining why their application is ineligible.

In REGIS, the status of the application will also change from 'Submitted' to 'Ineligible' on the project home page.

● **Ineligible**

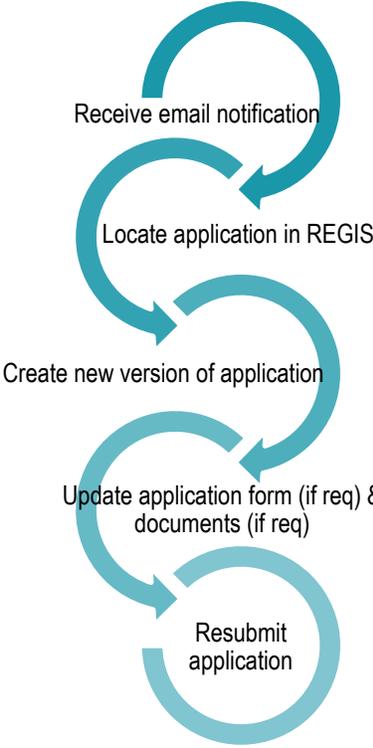
What information is needed?

You should have the following information ready before resubmitting the application:

- ❖ your REGIS user name and password
- ❖ the email sent from REGIS with the explanation of why the application was deemed ineligible
- ❖ updated project documentation to upload, if required.

How does it work in REGIS

The following diagram illustrates the process of resubmitting an application in REGIS.



Resubmitting the application in REGIS

Step 1. Update documents

If you have been asked to make changes to or update documents, complete this step before you log in to REGIS.

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

Step 2. 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 all the applications (ETH and STE) associated with the project.

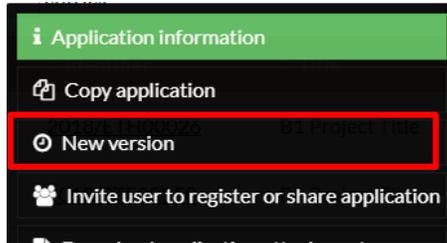
● **Ineligible**  Click the 'Projects' icon to take you to Project View.

Seek out the application with the status of 'Ineligible'.

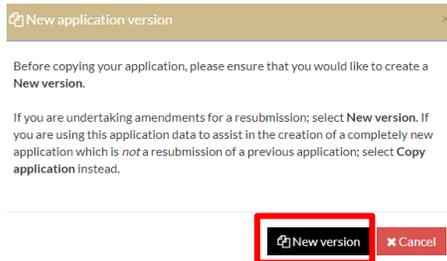
Step 3. Create a new version of the application

Click on the 3 dots next to the identifier of the ineligible application.

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



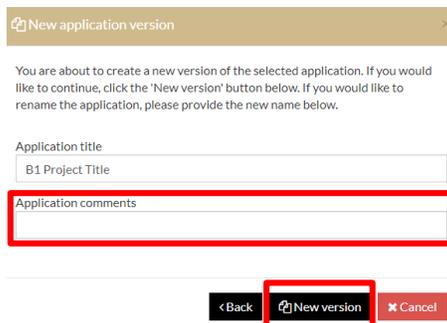
A warning message titled 'New application version' will appear. Click on the 'New version' button.



A second message will appear. Unless you have been instructed, **do not** change the Application title.

In the application comments cell, add a note to describe why you are submitting a new version, e.g. Resubmission after ineligible notification.

Then click 'New version'.



Step 4. Update the form

The status of the application will have changed from 'Ineligible' to 'In Progress'

In Progress

You can now edit the form.

Click on the application identifier [2018/STE00050](#)

An editable version of the form will open.

Make any changes required to the application form.

Step 5. Update, add or remove documents

On the left-hand side menu of the form:

- ❖ HREA: Upload (upload revised HREA)
- ❖ SSA: Part F Attachments – Sites Specific Documents (upload revised SSA)

5A. To update a document on the HREA

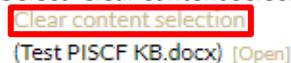
Do not change the electronic filename of any updated documents. The HREA requires the electronic filename to remain the same even when a new version of the document is uploaded.

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'.

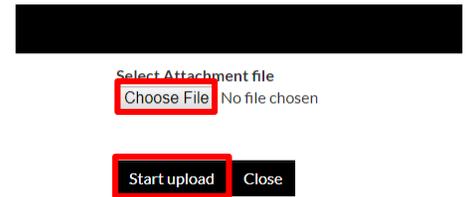


You can now select the 'Upload New' button. The upload wizard will appear.



Click on 'Choose File' and browse for the document to be uploaded.

Now 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.



5A. 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

5B. 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

5C. To remove a document

Select the document to be removed by

Document Title
 Master PISCF

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



Step 6 Resubmit the application

Once you have completed all the changes to the application form and the documents, resubmit the application 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
- ❖ SSA: Part G Declaration

Submitted The status of the application will now be 'Submitted'.

For SSA 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- Submitting SSA after HOD Decision

Once you have resubmitted the application, the research office will manage the application review and approval process. If your application is now eligible, it will progress to the appropriate review.

If you have any questions, contact your research office.

What next?

The research office will review the eligibility of the new submission and will send the outcome of the eligibility via a REIGS email.



For technical assistance, contact
 REGIS HELP DESK
support@f1solutions.com.au
1300 073 447