

Completing Project Registration

What is Project Registration?

The first step in initiating your human research project in REGIS is to register it. Project registration information:

- ❖ will help identify if a Human Research Ethics Application (HREA) or Site Application (SSA/STE), or both, are required.
- ❖ will determine what other information you will need to provide to complete your application/s

Project Registration should only be completed once per study. Once project registration has been completed, any new sites can be added under that PID.

Project Registration Scenarios

There are two types of project registration scenarios (Ethics in NSW/ACT/TAS or Ethics outside of NSW/ACT/TAS). Click the appropriate link below for details instructions.

1. ["Completing Project Registration – when Ethics and Governance is in NSW/ACT/TAS \(site only\)"](#)
2. ["Completing Project Registration – Ethics Submitted/Approved in another state/jurisdiction \(VIC/QLD/SA/WA\)"](#)

What information is needed?

Have the following information ready to complete project registration:

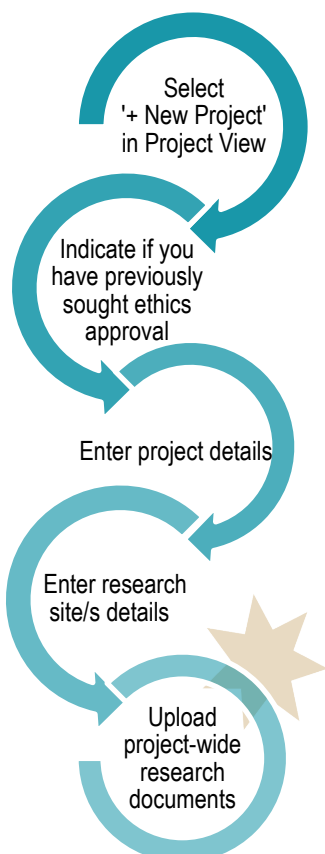
- Project details – see Step 4
- Research site information including Principal Investigator details – see Step 4C
- Research protocol
- Other project-wide documents


Tip: Team members with the roles of CPI and PI must have a REGIS account before you can complete project registration. You can save your form and complete it later.

How does it work in REGIS?

Anyone with a REGIS account can register a project in REGIS. The following diagram is an overview of the project registration process in REGIS.

For applications submitted under [National Mutual Acceptance \(NMA\)](#), project registration should be completed by the lead site.



Tip: When the  icon appears at the end of a question, click for further information.

Completing Project Registration When Ethics is in REGIS

Step 1

Select the 'Projects' icon along the top menu bar to be brought to your projects page.

Tip: Depending on your screen size, you may see either of the icons above.

Step 2

Create a new project registration by clicking on the black 'New Form' button.

Step 3. Introduction

Read the instructions and guidance provided on this page.

Step 4: Answer the Registration questions

Part A: Previous ethics application

A1 answer is 'No', proceed to Part B in the registration.

Tip: If you have been asked to re-submit a new Ethics application due to HREC expiry you should respond "No".

Part B: Project details

Answer every question on this page and use the help icons next to questions to get question specific guidance.

The Questions B3.1 to B3.3 have been designed to assist applicants to correctly identify if their study should be submitted as a Clinical Trial.

Part C: Research site/s details

Tip: Incorrect site selection will have a major impact on the application process. Consult with the local research office if you are unsure of the sites you should list.

To provide the HREC with a full list of sites they are reviewing, you need to list **ALL** of the sites under the relevant jurisdictional tabs, i.e. ACT, NSW & TAS Health or Other Health Jurisdictions.

If the PI has an account in REGIS, their email address will be available for selection. If they are not listed, please ask them to register for REGIS by clicking the **Invite to Register** button.

The person completing Project Registration can now add up to two 'Administration' contacts, under 'Other Administration Contacts', to allow them access to the Ethics Application on creation. This can be done by clicking the 'Add Another' button.

Please refer to the [Sharing Access to an Application/Project QRG](#) on how to share/allocate delegate access. Administration Staff and Associate Investigators can be added here.

Multiple sites can be added in this section by clicking the black 'Add Another' button at the bottom left

Which Project Centre is my site under?

A project centre is the Local Health District. If you are unsure, use the search bar above the table to type in the site name. If the project centre is in REGIS, it will appear. If it does not appear, contact the local research office for assistance before submission.

If you are unsure of the Project Centre use the search bar. Once you select the Project Site the Project C

Part D: Coordinating Principal Investigator (CPI)

The CPI has overall responsibility for the research project at all sites.

If you are the CPI, select 'yes'. If you are not, select 'no' and enter the email address of the CPI.

If the CPI is not listed in REGIS, please ask them to register for REGIS before you complete project registration.

Tip: Entering someone other than the CPI here will have flow on effects and WILL delay your application review.

The person completing Project Registration can now add up to two 'Administration' contacts, under 'Other Administration Contacts', to allow them access to the Ethics Application on creation. This can be done by clicking the 'Add Another' button.

Part F: Attachments

Upload/Register all project-wide/master documents for the research project, even if they are in draft form.

Note: How the document is described here is how it will flow through to the HREA form and how it will appear on the approval notification.

F1 Project Description/Protocol

Document title should be clear and descriptive as this is how it will appear on the approval notification.

F2 Other relevant documents, project-wide documents and others required for submission with HREA

Upload each document to be submitted to the HREC, even if still in draft. You will have the opportunity to upload completed documents when completing the HREA.

Document Type: Select from dropdown.

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Step 5 Complete registration

Tip: Ensure all details are correct BEFORE completing registration. The project registration CANNOT be edited or changed after submission.

Ensure REGIS is generating the site applications you require before completing registration. If you do not see the applications/sites, you need to check your responses under Part A - C

The following applications will be generated:

Contact your local research office if you need help.

Click **Complete Registration** to finalise.

Once Project Registration is completed:

- ❖ The project will be assigned a PID – this is an overarching Project Identifier under which ethics (ETH) and/or site governance (STE) applications will be managed
- ❖ If ethical review has not yet been sought, a HREA will be generated – see **Quick Reference Guide: HREA/Ethics Application - Completing and Submitting**.

Completing Project Registration – Ethics Submitted/Approved in another State/Jurisdiction (VIC/QLD/SA/WA)

Step 1

Select the 'Projects' icon on the top menu bar to be brought to your projects page.

Tip: Depending on your screen size, you may see either of the icons above.

Step 2

Create a new project registration by clicking on the black 'New Form' button.

Step 3. Introduction

This page provides useful **instructions and guidance**.

Step 4: Answer the Registration questions**Part A: Previous ethics application**

A1 answer 'Yes'.

A2 Enter the unique identifier or reference that applies to the Ethics application.

A warning message will appear if the unique identifier or reference has already been used in another project registration form. You are advised of the Project ID, the CPI's name and HREC.

ⓘ This ethics application has been registered in REGIS. The application id has been used for the following project(s):

- Project Id: 2020/PID00960, CPI: Kylie Becker, HREC: Anglicare Southern Queensland Human Research Ethics Committee

A new site should be created under this PID, please contact the CPI and request a new site application be created. [see quick reference guide: Create a new site application.](#)

DO NOT CREATE A NEW PID

Do not complete project registration, contact the CPI to discuss further.

Note: This warning message will not stop the submission of your project registration, but if you proceed you will be creating a duplicate application in REGIS.

A warning message will also appear if an ETH identifier is listed in section **A2**.

A2 Ethics application ID *

2020/ETH00870

This Ethics application has previously been added to REGIS under project identifier 2020/PID00973, please contact the project owner Corinne McDonough (corinne.mcdonough@health.nsw.gov.au) to be granted access to the existing application

A3 Select the HREC your ethics application was submitted to from the drop-down list.

A4 HREC code is prefilled based on response to A3.

A5 If you are using a NHMRC certified HREC in QLD, VIC, SA or WA, your response will be 'Yes'. This means that REGIS will not create a HREA.

A7 This question appears based if A6 = 'Approved' enter the date of the decision notification document.

Part B: Project details

Answer every question on this page.

Use the helptext icons next to questions to get question specific guidance. The questions B3.1 to B3.3 have been designed to assist applicants to correctly identify if your study should be submitted as a Clinical Trial.

Part C: Research site/s details

Tip: Incorrect site selection will have a major impact on the application process. Consult with the local research office if you are unsure of the sites you should list.

You need to list **ALL** sites under ACT, NSW & TAS Health where this research project will be conducted.

Tip: This is a good opportunity to delegate the responsibility of editing and submitting the application to other REGIS user(s). Please [refer to the Sharing Access to an Application/Project QRG on how to share/allocate delegate access](#). [Administration Staff and Associate Investigators can be added here](#).

If the PI is not listed in REGIS, please ask them to register a REGIS account before you complete project registration.

Click the black 'Add Another' button to add other team members.

Click the black 'Add Another' button at the bottom left, to add another site.

A project centre is the Local Health District. If you are unsure, use the search bar above the table to type in the site name. If the project centre is in REGIS, it will appear. If it does not appear, contact the local research office for assistance before submission.

If you are unsure of the Project Centre use
Once you select the Project Site the Project

roy
Royal Hospital for Women
Royal North Shore Hospital
Royal Prince Alfred Hospital

Part D: Coordinating Principal Investigator (CPI)

The CPI has overall responsibility for the research project at all sites.

If you are the CPI, select 'yes'. If you are not, select 'no' and enter the email address of the CPI.

If the CPI is not listed in REGIS, please ask them to register for REGIS before you complete project registration. You can invite people who do not have a REGIS account and share the Project Registration with current users by

clicking **Invite to Register** button.

Tip: Entering someone other than the CPI here will have flow on affects and will delay your application review.

Part F: Attachments

Upload/Register all project-wide/master documents for the research project, even if they are in draft form.

F2 Other relevant documents, project-wide documents and others required for submission with HREA**Ethics application (HREA or other)**

Upload a .zip file of the HREA and any other master documents that were submitted to the HREC.

Ethics application decision notification

If ethics approval has been received upload this document separately.

Step 5 Complete registration

Tip: Ensure all details are correct before completing the registration. The project registration CANNOT be edited or changed after submission.

Ensure REGIS is generating the site applications you require before you complete registration. If you do not see the applications/sites you need to check your responses under Part A - C.

The following applications will be generated:

SSA for each of the following NSW Health sites:

Short Street Centre, Ms Kylie Becker (PI)

Contact your local research office if you require further assistance.

Click **Complete Registration** to finalise.

Once Project Registration is completed:

- ❖ The project will be assigned a PID – this is an overarching Project Identifier under which site governance (STE) applications will be managed
- ❖ STE (SSAs) for NSW, ACT & TAS sites. see *Site Application – Completing, Requesting Support and Submitting*.

Project Registration – When A Project Is Already Registered

Any study/project should only be registered once in REGIS.

A warning message will appear if the unique identifier, reference, or ETH identifier has already been used in another project registration form.

❗ The ethics application Id in question A2 has been used in other project registration forms. Please check the application Id. The application Id has been used for the following project(s):

- Project Id: 2020/PID00970, CPI: Corinne McDonough, HREC: Austin Health Human Research Ethics Committee

A2 Ethics application ID * ?

2020/ETH00870

This Ethics application has previously been added to REGIS under project identifier 2020/PID00973, please contact the project owner Corinne McDonough (corinne.mcdonough@health.nsw.gov.au) to be granted access to the existing application

Contact the CPI to discuss further before proceeding.

If a new site is required to be added to an existing project, please contact the Owner (lead site) of the Project to have the site application created.

See QRG [Create a new site application](#)

Warning: Site applications cannot be created under one PID and transferred to another PID.