

Completing Project Registration – National Mutual Acceptance Projects

Ethics submitted/approved in another state/jurisdiction (NSW/ACT/VIC/QLD/WA)

What is National Mutual Acceptance?

National Mutual Acceptance (NMA) is the system of single scientific and ethical review of multi-centre human research projects across all Australian jurisdictions (public health organisations only).

A full list of NMA certified human research ethics committees (HRECs) can be found [here](#).

What is project registration?

Research GEMS allows projects that are either under review or have been approved from a NMA certified ethics committee to be registered.

Project registration information:

- ❖ Will create the SA Health project.
- ❖ Will identify the site/s requiring a Site Specific Assessment (SSA) application.

NMA project registration scenarios

There are two types of NMA project registration scenarios (ethics approval granted or still pending).

- ❖ [“Completing Project Registration – when Ethics approval has been received from a NMA certified HREC”](#)
- ❖ [“Completing Project Registration – when Ethics approval is still under review from a NMA certified HREC”](#)

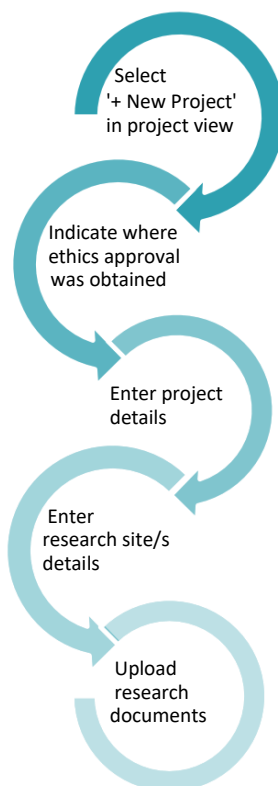
- ❖ Research site information including principal investigator (PI) details
- ❖ Study protocol
- ❖ NMA certified ethics committee Details (including unique NMA ID)
- ❖ Other project-wide documents

Tip: 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.



Completing Project Registration – When ethics approval has been received from a NMA certified HREC

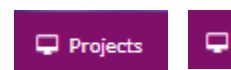
What information is needed?

Have the following information ready to complete project registration:

- ❖ Project details

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 'Yes'.

A2 Enter the unique ethics application identifier or reference (20 character limit)

Note: A warning message will appear if the unique identifier, reference or ethics (HRE) identifier has already been used in another project registration form. Contact the CPI

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

- Project Id: 2023/GEM00002, 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

to discuss further.

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


A4 HREC code is prefilled based on response to A3.

A5 If your NHMRC certified HREC is in NSW, ACT, QLD, VIC or WA, your response should be 'Yes.' This means that a HREA will **not** be created.

A7 This question appears if response in A6 is 'Approved.' Enter the date of the decision notification document.

Part B: Project details

Answer every question on this page.

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

Part C: Research site/s details

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.

Use the '+Add row' button to add project sites.

+ Add row

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 site/s you should list.

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

For further information on sharing and permissions, see user guide [Sharing access to applications and projects](#).

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

Invite to Register

Which Project Centre is my site under?

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 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

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 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 affects 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.

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

Ethics application (HREA or other)
Upload the HREA and any other master

documents that were submitted to the approving HREC.

Note: This should include the latest version of the Study Protocol.

Ethics application decision notification

Upload the ethics approval documentation separately. Under document type, select 'Ethics application decision notification' from the drop-down list.

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 to 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 assistance.

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 the SSA application/s will be managed.

Follow user guide '[Submitting the site application and requesting Head of Department support](#)' to obtain authorisation to conduct the study at a site.

Note: If ethics has not been approved yet, and is still in the 'In progress' status, additional sites can be added by using the '+New Site' button. Click [here](#) for detailed instructions.

Completing Project Registration – When ethics approval is still under review from a NMA certified HREC

A project can be registered and SSA application/s created before a NMA certified HREC has granted ethics approval. In this scenario, follow these steps.

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A warning message will appear if the unique identifier, reference or ethics (HRE) identifier has already been used in another project registration form. Contact the CPI to discuss further.

⚠ This ethics application has been registered in GEMS. The application id has been used for the following project(s):
• Project id: 2023/GEM00002, 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

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


A4 HREC code is prefilled based on response to A3.

A5 If your NHMRC certified HREC is in NSW, ACT, QLD, VIC or WA, your response should be 'Yes', this means that SA will not create a HREA.

A6 Select the outcome or status as 'Review currently underway'.

Part B: Project details

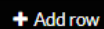
Answer every question on this page.

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

Part C: Research site/s details

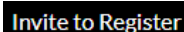
List **ALL** sites under the relevant jurisdictional tabs, i.e. SA Health or Other.

Use the '+Add row' button to add project sites.

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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 site/s you should list.

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 by clicking the 'Invite to Register' button.

 Invite to Register

Site team members can be added here, and their level of access specified. If an administration contact is given edit access, you can also delegate them submit permission to be able to certify and submit forms on behalf of the PI.

For further information on sharing and permissions, see user guide [Sharing access to applications and projects](#).

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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 the HREA and any other master documents that were submitted to the approving HREC.

Note: This should include the latest version of the Study Protocol.

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 completing registration. If you do not see the applications/sites you need to return to Part -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 submit.

Once project registration is submitted

The project will be assigned a GEM Identifier – this is an overarching Project Identifier under which ethics and SSA application/s will be managed.

Note: If ethics has not been approved yet, and is still in the 'In progress' status, additional sites can be added by using the '+New Site' button. Click [here](#) for detailed instructions.

When ethics approval has been obtained from the NMA certified HREC

The project CANNOT commence at a site until ethics approval have been obtained.

The research governance officer (RGO) of the site/s must be notified when ethics approval has been obtained for a SSA application/s to be authorised.

Each site must be notified separately.

The CPI, authorised delegate/s and/or person/s with edit permission will have access to the form to upload the ethics approval documentation.

Step 1. Locate the SSA application

The Project Details page will show a list of the projects you have access to. Click on the project and a list of associated SSA application/s will be presented.

TITLE	STATUS
035382 - Upload Final Ethics Approval	In Progress

Step 2. Open form

Select the SSA row and this will open the SSA details page. Click on 'Application information' and select 'Forms' to open form 'Upload Final Ethics Approval.'

Step 3. Complete form

Document type: Select 'Ethics application decision notification' from the drop-down list.

Document title: Provide a clear and descriptive document descriptor.

Version and date: As listed on the document. If the document does not have a version, enter 0.

Use the 'Add row' button to upload any other relevant ethics approval documents

+ Add row

Click 'Submit' and once submitted, the status of the form will change from 'In progress' to

Submitted

For multi-centre studies, complete steps 1 – 3 for all sites.