

Ethics Amendment - Completing & Submitting

What is an Amendment

Amendments are changes, or modifications to a research study.

HREC approval is required before the project team may introduce any amendment to a previously approved research project which are likely to affect to a significant degree:

- The rights, safety and welfare of the participants of the research;
- The scientific value of the research;
- The conduct or management of the research;
- The monitoring requirements, or;
- The quality or safety of any investigational medicinal product/device used in the research.

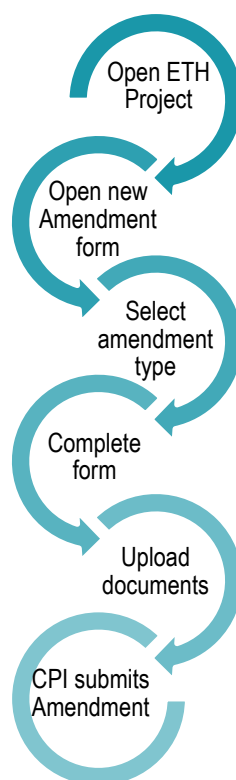
The following Amendment types require application via REGIS

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

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

Note: If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be provided.

Request for an extension of HREC Approval to extend the project beyond the original period granted by the HREC



Addition of a New Site update the study details of the additional site(s) and investigator(s) so that any SSA for new NSW/ACT sites can be generated and the new site investigators are notified

Change to CPI/PI notify the HREC of changes to the Coordinating Principal Investigator and/or site Principal Investigator(s). The relevant site research offices will similarly need to be notified.

How does it work in REGIS?

The steps to submit an Amendment in REGIS are shown in the diagram at left.

The Project Owner (CPI) has full access to complete and is the only person who can submit the amendment form. The CPI is able to give edit and view permissions to others.

Any person who had been granted Edit permissions during the application process (pre-approval) will continue to have access to the project (post approval). Editors can complete the application form but cannot submit.

The amendment form can be saved using the 'save' icon at any time and completed at a later date. Once saved, the Amendment will stay 'In Progress' for up to 365 days.



Form Status

- In Progress
- Submitted
- Approved

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.

Complete & submit the Amendment

Step 1. Locate project

Click the 'Projects' icon to see all projects.



Click the required Project 'Identifier' (PID) or 'Title' in the list of projects

Step 2. Select the Ethics Project

This is where you are able to manage post approval activity. (e.g. amendment and safety). Only an approved study can

have an amendment created

Click on the Ethics (ETH) identifier

Identifier

2018/ETH00061

Or click on the

(option icon) next to the Identifier and then select. **Project information**

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

Step 3. Open Amendment Form

Select 'Form' from the left-hand menu. **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 (described on page 1), and provide a response to all questions.

Document Upload

"**updated version of an approved document**" is available only when the document is already physically located in REGIS.

e.g. Studies that have been migrated from a legacy system will have HREC approved documents but they will not yet be available to **update** in REGIS. User should select "No" the first time a document is being entered into REGIS. If you are unsure if the document exists in REGIS select "yes" if the document does not appear in the Document Title/Descriptor drop down change the response to "no" and follow the prompts.

No New or Updated Documents

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



Uploading a new Documents

If uploading a **new document** select No

Yes No

Document Title/Descriptor: Should be in the following 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).

Click and the upload wizard will appear.

Upload New

Choose the file and then 'Start upload'

Select Attachment file

Choose File KCTP_Protocol_REGIS.docx

Start upload Close

To add more documents select 'Add row'



Uploading updated Documents

If you are uploading an **updated version of an approved** select **Yes**

Yes No

Document Title/Descriptor: select the form you are updating 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).

Upload New

Click the upload wizard will appear, choose the file and then 'Start upload'

Select Attachment file

Choose File KCTP_Protocol_REGIS.docx

Start upload Close

Note: The Filename **MUST** match the original to allow the system to successfully manage document versioning.

This is correct if the details at Document Filename and the details in the brackets at the end of the page are the same.

Upload file *

Warning: filename must match original file name

Document Filename *

KCTP_Protocol_REGIS.docx

Clear content selection (KCTP_Protocol_REGIS.docx)

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, you will be taken back to the forms section of the ethics project.

Status

Submitted

Title

002181 -

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

Download Attachments

What Next?

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

For technical assistance, contact REGIS HELP DESK

support@f1solutions.com.au
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