

Completing Project Registration

What is Project Registration?

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

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

Project registration is completed once per study. When project registration has been completed, any new SA Health sites can be added under that GEM identifier.

Project Registration Scenarios

There are two types of project registration scenarios (Ethics in SA or Ethics outside of SA) select the appropriate link below for details instructions.

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

What information is needed?

Have the following information ready to complete project registration:

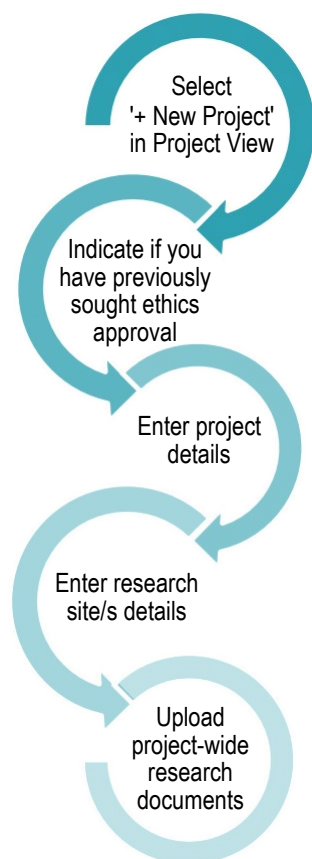
- Project details – see Step 4
- Research site information including PI details – see Step 4C
- Research protocol
- Other project-wide documents

Tip: Team members with the roles of CPI and PI must have a GEMS account before you can complete the project registration. You can save your registration at any time and return to it at a later point.

How does it work in GEMS?

Anyone with a GEMS account can register a project in GEMS.

The following diagram is an overview of the project registration process in GEMS.

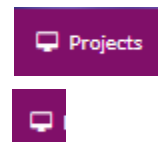


Tip: When the ? icon appears at the end of a question, click for further information.

Completing Project Registration – When Ethics is in South Australia

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 '+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.

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

Part B: Project details

Answer every question on this page.

Use the help text icons next to questions to get question specific guidance.

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.

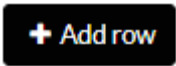
List **ALL** sites under the relevant jurisdictional tabs, i.e. SA Health or Other.

Tip: The PI is the only person who can submit the SSA in GEMS.

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

Click the **Invite to Register**

Use the Add Row to add/remove project sites.



Which Project Centre is my site under?

A project center is the Local Health Network, if you are unsure use the search cell above the table to type in the site name and if the project centre is in GEMS, it will appear. If it does not appear, contact the local research office for assistance before submission.

If you are unsure of the Project C
Once you select the Project Site t

- Eyre and Far North Local Health
- Flinders and Upper North Local
- North Eastern Mental Health

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

*Tip: Entering someone other than the CPI here will have flow on effects 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.

Note: How your document is described is how it will appear on the approval notification so ensure it is clear and

descriptive, think about how you would want it to 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 you intend to submit to the HREC, even if still in draft. You can upload completed documents when completing the HREA. Ensure that your document description is clear and descriptive.

Step 5 Complete registration

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

Ensure GEMS 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 SA Health sites:

Women's and Children's Hospital, Stephen Shillabeer (PI)

Contact the local research office if you need help.

Click **Complete Registration** to finalise.

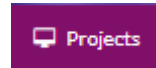
Once project registration is completed:

- ❖ the project will be assigned a GEM Identifier – this is an overarching Project Identifier under which ethics (HRE) and/or site governance (SSA) applications will be managed
- ❖ if ethical review has not yet been sought, a HREA will be generated – see **User Guide: Ethics Completing & submitting the Application.**

Completing Project Registration – Ethics Submitted/Approved in another State/Jurisdiction (NSW/VIC/QLD/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 **+ 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.

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/PID00970, CPI: Corinne McDonough, HREC: Austin Health 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 the system.

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

A2 Ethics application ID *

2020/ETH00867

This Ethics application already exists in REGIS under project identifier 2020/PID00969. A new site should be created under this PID, please contact the owner Nisha Thomas (nisha.thomas@f1solutions.com.au) and request a new site application be created. DO NOT CREATE A NEW PID

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 NSW, QLD, VIC or WA, your response will be 'Yes', this means that SA 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 help text icons next to questions to get question specific guidance.

Part C: Research site/s details

Only add the SA Health Sites where this research project will be conducted.

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.

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

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

A project centre is the Local Health Network, 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 C
Once you select the Project Site t

north|
Eyre and Far North Local Health
Flinders and Upper North Local
North Eastern Mental Health

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 GEMS before you can complete registration.

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.

Note: How your document is described is how it will appear on the approval notification so ensure it is clear and descriptive, think about how you would want it to appear on the approval notification.

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 GEMS 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 and C to check your responses.

SSA for each of the following SA Health sites:

Women's and Children's Hospital, Stephen Shillabeer (PI)

Contact the local research office reviewing your application if you require further assistance.

Click **Complete Registration** to finalise.


Once project registration is done:

- ❖ The project will be assigned a GEM Identifier – this is an overarching Project Identifier under which site governance (SSA) applications will be managed
- ❖ SSA for SA Health 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 GEMS.

A warning message will appear if the unique identifier, reference or HRE 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, you should contact the Owner (lead site) of the Project to have the site application created.

See the User Guide: [Create a new Site Application.](#)

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