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:

a) information previously given in the HREA
b) protocol
c) 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: If you are requesting more than a 12 month extension you should contact the Research Office first, a full re-submission may be required.
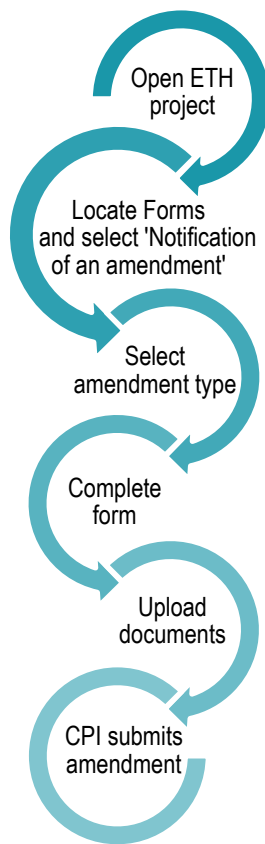
Addition of a Site update the study details of the additional site(s) and investigator(s). NSW sites will have a site application form generated in REGIS.

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 is able to 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 at a later date.

Open ETH project
↓
Locate Forms and select 'Notification of an amendment'
↓
Select amendment type
↓
Complete form
↓
Upload documents
↓
CPI submits amendment

Once saved, the 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.

● **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 project

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

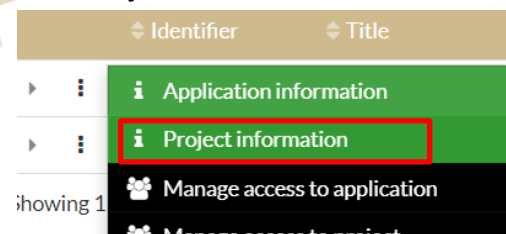🖳 **Projects**
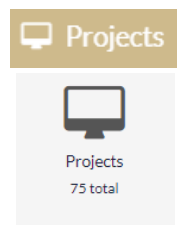
Projects
75 total

Search using the project title to filter down the options.

Click the required Project identifier (PID)

Step 2. Select the Ethics Project

The Ethics Project is where users manage post approval activity. (e.g. amendment, safety and annual reporting). Only an approved study can have an amendment created.

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

⇕ Identifier	⇕ Title
▶ ⋮	ℹ Application information
▶ ⋮	ℹ Project information
Showing 1	👥 Manage access to application
	👥 Manage access to project

Both of these options will take you to the Project Information page

Step 3. Open Amendment Form

Select 'Forms' from the menu on the left

📇 Forms

Select '+ New form'

✚ New form

Select '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 (from the drop-down list on page 1), and provide a response to all questions.

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

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

Note: If you are unsure if the document already exists in REGIS select "Yes" and if the document 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: Follow this format: <short description of doc type>-<brief unique descriptor>
(**PISCF-Intervention, IB-DrugName**) **20 characters max.**
Document Filename: will prefill
Document Type: select from the dropdown
Version and Date: these are the version and date of the document (normally listed in footer).

This information will give the file a REGIS title

Note: Current functionality of the system requires electronic file names to remain the same throughout the life of the study. Don't add version or dates to the electronic file name.

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

To add more new documents select the 'Add Row' icon

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: this will preload.
Document Version and Date: *new* version and date of the document (normally listed in footer).

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

Note: Current functionality of the system requires the electronic filename to match the original.

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

Step 6. Declaration

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

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

♦ Title	♦ Status
014884 - Notification of an amend…	● Submitted

To download a copy of the amendment form and any attached documents click options (3 vertical dots) and then 'Download Attachements'.

⋮ **⬇ Download Attachments**

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).

For technical assistance, contact REGIS HELP DESK

support@f1solutions.com.au
1300 073 447