

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

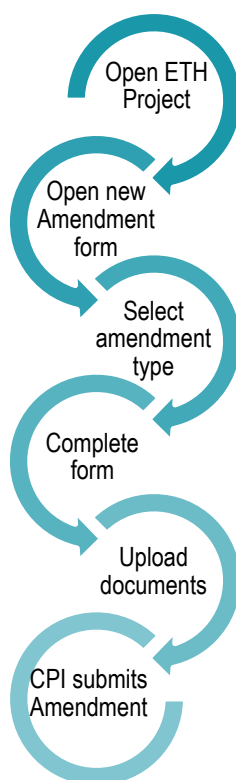
General Amendment affecting the conduct, the design, or the methodology of a trial and includes changes to:

- 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 an SSA for each new site 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 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

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

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



If uploading **a new document** select No

Yes No

Document Title/Descriptor: used to give a brief description of the document when multiple types of the same document are being submitted. E.g. drug name for Investigators Brochure, Carer/Genetic for PISCF, Mini Mental for Questionnaire. **20 characters max.**

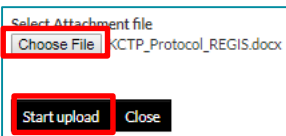
Document Filename: select from the dropdown.

Document 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'



To add more documents select 'Add row'



If you are uploading an **updated version of an approved** select **Yes** No

Yes No

Document Title/Descriptor: select the form you are updating from the dropdown options.

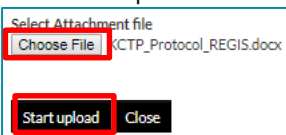
Document Filename: this will preload.

Document Type: this will preload.

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

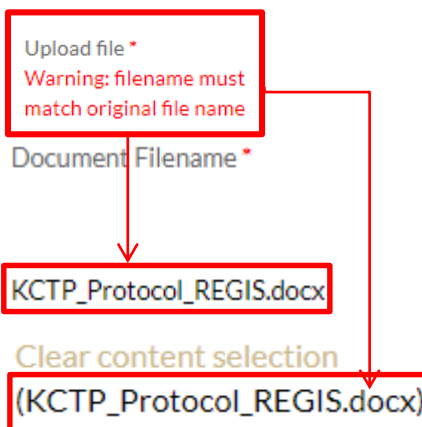
Upload New

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



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.



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

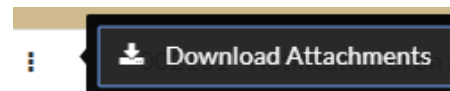
The status of the form will be 'Submitted'

Title

002181 -

Each amendment form is given a unique id number

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



What Next?

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

Once the amendment request has been reviewed you will receive notification via a system generated email. The amendment will either be approved, not approved or there will be a request for further information.

For technical assistance, contact
REGIS HELP DESK

support@f1solutions.com.au

1300 073 447