

QUICK REFERENCE GUIDE

* **RÉGIS** Ineligible notificationresubmitting application

FOR RESEARCH APPLICANT

Submitting a new version of an application after an ineligible notification

How does it work in REGIS?

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



System Withdrawal after 60 days.

Applications will be automatically withdrawn 60 days after being made

ineligible if a new version is not submitted to the Research Office.

New applications will need to be created and submitted after this time.

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 local guidelines and ones provided by NSW Health or ACT Health

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 details home page • Ineligible

Resubmitting an Ineligible, the ETH/HREA for STE/SSA go to page 3

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.

Step 2. Locate your application

When you log in to REGIS, 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 either of the Projects icons shown here to view all projects.



Find the application with the 'Ineligible' status.

The project title will appear at the top of

🖵 Top 5 projects

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the screen and you will see ETH application associated with the project.

Step 3. Create a new version of the application

Click anywhere on the application row to expand it for the menu option to appear, select New version.

IDENTIFIER 1 T TI
2021/ETH00636 Th
Application information
New version
Invite user to register or share application
Invite user to register or share application View submitted application

Do not change the version. Click 'New version'.

	×
Where would you like to continue from? Version	
1.00 - Initial Application (Ineligible)	۳

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

Add a note to describe why you are submitting a new version, e.g. Resubmission after ineligible notification. Click 'New version'.

² New application version	×
You are about to create a new version of the selected application. If you to continue, click the 'new version' button below. If you would like to re application, please provide the new name below.	i would like name the
Application title	
The New REGIS	
Application comments	

<Back Cancel

Step 4. Update the form

Click on the hyperlinked (In Progress) application identifier to open the form and make any changes required to the application form.

Step 5. Making changes to the project team

5A. Changing the CPI

To change the CPI to another person already listed on the HREA. Navigate to Project Team Details. Project Team Details

Q1.9.10 change the roles for each team member required. Update Q1.9.12 to reflect updated roles.

To add a new person and change them

<u>to CPI navigate to Project</u> <u>Team.</u>

Select Add another and complete Q1.9.1-Q1.9.3

Principal Investigator



Project Team

A new section will be created in Project Team Details.

Q1.9.4 = MUST be the new CPIs REGIS username/email Q1.9.10 = MUCT be Coordinating

Change the role of the previously listed CPI to an appropriate role.

Step 6. Update, add or remove documents

Navigate to the Upload section on the left-hand side menu.

6A. To Update a Document

Q4.1 Protocol: To update the Protocol with a new version click on the **x** to remove the old document

Q4.1 Attach the <u>Project Description/Protocol</u> to your H • It is recommended that you use one of the templates p • Individual attachments are limited to 10 MB in size.

File Name

× Protocol_v 1.doc>

Then drag and drop or browse your local files for the new protocol.

× Protocol_v2 dated 12 Jan 22.docx

Q4.2 Other Documents: To update study wide (master) documents with a new version click on the **x** to remove the old document.

C	4.2.1 Upload attachment *		
	File Name	Size	
	X Mater PIC v1 100122.docx	18.24 kB	

Then drag and drop or browse your local files for the new document.

Q4.2.1 Upload attachment *	
File Name	Size
X Mater PIC v2 120122.docx	18.24 kB

Then update the description of the attachment including the version and date

Q4.2.2 Description of attachment *

Master PICF version 2 dated 12 January 2022

Note: The document Type and Description is what the Research Office will see and how the document will appear on the approval notification.

Document Type *

Q4.2.2 Description of attachment *
Master PICF version 2 dated 12 January 2022

6B. To Add a New Document

To add a new study wide document

Document Type: Select from dropdown

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Upload attachment: Drag and drop or browse your local files for the new document.

6C. To remove a document

Use the red bin icon to remove a document and the entire document row, ONLY if the document is not required. To update an existing document, follow the steps in **6A**.

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 Generate HREA Document Generate HREA document

The status of the application will now be 'Submitted' and the Research Office has your application.

Resubmitting the STE 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.

Step 2. Locate your application

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

🖵 Top 5 project

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If not listed in your top 5 projects, use either of the Projects icons shown here to view all projects.





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Find the application with the 'Ineligible' status.

Ineligible

The project title will appear at the top of the screen and you will see all STEs associated with the project.

Step 3. Create a new version of the application

Click anywhere on the application row to expand the row for the menu option to appear, select New version.



Do not change the version. Click 'New version'.

Where would you like to continue from?	
Version	
1.00 - Initial Application (Ineligible)	*

Cancel New version

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

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

Click 'New version'.

C New application version			
You are about to create a new version of the selected application. If you would like to continue, click the 'new version' button below. If you would like to rename the application, please provide the new name below.			
Application title			
The New REGIS			
The New REGIS			
The New REGIS Application comments			

The status of the application will now be 'In Progress', making the form editable.



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

Step 5. Making changes to the project team

5A. Changing the PI

B2 enter the new PIs email address this will need to be their REGIS username.

B8 select Add another and enter the details of the previously listed PI if required.

Step 6. Adding a Head of Department

Navigate to Part C: Departments and Services.

Leave any HODs already listed in the form and select

Add Another

Add Another

C1 Select the department from the dropdown menu or start typing the department name to filter the list.

C1. Department *

me	
HNE - Mental Health Services	
HNE - Greater Metropolitan Health Services	

C4 clearly state what type of support you are requesting from the HOD.

Step 7. Update, add or remove documents

Navigate to the Part F Attachments -Sites Specific Documents

6A. To Update a Document

To update site documents with a new version, click on the x to remove the old document.

File Name	Size
SS PISCF version <u>1.docx</u>	11.26 kB

Then drag and drop or browse your local

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files for the updated document.



Then update the description of the attachment including the version and date

Document Descriptor*

Site PICF version 2 dated 13 January 2022

Note: The document Type and Description is what the Research Office will see and how the document will appear on the approval notification.

Document Type Participant Information Sheet Document Descriptor Site PICF version 2 dated 13 January 2022

6B. To Add a New Document

To add a new site document

Document Type: Select from dropdown

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Upload attachment: Drag and drop or browse your local files for the new document.

7C. To remove a document

Use the red bin icon to remove a document and the entire document row, ONLY if the document is not required. To update an existing document, follow the steps in 7A.

Step 8 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 using the left-hand menu. Click on Part G Declaration

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

It is the applicant's responsibility to communicate with any HODs regarding their study.

If no new HODs added the application will be in a status of Submitted and the research office has received your application.

What next?

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



