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

Incorrect information can delay the approval and authorisation process.

Project Registration Scenarios.

There are two types of project registration scenarios (Ethics in NSW/ACT or Ethics outside of NSW/ACT) select the appropriate link below for details instructions.
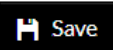
1. "Completing Project Registration – when Ethics and Governance is in NSW/ACT"

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

QRG-ResApp-Project Registration-v5.docx5

Team members with the roles of CPI and PI must have a REGIS account before you can complete project registration.

You can save your registration at any time to return to later or to complete another section.

Save

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.
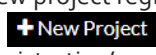
Select 'New Project' in Project View

Indicate if you have previously sought ethics approval

Enter project details

Enter research site/s details

Upload project-wide research documents

Tip: When this icon appears at the end of a question, click for help.

Completing Project Registration – when Ethics is in NSW/ACT

Step 1
Select the 'Projects' icon on the top menu bar to create a new project and view all your projects.

Projects

Step 2
Create a new project registration by clicking on + New Project and select 'Project Registration'.

Step 3. Introduction
This page provides useful **instructions and guidance.**

Step 4: Answer the Registration questions

Part A: Previous ethics application
A1 answer is 'No', proceed to Part B in the registration.

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.

Use the helptext icons next to questions to get question specific guidance.

Part C: Research site/s details

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.

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

The PI is the only person who can submit the SSA/STE in REGIS.

If the PI has an account in REGIS, their email address will be available for selection. If they are not listed, invite them to register in REGIS.

Click **Invite to Register**

⊕ ⊖   Use the plus/minus signs at the bottom to add and remove project sites.

Which Project Centre is my site under?

A project centre is the Local Health District, if you are unsure use the search cell above the table to type in the site name and the project centre will appear.

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

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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, you will need to invite them to register in REGIS before you can complete registration.

✋ *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.

Electronic filenames should not include any versioning or date. e.g. Protocol_REGIS or PISCF1_REGIS

F1 Project Description/Protocol
Document title should be in the following format: "<DocType>-<acronym>-<version>-<date>".

(**Protocol-SWIMTrial-v10.3-10Jan2020** or **Protocol-v10.1-10Jan2020**)

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

Upload each document you intend to submit to the HREC even if still in draft. You can upload completed documents when completing the HREA. Document descriptor should be in the following format:

<short description of doc type>-<brief unique descriptor>
(**PISCF-Intervention, IB-DrugName**)
Add document version/date in the specific cell and follow format for F1/F2 to speed up approval/reduce errors.

Step 5 Complete registration

✋ *Ensure all details are correct before you complete registration. The project registration CANNOT be edited or changed after submission.*

Ensure REGIS is generating the applications you require before you complete 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:

The Children's Hospital at Westmead, Ms Kylie Becker (PI)

Contact the 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: Ethics Completing & submitting the Application.*

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 create a new project and view all your projects.

🖥 Projects

Step 2
Create a new project registration by clicking on **+ New Project** and select 'Project Registration'.

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.

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.

> **For further assistance if needed, contact your local research office at these links – NSW or ACT.**

NSW GOVERNMENT | Health

ACT Government Health

A5 If you are using a NHMRC certified HREC in QLD, VIC, SA or WA, your response will be 'Yes' - 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.

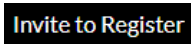Use the helptext icons next to questions to get question specific guidance.

Part C: Research site/s details

Only add the ACT Health and NSW Health Sites where this research project will be conducted.

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.

If the PI has an account in REGIS, their email address will be available for selection. If they are not listed, invite them to register in REGIS.

Click **Invite to Register**

Use the plus/minus signs at the bottom to add and remove project sites.

A project centre is the Local Health District, if you are unsure use the search cell above the table to type in the site name and the project centre will appear.

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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, you will need to invite them to register in REGIS before you can complete registration.

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.

Electronic filenames should not include any versioning or date. e.g. Protocol_REGIS or PISCF1_REGIS

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

Ensure all details are correct before you complete registration. The project registration CANNOT be edited or changed after submission.

Ensure REGIS is generating the applications you require before you complete 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:

SSA for each of the following NSW Health sites:

Short Street Centre, Ms Kylie Becker (PI)

Contact the local research office if you need help.

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.*

Project Registration – When A Project Is Already Registered

Any study/project should only be registered once in REGIS. If a new site is required you should contact the Owner (lead site) of the Project to have the site application created.

See. QRG Create a new site application

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

For further assistance if needed, contact your local research office at these links – NSW or ACT.