

Ethics Amendment - Completing & Submitting

Amendments in REGIS

The following Amendment types require application via REGIS.

General Amendment affecting the conduct, design or methodology of a trial and includes changes to:

- information previously given in the HREA
- protocol
- information sheet(s) and consent form/s for participants or to any other supporting documentation for the study.

Request for an extension of HREC

Approval to extend the project beyond the original period granted by the HREC

Note: For requests of over 12 months you should contact the Research Office first, a full re-submission may be required.

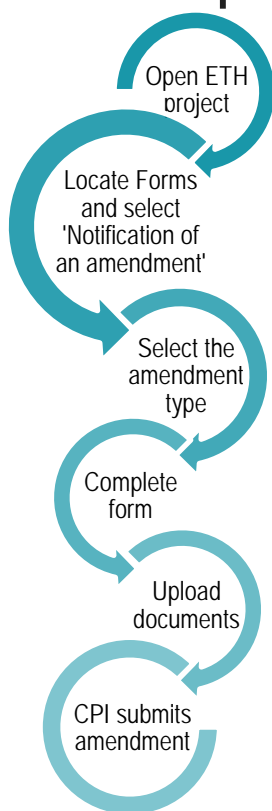
Addition of a Site update the study details of the additional site(s) and investigator(s). NSW sites will have a site application form generated in REGIS.

Change to CPI/PI notify the HREC of changes to the Coordinating Principal Investigator and/or site Principal Investigator(s).

How does it work in REGIS?

The CPI has full access to complete the amendment form and is the only person who can submit. The CPI can give edit and view permissions to others. Editors can complete the application form but cannot submit.

The amendment form can be saved at any time and completed later. A saved amendment is live for 365 days.




Form Status

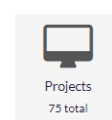
- **In Progress** Form is with the applicant for completion or editing.
- **Submitted** Form is with the research office.
- **Information Required** Form has been reviewed and further information is required before a decision can be made.
- **Information Provided** Form has been resubmitted with requested information.
- **Approved** Form has been reviewed and approved. An email notification will be sent to the CPI and Admin Contacts.

Complete & submit the Amendment

Step 1. Locate ETH project


If the project is not visible in the "Top 5 projects" section select  Projects to see all.

Click the required Project identifier (PID)



Step 2. Select the Ethics Project

Only an approved study can have an amendment created.

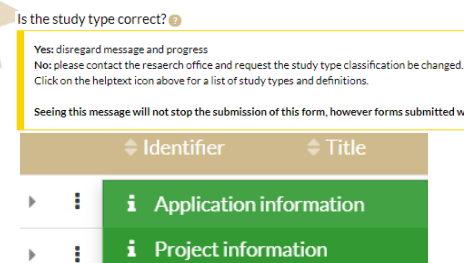
Click on the three dots  next to the identifier and then select 'Project information'

Step 3. Open Amendment Form

Select 'Forms' then '+New Form'.

Step 4. Complete the amendment form

A warning will appear 'Is this study type correct?', ensure it is correct before



proceeding. If it is incorrect you will need to contact the Research Office.

Respond to the mandatory COVID-19 question/s ([see COVID-19 Data Collection – Applicant Guidance](#))

Select the type of amendment and provide a response to all questions.

Clinical trial studies will have clinical trial specific questions.

Note: 'PI (All Other)' are no longer required to have a REGIS account. NSW and ACT PIs still require REGIS accounts.

Document Upload If there are **no documents required** click the document checkbox and select the Delete icon



Uploading a New Document A new document is a document that does not yet physically exist in REGIS.

Note: Unsure if the document already exists in REGIS? Select 'Yes', if it does not appear in the Document Title/Descriptor drop down change the response to 'No' and follow the below instructions.

Uploading a new document select 'No'



Document Title/Descriptor: Provide a clear and descriptive document description.

Document Filename: Will prefill
Document Type: Select from the dropdown

Version and Date: Version and date of the document (normally listed in footer).

This information will give the file a REGIS title.

Note: How you name your document in the 'Document Title/Descriptor' section is what the Research Office will see and how it will be listed on the approval notification. See below example;

Document descriptor - your name for the file *

Master R3447-001 Arm 1

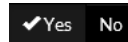
Click 'Upload New', 'Choose File' and then 'Start upload'

To add further new documents, select the '+' icon to add rows.



Uploading a New Version of a Document A new version of an approved document is used when the document is already physically located in REGIS.

If you are uploading an **updated version of an approved** select yes.



You will select the title of the document you are updating:

Document Title/Descriptor: Select the form from the dropdown options.

Document Filename: This will preload.

Document Type: Will preload.

Document Version and Date: Provide the new version and date of the document (normally listed in footer).

Click 'Upload New', 'Choose File' and then 'Start upload'

The Document Filename will appear next to the title/descriptor.

Step 6. Declaration

CPI must submit the amendment. If you are not the CPI the save the form and notify the CPI that it is now ready to submit.

*Note: For the submission of a **General Amendment**, the yellow warning message below will appear asking that the form ID be noted as this will be needed in the **Site General Amendment**.*

General Amendment: Once this form is submitted you will be taken back to the forms page. Please note down the form ID as this will be needed in the site general amendment form.

Once submitted the status of the form will be 'Submitted'. Each amendment form is given a unique identifier number

Title	Status
014884 - Notification of an amend...	Submitted

Click the three dots next to the title and select 'Download attachments' to download a copy of the amendment form and any attached documents.

What Next?

The amendment will be received by the Research Office managing the Ethics application.

Once reviewed you will receive either an approval notification or a request for further information (see **Ethics**)

Amendment – Responding to an Information Request).

Upon approval, the amendments indicated in the following section will be automatically shared with the related Sites in REGIS. This will reduce duplicate submissions.

What is automatically shared with the RGO in REGIS?

When Ethics is in REGIS, the following approved amendments will be **automatically shared** with the Research Governance Office:

- ❖ Change to CPI
- ❖ Change to PI
- ❖ Request for an Extension of HREC

What needs to be submitted to the RGO in REGIS?

The following Site Amendments need to be submitted via REGIS;

- ❖ General Amendment

The following Site Amendments are submitted directly to the RGO and do not need Ethics approval.

- ❖ Changing Site Investigators and Administration Contact
- ❖ Contract Changes

For more information related to Site Amendments see – **Site Amendment – Completing and Submitting QRG.**