

# 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 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.

1. [Completing Project Registration – when Ethics and Governance is in NSW/ACT](#)
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
- Research site information including PI details
- Research protocol
- Other project-wide documents

Team members with the roles of Coordinating Principal Investigator and Principal Investigator must have a REGIS account before you can complete project registration.

*You can save your registration at any time and return to, at a later point.*

The CPI and PI can also delegate submit access to anyone with a REGIS account. **This does not remove the overall responsibility from the CPI or PI.**

For **Non-Clinical Trials**: Two Administration contacts can be added with submit access, per Ethics and Site application.

For **Clinical Trials**: Two Administration contacts can be added with submit access, per Ethics and Site application and one Associate Investigator can be added with submit access, per Site application.

*Note: If the CPI or PI is not the person submitting Project Registration then upon submission, an email will be sent to the CPI or PI to approve any users added with 'submit' access.*

## Sharing and Roles

**Share with View access:** User can only view the application and forms

**Share with Edit access:** User can view and edit the application and forms

**Share with Edit and Submit access:** User can view, edit, and submit applications and forms

**Administration:** User is copied into all outgoing system correspondence. Administration contacts can also be given submit access.


## 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.



 *When the '?' icon appears at the end of a question, click for further information.*

## When A Project Is Already Registered

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

If a study with this identifier has already been registered in REGIS **DO NOT** complete another project registration.

A warning message will appear to advise of the Project ID, the CPI's name and HREC. Contact the CPI/lead to request they add your site.

**⚠ 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**

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

*The warning message will not stop the submission of your project registration. Progressing after seeing this warning message will create a duplicate application that **cannot** be transferred or migrated to an existing PID.*

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

## Completing New Project Registration – When Ethics is in NSW/ACT Including If you have been asked to re-submit a new Ethics application due to HREC expiry.

**Step 1 Create a new** project registration by clicking the + New form icon, located on your homepage.

 **New form**

### Step 2 Answer the Registration questions

**Part A: Previous ethics application A1 = 'No',** to create a new HREA for review by a NSW/ACT HREC.

**Part B: Project details** answer every question on this page.

**Part C: Research site/s details** this section provides a full site list to the HREC, transfers team details to the HREA and creates any NSW site application forms.

List **ALL** of the sites under the relevant jurisdictional tabs, i.e. ACT Health, NSW Health or Other health jurisdiction or organisation.

***Incorrect NSW Health 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.***

**Project Centre (ACT/NSW)** a project centre is the Local Health District.

If you are unsure of the Project Centre type the site name into the cell above the table and if the project centre is in REGIS, it will appear. If it does not appear, contact the local research office for assistance before submission.

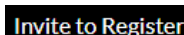
If you are unsure of the Project Centre use th  
Once you select the Project Site the Project C

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

**Project Site ACT/NSW** a list of sites will be available for selection or you can start typing the site name to filter the list.

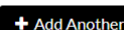
**Project Site Other** is a freetext field, type the name as you want it to appear in the approval email.

**Principal Investigator email (REGIS username)** start typing the PIs REGIS username into the field if an account exists their email address will be available for selection.

If they are not listed, invite them to register in REGIS. Click 

**Other Team Members** can be added here. Use the + Add Another button to add team members, such as Administration contacts and Associate Investigator/s. You can indicate the type of access required for the team members such as

Other team members



'View' or 'Edit'. If an Administration contact is given 'Edit' access, you can also delegate them 'Submit' access. For Clinical Trials, an Associate Investigator can also be given 'Edit' and 'Submit' access.


Other team members

| REGIS Username *               | Team member name                   | Role *         |
|--------------------------------|------------------------------------|----------------|
| kylie.becker@health.nsw.gov.au | Emeritus Professor<br>Kylie Becker | Administration |

Allow access to REGIS form? \*

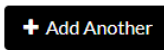
Does this person have authorisation to submit the SSA and other project related forms on behalf of all members of the research team? \*

Yes  No



Any team member added here will flow through to the Site application with the view, edit or submit access as indicated (if Project Registration is submitted by the PI).

Refer to [Sharing and Roles](#) for further information

Add multiple sites by selecting + Add Another 

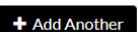
**Part D: Coordinating Principal Investigator (CPI)** the CPI has overall responsibility for the research project at all sites.

If the CPI is not listed in REGIS, you will need to invite them to register before you can complete registration.

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

**Other Team Members** can be added here. Use the + Add Another button to add team members, such as Administration contacts.

Other team members



You can indicate the type of access required for the team members such as 'View' or 'Edit'. If an Administration contact is given 'Edit' access, you can also delegate them 'Submit' access.


Any team member added here will flow through to the Ethics application with the view, edit or submit access as indicated (if Project Registration is submitted by the CPI).

Anyone with a REGIS account can submit the Project Registration.

**Part F: Attachments** the minimum requirement for Project Registration is uploading a Project Description/ Protocol.

*Type the descriptor for each document exactly how you want it to appear in the HREA and on the approval notification.*

**F1 Project Description/Protocol** type descriptor and upload the individual document.

 Drop files to attach, or [browse](#)


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

Upload each document to be submitted to the HREC. You will have the opportunity to change any updated documents when completing the HREA.

**Document Type** select from dropdown.

**Document Descriptor** type 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.

Upload each individual document.

 Drop files to attach, or [browse](#)

**Step 3 Complete registration**

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

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

The following applications will be generated:

A HREA

SSA for each of the following NSW Health sites:

Children & Young People's Mental Health, Emeritus Professor Kylie Becker (PI)

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: Ethics Completing & submitting the Application**.

## Completing New Project Registration – Ethics

Submitted/Approved in another State/Jurisdiction (VIC/QLD/SA/WA)

**Step 1 Create a new project registration**

by clicking the + New form icon, located on your homepage.

 New form

**Step 2 Answer the Registration questions**

**Part A: Previous ethics application**  
A1 = 'Yes'.

**A2** Enter the unique identifier or reference that applies to the Ethics application in one of the accepted formats (should appear on any HREC correspondence)

- **Queensland:**  
HREC/12345/site-name-year-1234567 v1 OR  
DM MDF/56789/DEF-1028-345678 V2
- **South Australia:**  
HREC/19/ABC123  
OR  
2021/HRE00100
- **Victoria:**  
HREC/12345/site-name-year-1234567 v1 OR  
DM MDF/56789/DEF-1028-345678 V2
- **Western Australia:**  
RGS0000001234S

**A3** Select the HREC from the drop-down list or start typing to filter the options.

**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 OR you have submitted an EPCT through Bellberry eProtocol, your response will be 'Yes'. No HREA will be created.

***IMPORTANT!** If you are unsure what NMA/NHMRC certified HREC is or unsure if the reviewing HREC falls under this, use the help icon located next to the question for further information or contact the reviewing HREC to clarify. **Selecting 'No' here WILL create an Ethics application in REGIS for completion.***

**A7** This question appears based if A6 = 'Approved' enter the approval date on the approval letter/email/certificate.

**Part B: Project details** answer every question on this page.

**Part C: Research site/s details** to alert the system which NSW Health sites require a site application form.

***Incorrect NSW Health 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.***

**Project Centre (NSW)** a project centre is the Local Health District.

If you are unsure of the Project Centre type the site name into the cell above the table and 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 below. Once you select the Project Site the Project C

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

**Project Site NSW** a list of sites will be available for selection or you can start typing the site name to filter the list.

**Principal Investigator email (REGIS username)** start typing the PIs REGIS username into the field if an account exists their email address will be available for selection.

If they are not listed, invite them to register in REGIS. Click **Invite to Register**

### Other Team Members

can be added here. Use the + Add Another button to add team members, such as Administration contacts and Associate Investigator/s. You can indicate the type of access required for the team members such as 'View' or 'Edit'. If an Administration contact is given 'Edit' access, you can also delegate them 'Submit' access. For Clinical Trials, an Associate Investigator can also be given 'Edit' and 'Submit' access.

Other team members

+ Add Another

| REGIS Username *   | Team member name                   | Role *         |
|--|------------------------------------|----------------|
| <input type="text" value="kylie.becker@health.nsw.gov.au"/>  | Emeritus Professor<br>Kylie Becker | Administration |
| Allow access to REGIS form? *  | <input type="text" value="Edit"/>  |                |
| Does this person have authorisation to submit the SSA and other project related forms on behalf of all members of the research team? * |                                    |                |
| <input checked="" type="radio"/> Yes<br><input type="radio"/> No   |                                    |                |
| <b>+ Add Another</b>   |                                    |                |

Any team member added here will flow through to the Site application with the view, edit or submit access as indicated (if Project Registration is submitted by the PI).

Refer to [Sharing and Roles](#) for further information

Add multiple sites by selecting + Add Another.

+ Add Another

### Part D: Coordinating Principal Investigator (CPI)

has overall responsibility for the research project at all sites. They may be from another jurisdiction.

If the CPI is not listed in REGIS, you will need to invite them to register before you can complete registration.

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

Anyone with a REGIS account can submit the Project Registration.

### Part F: Attachments

**F2 Other relevant documents, project-wide documents and others required**

**for submission with HREA** If the study has been approved by the HREC you will need to upload the approval letter/email/certificate and the listed approved documents.

### Ethics application (HREA or other)

Upload a .zip file of the HREA and any other master documents that are listed on the approval letter.

### Ethics application decision notification

Upload this document separately.

### Step 5 Complete registration

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

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

The following applications will be generated:

SSA for each of the following NSW Health sites:

Children & Young People's Mental Health, Emeritus Professor Kylie Becker (PI)

Click **Complete Registration** to finalise.

### Once project registration is done

- ❖ 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 sites. see **Site Application – Completing, Requesting Support and Submitting.**

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).