

Completing Project Registration

What is project registration?

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

- ❖ Will help identify if a Human Research Ethics Application (HREA) or Site Specific Assessment (SSA) application, 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 detailed instructions.

[Completing Project Registration – when Ethics and Governance is in South Australia.](#)

[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 Principal Investigator (PI) details – see Step 4C.
- ❖ Research protocol.
- ❖ Other project-wide documents.

Team members with the roles of Coordinating Principal Investigator (CPI), PI or Administration Contact 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.

Sharing access

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

Share with view: User can only view the application and forms.

Share with edit: User can view and edit the application and forms.

Share with edit and submit: User can view, edit, and submit applications and forms.

Administration contact: User is copied into all outgoing GEMS correspondence. Administration contacts can also be given submit permission as a delegate.

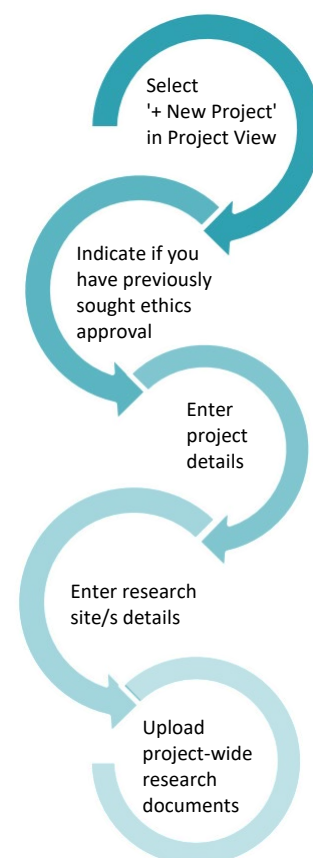
- ❖ For Non-Clinical Trials: Two administration contacts can be added with submit permission, per ethics and SSA application.
- ❖ For Clinical Trials: Two administration contacts can be added with submit permission, per ethics and SSA application and one Associate Investigator (AI) can be added with submit permission, per SSA application.

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' permission.

For further information on sharing and permissions, [click here.](#)

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'.

Introduction

This page provides useful instructions and guidance.

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 Human Research Ethics Committee (HREC) expiry you should respond "No".

Part B: Project Details

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

Part C: Research Site/s

Tip: 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 (interstate sites).

Site team members can be added here, and their level of access specified. This includes being able to submit the SSA and other forms on behalf of the PI.

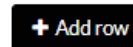
For further information on sharing and permissions, [click here](#).

For Clinical Trials, an AI can also be given edit and submit permission. Refer to [Sharing and Roles](#) for further information.

If the PI and site team members have 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' button to add 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.

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*

Ethics administration contacts can be added here and delegated submit permission to be able to certify and submit forms on behalf of the CPI.

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' permission.

Part F: Upload attachments

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

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 itself. Ensure that your document description is clear and descriptive.

Step 3. 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 submit.

Once project registration is submitted:

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 [Completing an ethics application](#).

Completing project registration –

Ethics submitted/approved in another State/Jurisdiction (NSW/ACT/VIC/QLD/WA)

If an ethics application has been submitted or approved by another public health organisation ethics committee in another state, your study does not require an ethics application to be lodged in GEMS. **A Site Specific Assessment (SSA) is still required.**

These applications need to be approved by a [National Mutual Acceptance \(NMA\)](#) certified committee.

Full details of the NMA process can be found in the **‘Completing Project Registration – NMA’** user guide.

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.

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

- Project Id: 2022/GEM00188, CPI: Jamie Francis, HREC: ACT Health Human Research Ethics Committee

A new site should be created under this GEMS Project, please contact the CPI and request a new site application be created. *see user guide: [Creating a new site application](#).*

DO NOT CREATE A NEW GEMS PROJECT

Contact the CPI to discuss further before proceeding.

If a new site is required, you should contact the Owner (lead site in South Australia) of the project to have the site application created.

See the User Guide: [Adding a new site application – existing applications](#).

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