



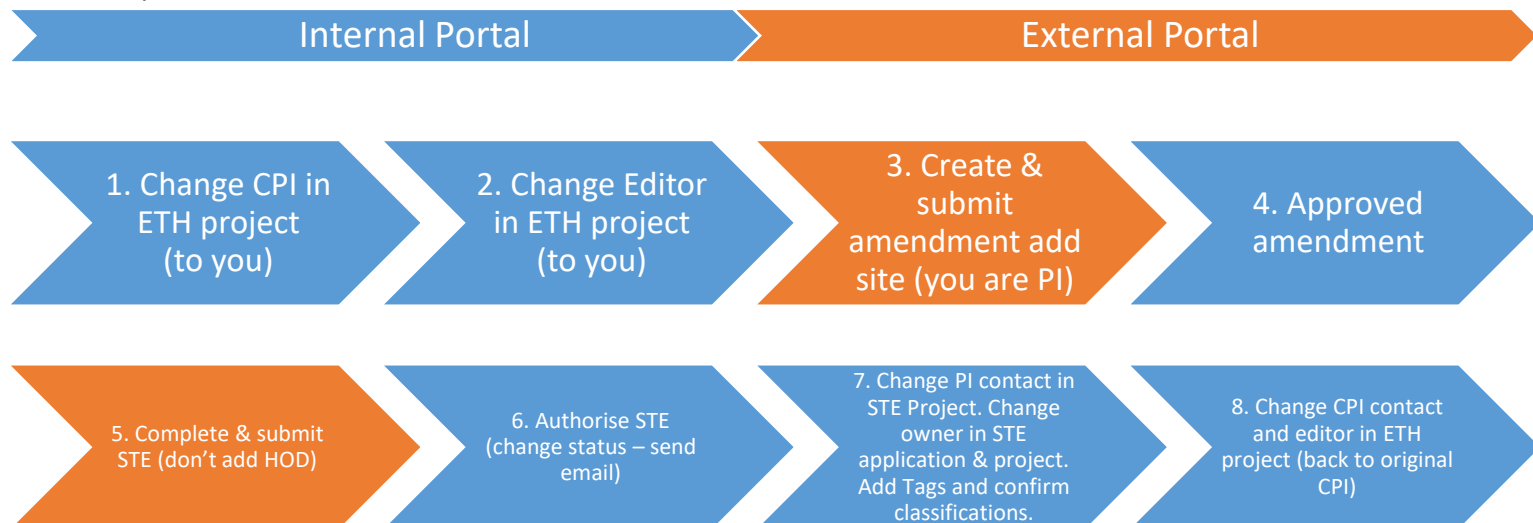
Guidance for Research Office: Manual SSA/STE creation and authorisation

This manual SSA/STE creation document has been provided to allow any site applications that were missed during the data migration process, which ceased in December 2019. This process allows a Research Office to manually create a site application/project.

This user guide is intended for Research Offices to create pre-approved Site-Specific Applications manually for a specific project in REGIS where a ETH already exists. A series of steps are involved to create a Site Application manually through the both internal and external portal.

This manual data entry process should only be used up to July 2020 after this time researchers will be expected to follow the current “addition of site” functionality.

The overall process involved is described below.



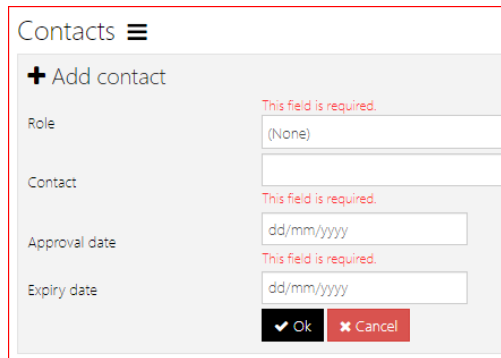
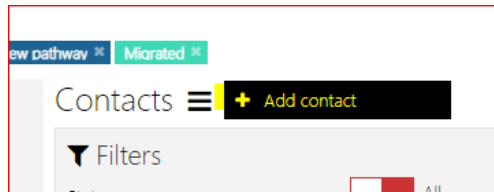
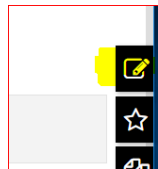
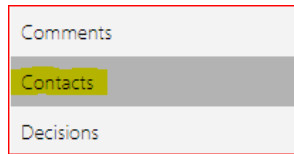
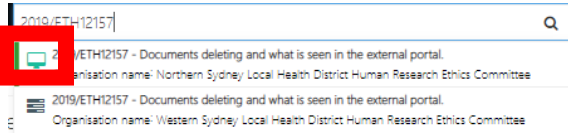
Pre-requisites: It is assumed that the person making these changes is a member of a research office and lead HREC of the study. The person making these changes need to have the specific permission (REGAdmin) to access the internal and external portal and to make the changes described.

If you do not have access to the Ethic application/project (not the lead HREC), please get in touch with REGIS team, and permission will be assigned to your account for 48 hours.

Internal Portal
Step 1:

Assign role of CPI in the Ethics Project

Locate the **ETH Project** that requires a site to be added to it



Click on Management from the left menu

Click on Contacts from the extended menu

Click on Edit button from the right

Click on “hamburger” icon & then on Add contact

Complete the wizard adding yourself as the CPI

Role = Coordinating Principal Investigator.

Contact = Click the three buttons and search for your user account.

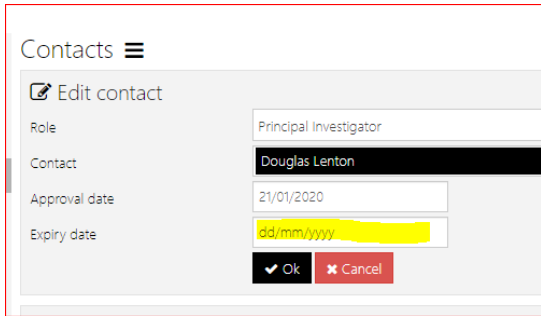
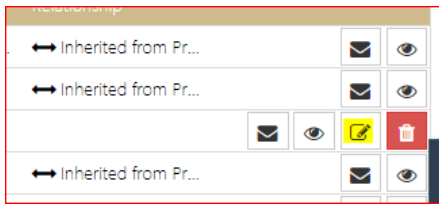
Approval date = Today.

Expiry date = blank.

Expire the existing Coordinating Principle Investigator

Locate the existing CPI (the person who has empty under the heading relationship)

Click on Edit item



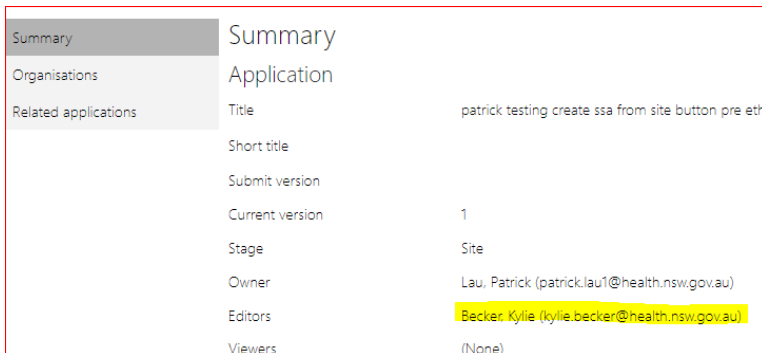
Set the expiry date to yesterday's and click **Ok** to commit the change

Click **Save** from the right panel menu

Internal Portal

Step 2:

Add yourself as the Editor to the ETH project



Click on Details from the left menu

Click on summary

Click on Edit from the right menu panel

Locate the Editor, click on "3" dots to add the person carrying out this change to have Editor access

Click **Save** to commit the change

External Portal
Step 3:

Proceed to external portal



The external portal can be access through your start menu

Locate the study.



Search:

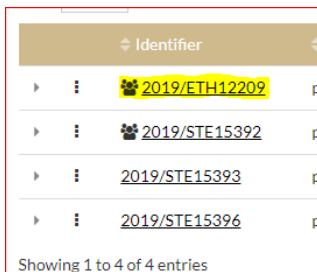
0 out of 0 filters applied

If you cannot identify the study through the PID's on the homepage click on the Project icon on the top menu bar

Filter studies by title using the search option

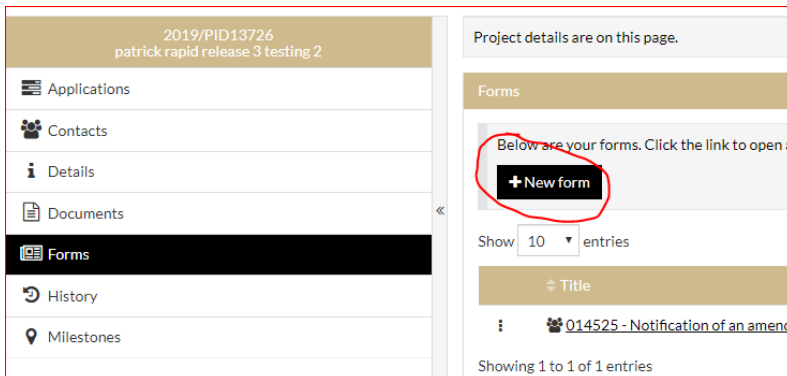
Select the study

Create and Submit Amendment "Addition of New Site"

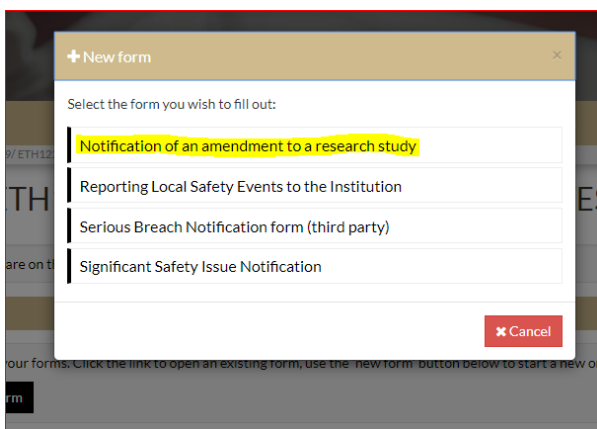


Select the Ethic Identifier to be taken to the Ethics Project

(the ethics project is where ethics post approval documents are managed)



Click on Forms from the left menu and then "+New form" button



Select Notification of an amendment to a research study

Project Details and Amendment Type

Select Addition of a New Site

Select Amendment Type*

The types of amendment that can be submitted to the HREC are:

- General amendment
- Request for extension of HREC approval
- Addition of a New Site
- Change to CPI/PI

Show Detailed Description of Amendment Types

Please select the amendment type from the drop-down list. Based c

Addition of a New Site

Addition of New Research Site/s

NSW Health



List all documents that a

Upload as a new \



Yes No



Select the NSW Health tab.

Project Centre = The LHD of the site you are adding

Project Site = The site

Site Investigator Detail

Principal Investigator email address = your email address/REGIS user account

Contact phone = 0000 000 000 or similar

Position = Principal Investigator

Employer = LHD/site

Describe the person's expertise at this site = PI

Is the new investigator an employee = yes

Is the new investigator a student = No

Are you adding a new site to a single centre study = No

You can add multiple sites to this form by selecting the add icon

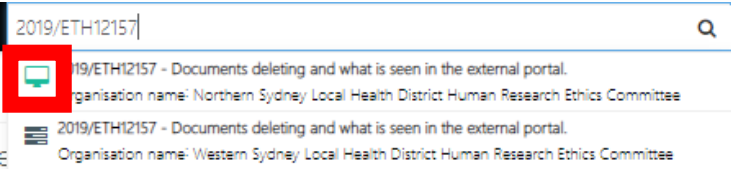

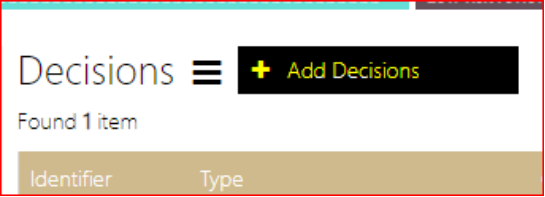
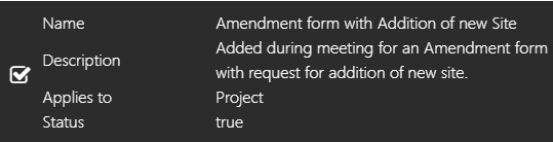
Conflict of interest = No

Document

Remove the document line by clicking on the checkbox and then the minus icon

Submit the form

		if you don't see the submit button the system does not recognise you as the CPI you should check step 1 and 2.
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Internal Portal Step 4:	Return to the internal portal and approve the amendment to add a new site NOTE: as this site is already an approved site – the amendment approval is an administrative step and does not required the review of the HREC or EO.	
	Locate the ETH Project 	ETH Project that requires the amendment to be approved.
	  	Click on Management and then Decisions from the left menu Click on Edit from the right menu panel Click on “hamburger” icon and then “+ Add Decisions” Complete the decision wizard Current due date = blank Type = click three dots to select amendment type “Amendment form with Addition of new Site”

Decisions ☰

+ Add New

Current due date

Type **Amendment form with Addition of new Site**

Entity **Project related form**

Project related form **014418 - Notification of an amendment to a research study**

User **Lau, Patrick**

B I U

data migration

Notes



User decisions

Found 1 item

Name **Becker, Kylie**

Decision **Approved**

Comments **data migration**

Save **Cancel**

Name **Becker, Kylie**

Decision

Reason

Assigned **28/01/2020 2:40:20 PM**

Submitted

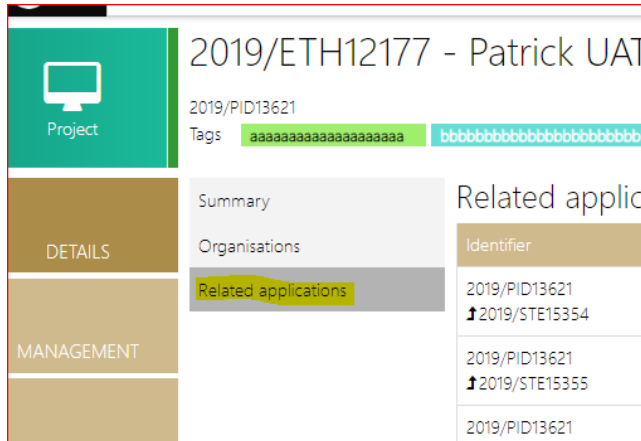
9480	Amendment form...	Approved	28/01/2020	Form - 014443 - ...				
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Entity = Project related form
 Project related form = select the last submitted form (the latest number)
 User = yourself.
 Notes = "manual data migration process"

Click Save at the bottom of this form to commit the change

View user decision.

Select the decision to finalise (click your name) then add decision "approved" comment "data migration" and click save to commit the decision



The email icon will appear on the decision line click the mail icon and send the email to finalise the step.

The email generated by the system will save under related document as well as send to the addressee. You should change the body of the email to describe this decision was created to allow the manual data migration to take place. This was completed by XX person on xx date.

An "In Progress" STE will now show under Details -> Related applications

You now need to complete and submit the STE forms.

External Portal
Step 5:


Proceed to external portal



The external portal can be access through your start menu

Locate the study.



Search: 

0 out of 0 filters applied

If you cannot identify the study through the PID's on the homepage click on the Project icon on the top menu bar

Filter studies by title using the search option

Select the study

Select the “In Progress” STE Form

2019/STE15356 Patrick UAT regression test 29072019 2 Submitted

Part A: Project-Wide Information

No changes should be made to this section.

Part B: Site Team

Complete any mandatory questions. Other than the PI email all data entered can be dummy e.g. xx.

B7: if you know who the admin (coordinator) for this study is you can add their details here otherwise select no.

B8: select the Check the box at the top, and click on “-“ icon at the bottom to remove the entry, so no team members are required.

If the study is a clinical trial you may be required to add an Associate investigator – select “Person not in REGIS” add dummy data.

Part C: Site Team

Do not select a HOD from Part C

Check the box at the top, and click on “-“ icon at the bottom to remove the entry, so

No HOD is notified for this SSA creation.

Part F: Attachments – Site Specific Documents

Do not add any documents at part F

Check the box at the top, and click on “-“ icon at the bottom to remove the entry, so no documents are required.

If this is a clinical trial you may be required to add in documents. Use a dummy word documents and follow the prompts to add document types.

Once the SSA form is complete, please proceed to Part G and submit SSA to RGO

Submitted SSA

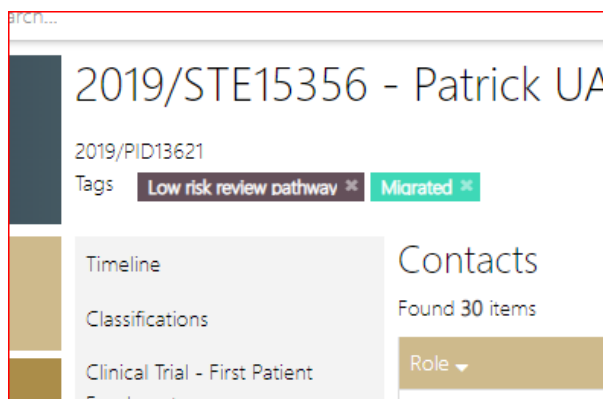
Internal Portal Step 6:

Return to the Internal Portal, Add tag/Classification and Authorise the site application

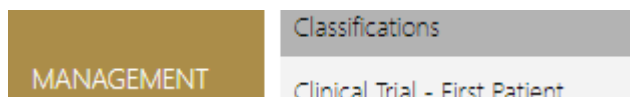
Locate the In progress/submitted STE

Tags and Classifications

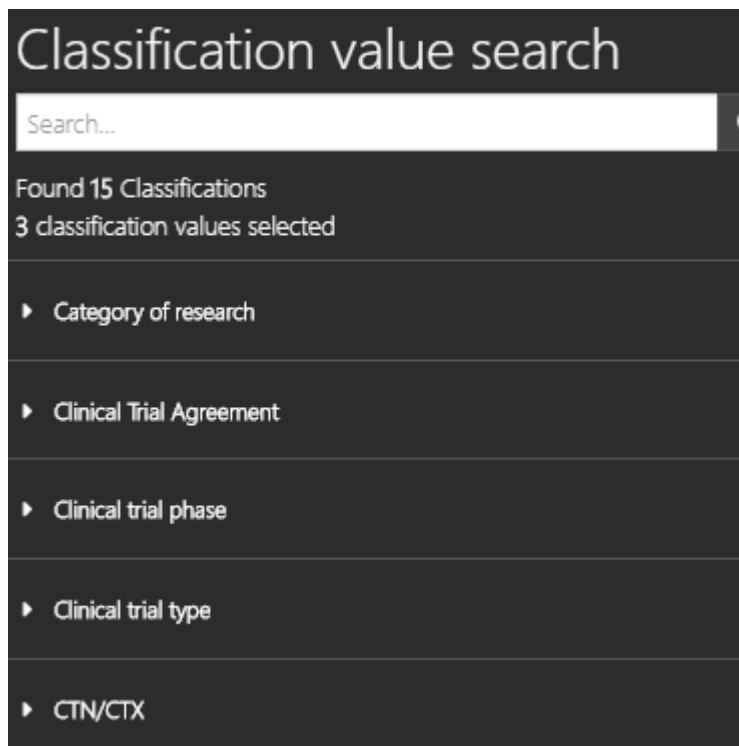
Add the "Migrated" tag to your SSA before authorisaion.



Add Ethics pathway classification and other required classifications.



Classifications  



Tags:

Add the tag migrated to the application.

The changes made now will flow to the STE project.

If not already you should select Edit on the far right menu.

Click anywhere at the end of the first Tag, type "Migrated" in the text field

Classifications:

Select Management and then classifications.

If not already select Edit.

Click on the hamburger and + Add classification

The classification window will pop out.

At a minimum the following classifications should be completed/confirmed.

Ethics Pathway (changing the classification will change the tag)

Study Type

If clinical trial

Clinical Trial Type

Sponsor Type

You can change/add multiple classifications before selecting ok and save.



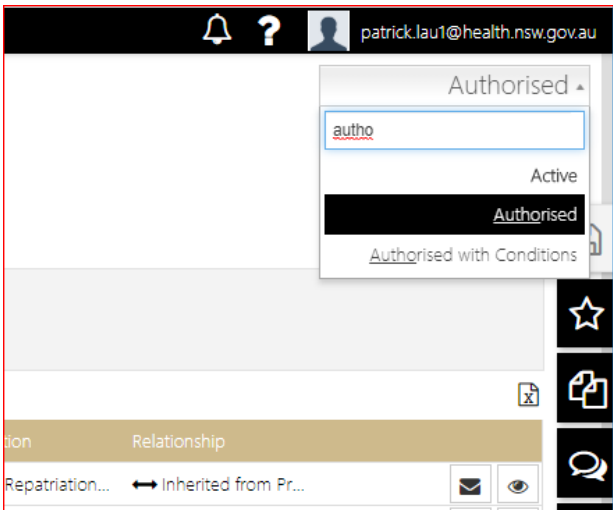
To remove any classifications select the delete icon next to the incorrect classification

Click Save to commit the change

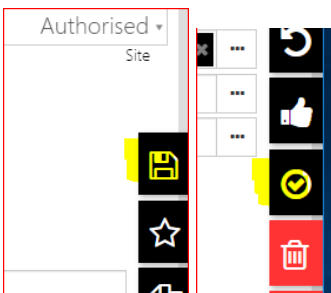
Authorise STE



Click on the Edit button from the right menu panel



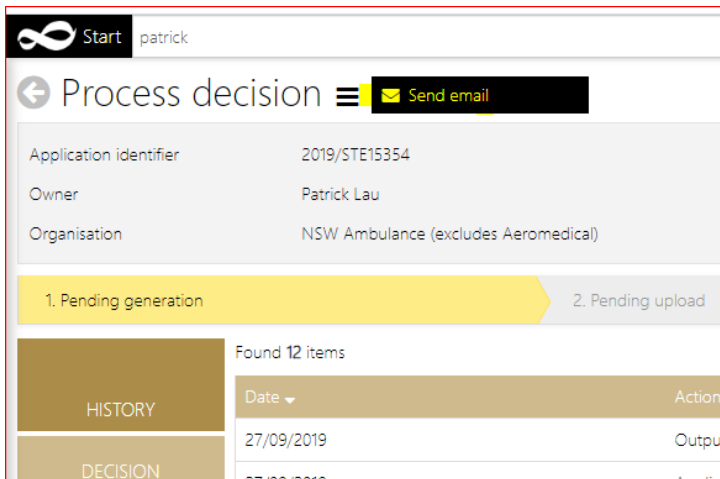
Change the status from the top right and search for Authorised



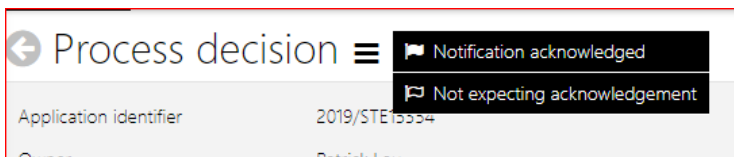
Click on Save and then on the “tick” icon to finalise authorisation.

Ensure email is addressed to yourself or RO email address.

Change body of email to describe the manual data entry process. E.g. authorisation email created as part of manual data migration process. Original approval conditions apply to this study.



Send Decision notification email



Click on **Not expecting acknowledgement**

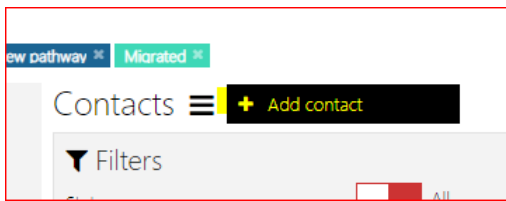
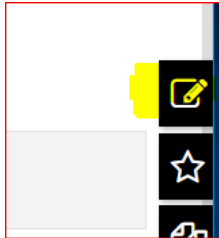
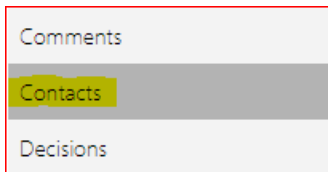
Internal Portal
Step 7:

Assign the correct Principle Investigator to the STE Project



Select the STE Project on the right hand menu.

Click on Management from the left menu



Contacts ≡

+ Add contact

Role This field is required.

Contact This field is required.

Approval date This field is required.

Expiry date This field is required.

Click on Contacts from the extended menu

Click on Edit from the right menu panel

Click on “hamburger” icon and + Add contact

Fill in the below detail to add the correct PI into the system

Role = Principal Investigator

Contact = select the user from the search option.

Approval date = todays dates

Expiry data = blank

Click **Ok** to commit the change.

Remove/Expire the existing Principal Investigator (you)

Contacts ≡

Filters

Status all

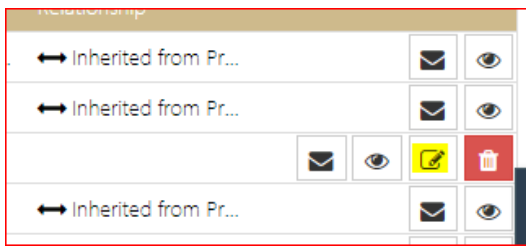
Found 25 items

Role	Contact	Phone	Email	Approval date	Expiry date	Fax	Org	Organisation	Relationship		
Principal Investigator	Iona Cunningham		iona.cunningham@h...	15/07/2019			Concord - Haematol...	Concord Reparat...	Inherited from Pr...		
Principal Investigator	Stephen FULLER		stephen.fuller@sydn...	05/12/2019			NH - Clinical School	Napean Hospital	Inherited from PI...		
Principal Investigator	Douglas Lenton		Douglas.Lenton@hea...	21/01/2020							
Principal Investigator	Pauline Warburton		pauline.warburton@h...	17/06/2019					Inherited from Pr...		
Principal Investigator	Dr Pauline Warburton		pauline.warburton@h...						Inherited from ap...		

Select the line where you are listed as Principal Investigator and the system allows an edit.

Hint: this is also the line where no relationship is listed.

Click on Edit item



Set the expiry date to yesterday (you may need to change the approval date to a date before the expiry date) and click **OK** to commit the change.

Click **Save** from the right menu panel

You will now have an expiry date and the correct PI should be added to the system.

Change the Owner of the STE Application and Project are the correct/real PI

Summary

Application

Title: New SSA

Short title:

System version: Submitted 1.00 - Initial Application

Stage: Site

Owner * **Becker, Kylie (kylie.becker@health.nsw.gov.au)**

Editors:

Viewers:

Principal organisation: Public Health

Select Details → Summary

Change the Owner to the correct PI and select save.



= Application



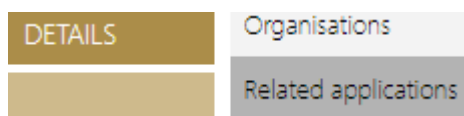
= Project

Do this in the STE application and STE project

Internal Portal Step 8:

Return the CPI role to the correct person.

Locate the **ETH Project** that requires the contact to be returned.



Program	Organisation	CPI/PI	Status	Relationship
Ethics	Justice Health & Forensic Mental He...	Patrick Lau	Approved	← Inherited from Project 2019/PID1...

Details → Related applications

Select the Project icon at the end of the Ethics application line.

Click on Management

Click on Contacts

MANAGEMENT

- Comments
- Contacts**
- Decisions



← Inherited from Pr...	✉	👁
← Inherited from Pr...	✉	👁
	✉	👁
← Inherited from Pr...	✉	👁

12/02/2020

12/02/2020

End date must be later than start date.

Contacts ☰

✍ Edit contact

Role: Coordinating Principal Investigator

Contact: Patrick Lau

Approval date: 29/07/2019

Expiry date: dd/mm/yyyy

OK Cancel

Remove Editor

Click on Edit from the right panel

Locate the current CPI (you), click Edit

Expire the CPI (you) you will need to change the approval date to date before the expiry date.

Click OK to commit the change.

Add a new role "Coordinating Principal Investigator"

Contact = correct CPI

Approval date= today's date

Expiry date = blank

Click OK to commit the change. Now click Save on the right hand menu.

In the Details → Summary section ensure that the Owner is the true CPI and the editor (you) is removed.

Summary

Project

Program	Ethics
Title	Patrick UAT regression test 29072019
Short title	
Owner	Lau, Patrick (patrick.lau1@health.nsw.gov.au)
Editors	Becker, Kylie (kylie.becker@health.nsw.gov.au)
Viewers	
Concept Associate	Salinas, MDEC (Evelyn.Dennis@health.nsw.gov.au)