



Resubmitting an ineligible ethics application

What is an ineligible application?

Each new application is assessed for eligibility to be reviewed by the HREC or RGO.

The research office is directed by guidelines provided by SA 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 Research GEMS, explaining why their application is ineligible.

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

● Ineligible

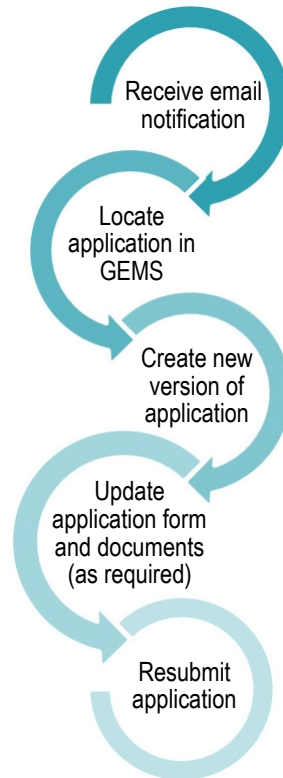
What information is needed?

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

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

How does it work in GEMS?

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



Resubmitting the application in GEMS

Step 1. Update documents

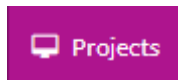
If you have been asked to make changes to or update documents, complete this step before you log in to GEMS.

Step 2. Locate your application

When you log in to GEMS, your home page lists your top 5 projects. If you can see the project here, open it by clicking on the project identifier.



If the project is not listed in your top 5 projects, use



Projects icon shown here to view all projects.

Click on the purple hyperlinked title to be taken to the Project Details home page.

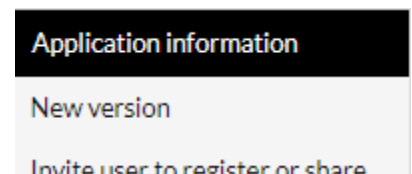
The project title will appear at the top of the screen and you will see all the applications (HRE and SSA) associated with the project.

Find the application with the 'Ineligible' status.

Step 3. Create a new version of the application

Click on 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. Unless instructed, **do not** change the version indicated.

A second message will appear. **DO NOT** change the Application title unless you have been instructed.

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 now be 'In Progress', making the form editable.

Click on the application identifier to open the form and make any changes required to the application form.

Step 5. Update, add or remove documents

Navigate to the documents section on the left-hand side menu of the

form (For the HREA: **Upload** and for the SSA: **Part F Attachments – Sites Specific Documents**)

For information on documents and descriptors, see the [File Naming Conventions user guide](#).

5A. 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.

Description of attachment: 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, 1 20 August 2020.

Document version: As listed on document

Document date: As listed on document

Select document and click 'Clear content selection'

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

Upload as a new version * ⓘ

Yes No

Click on the document to be uploaded and click the 'open' button.

5B. To Add a New Document

Click on the 'add row' at the bottom left of the document table. A new document row will appear.

Ensure that the description of attachment is clear and descriptive.

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, 1 20 August 2020.

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

Document Type: Select from dropdown menu.

Description of attachment: Enter a clear and descriptive document descriptor.

Document version: As listed on document

Document date: As listed on document

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

5C. 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 [5A. To Update a Document](#).

Select the document to be removed by ticking the Red **x** next to 'Document Title'

Step 6 Resubmit the application

Once you have completed all the changes to the application form and the documents, resubmit the

application by selecting the last menu item on the left-hand side menu.

Click on the following options as appropriate:

- ❖ HREA: Generate HREA Document
- ❖ SSA: Part G Declaration

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 GEMS that an SSA is ready for their decision. You will receive an email from GEMS when all HOD's have made their decision.

What next?

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