

Completing and submitting an Ethics Amendment on REGIS

Amendments are changes or modifications to a research study. Amendments are a **post-approval** process.

What types of amendments go through REGIS?

Currently only **three** types of amendments are accepted through REGIS:

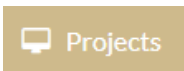
1. Change in Coordinating Principal Investigator and/or Principal Investigator
 2. Adding a new site
 3. Extension of time
- **Please note:** All other general amendments can be emailed to the Research Ethics office with an [Amendment Application Form](#) and supporting documentation to SCHN-Ethics@health.nsw.gov.au.

Who can complete the Amendment Form in REGIS?

The Coordinating Principal Investigator or any user that has been granted **edit access** throughout the application process. Only the **Coordinating Principal Investigator (CPI)** can generate and submit the amendment form.

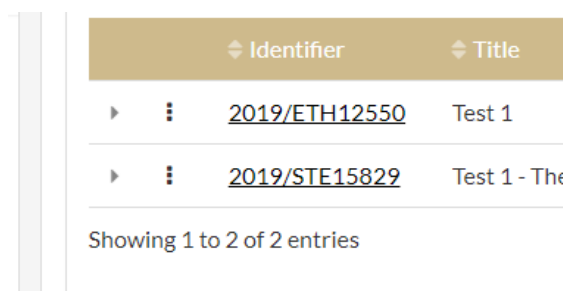
Completing an Amendment

1. Log in to REGIS, click on the 'Projects' icon on the top right-hand menu bar




2. Click on the Project Number (**2019/PIDXXXXX**)

3. This will then show your Ethics application (**ETH**) and your site application (**STE**)

A screenshot of a web interface showing a list of projects. The table has two columns: "Identifier" and "Title". There are two rows of data. The first row has the identifier "2019/ETH12550" and the title "Test 1". The second row has the identifier "2019/STE15829" and the title "Test 1 - The". Below the table, it says "Showing 1 to 2 of 2 entries".

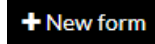
Identifier	Title
2019/ETH12550	Test 1
2019/STE15829	Test 1 - The

Showing 1 to 2 of 2 entries


4. Click on the Ethics (ETH) application identifier which will take you to the Project Information page. Or click on the  (option icon) next to the Ethics identifier and then select



5. Select 'Form' from the left hand menu and click on '+ New form'






6. Select 'Notification of an amendment to a research study'



Select the form you wish to fill out:

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

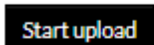

8. If there are **no documents required** for the amendment, click the document checkbox and select the delete icon  + 

9. If you are uploading a **new document**, select No  (as you are not uploading an 'updated version of an approved document')

10. Click 'Upload New', choose your file and then 'Start Upload'

Select Attachment file

KCTP_Protocol_REGIS.docx

11. To add more documents select 'Add row'



12. Once you have added all of your documents, **the 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

13. Once submitted, you will be taken back to the forms section of your ethics project and the status should have changed to 'submitted'. Each amendment form will be given a unique id number

Status	Title
● Submitted	002181 -

What's next?

The Research Ethics office will review your application at the next meeting and you will subsequently receive feedback. Please contact the Research Ethics if you have any queries on SCHN-Ethics@health.nsw.gov.au or (02) 9845 1253