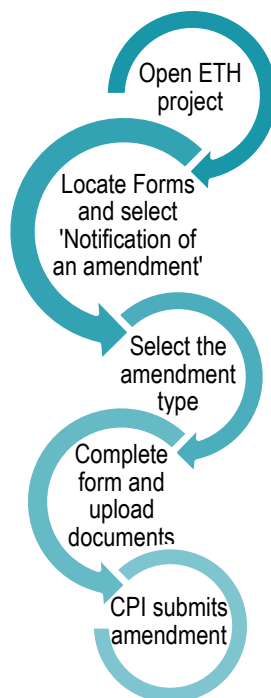


Ethics Amendment - Completing & Submitting

Amendments in REGIS

The following Amendment types can be submitted via REGIS.

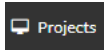
- ❖ **General Amendment** affecting the conduct, design or methodology of a trial and includes changes to:
 - information previously given in the HREA
 - protocol
 - information sheet(s) and consent form/s for participants or to any other supporting documentation for the study.
- ❖ **Request for an extension of HREC Approval** to extend the project beyond the original period granted by the HREC *For requests of over 12 months you should contact the Research Office first (NSW, ACT), 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).



- **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 Project at the top of the page to see all.

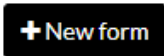
Click the Project identifier (PID).


Step 2. Select the Ethics Project

Click on the ETH identifier and then select 'Forms'.

Applications Details **Forms** Milestones

Step 3. Open Amendment Form

Select '+New Form' and then 'Notification of an amendment to a research study' 


Select the form you wish to fill out:
Notification of an amendment to a research study

Step 4. Complete the amendment form

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

Step 5. Document Upload

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.

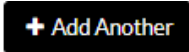
How does it work in REGIS?

This form supports multiple amendment types within a "Type" e.g. multiple General amendments OR multiple Site additions but does not allow for multiple amendment types i.e. if you wish to submit a General amendment AND an Addition of site, two amendment forms will need to be submitted.

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.

Select +Add Another for a row to appear

 + Add Another

Uploading a new document select 'No'

Upload as a new version *

Yes No

Document Title/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.

Document Type: Select from the dropdown

This information will give the file a REGIS title.

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

Document title/Descriptor * Document Type *

e.g. Participant Information Sheet Master PICF version 2 dated 12 January 2022

File Name	Size
 Mater PIC.v2.120122.docx	18.24 kB

Uploading 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.

Upload as a new version *

Yes No

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

New Document Title: 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.

New Document Title *

Master PICF Version 3 dated 12 January 2022

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

Upload file *

 Drop files to attach, or [browse](#)

Step 6. Declaration

The CPI must submit the amendment. If you are not the CPI, save the form and notify the CPI it is ready for submission.


An information box will appear before the submit button to describe the next steps. This is different for each amendment type

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.

*Note: If submitting a **General Amendment**, the ethics amendment form ID will be needed to complete 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

 Download Attachments

What is automatically shared with the RGO in REGIS?

When Ethics is managed by a NSW/ACT HREC, the following Ethics approved amendments will be **automatically shared** with the NSW Research Governance Offices:

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

What needs to be submitted to the RGO in REGIS?

- ❖ Site General Amendment

All Ethics approved documents will be automatically shared with the RGO and should not be uploaded in the site amendment form.

The following Site Amendments **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**.

What Next?

The amendment has been 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**).