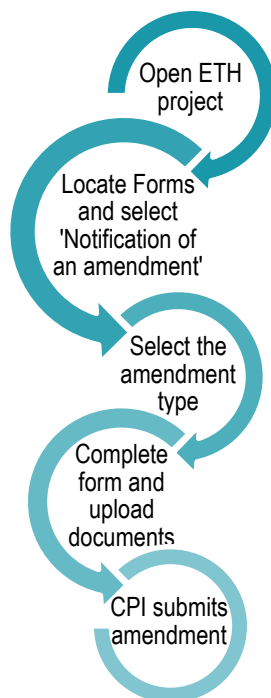# Ethics Amendment - Completing & Submitting

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:
  - Study Protocol
  - Information previously given in the HREA
  - 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 New Site** to 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/Administration** notify the HREC of changes to the Coordinating Principal Investigator, site Principal Investigator(s) or add/remove Administration contacts. Admin contacts can also be given 'Submit' access.

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 must be submitted.

Open ETH project

Locate Forms and select 'Notification of an amendment'

Select the amendment type

Complete form and upload documents

CPI submits amendment

The CPI has full access to complete the amendment form. The CPI can also share the form with others.

Share with View Access: User can only view the application and/or forms, but not make changes.

Share with Edit Access: User can view the application and/or forms and make changes.

Share with Edit & Submit Access: User can view the application and/or forms, make changes, and submit on behalf of the CPI.

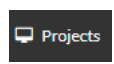The amendment form can be saved at any time and completed later. A saved amendment is stored for 365 days.

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.

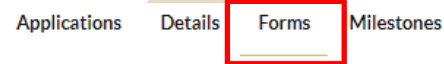## Complete & submit the Amendment

Step 1. Locate ETH project
If the project is not visible in the "Top 5 projects" section, click on 'Projects' at the top of the page.
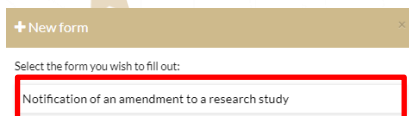
Click the Project identifier (PID).

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'

+ New form

Select the form you wish to fill out:

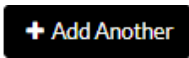Notification of an amendment to a research study

Step 4. Complete the amendment form
Select the type of amendment and provide a response to all questions.

Step 5. Document Upload
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 * ❓
Master PICF version 2 dated 12 January 2022	Participant Infor...✕ ▾

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

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

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 document,* 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

Document Filename: This will preload. Then drag and drop or browse your local files for the new document.

Upload file *

☁ Drop files to attach, or bro...

Step 6. Declaration
The CPI or their delegate(s) can now submit the amendment. If you do not have access to submit, save the form, and notify the CPI or delegate it is ready for submission.
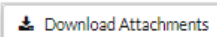
An information box will appear before the submit button to describe the next steps.

> **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

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?
If the CPI is not the user submitting the change of Administration contact (indicating submit access), an automatic email will be sent to the CPI to approve.

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*).

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
- ❖ Site General Amendment

What needs to be submitted to the RGO in REGIS?
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**.