

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



## Overview

This guideline will provide the necessary information for researchers, coordinators and study personnel to submit their site specific assessments (SSA) via the Research GEMS Application. This guide is specifically for commercially sponsored clinical trials that have previous or currently in process of being approved by another ethics committee under the National Mutual Acceptance scheme.

## Scope

This guideline will help to achieve the following:

- Register a project
- Submit an external ethics SSA application
- Understand the process of applications from start to authorisation

## Definitions & Acronyms

- GEMS – Governance and Ethics Management System
- SSA – Site Specific Assessment – known as Site Application
- Project – Study
- PI – Principal Investigator
- AI – Associate Investigator

## Quick Links

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# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – NMA Ethics Preparing Project Registration and SSA Submission



**Health**  
Central Adelaide  
Local Health Network

## Procedures

### Registering a Project

1. Go to the GEMS Website located [here](https://gems.sahealth.sa.gov.au/)  
<<https://gems.sahealth.sa.gov.au/>>
2. Login/Register Account

gems.sahealth.sa.gov.au

Apps HealthCALHN Rese... Licence agreement... https://myip.had.sa... Credentialling Welcome - GEMS Post Approval Moni... Research GEMS Use... Velos Test Velos PRD

Government of South Australia  
SA Health

the hospital research foundation  
TOGETHER FIGHT

Welcome to Research GEMS

User name

Password

Log in

Can't access your account?  
[Reset your password](#)

Don't have a Research GEMS account?  
[Register now](#)

If you require assistance with your application, please contact the Research Office that you will be submitting to. Contact details are available on the SA Health website.

User guides are also now available via the [Research GEMS User Guides page](#).

To register a technical issue/fault, please contact the Research GEMS support team on [gems@sa.gov.au](mailto:gems@sa.gov.au), 9am-4pm Monday-Friday (excluding Public Holidays).

RESEARCH  
**GEMS** SA

- a. If your account is set up, login with your username and password
  - i. If you have received an email but have not yet logged in before, click 'Reset your password' and enter the email address the original email went to
- b. If your account is not set up
  - i. Try logging in with your SA Health government email address (@sa.gov.au);
  - ii. If unsuccessful, then, click 'Register Now' and register your details using either your SA Health email or Institutional email (e.g. University email)
- c. Once you have successfully logged in, click 'Agree' to License Agreement Statement

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#### Licence agreement

This is a restricted system. Use of this system is monitored at all times and requires explicit permission from the system administrator. If you do not have this permission, you are violating the regulations of this system and can and will be prosecuted to the full extent of the law.

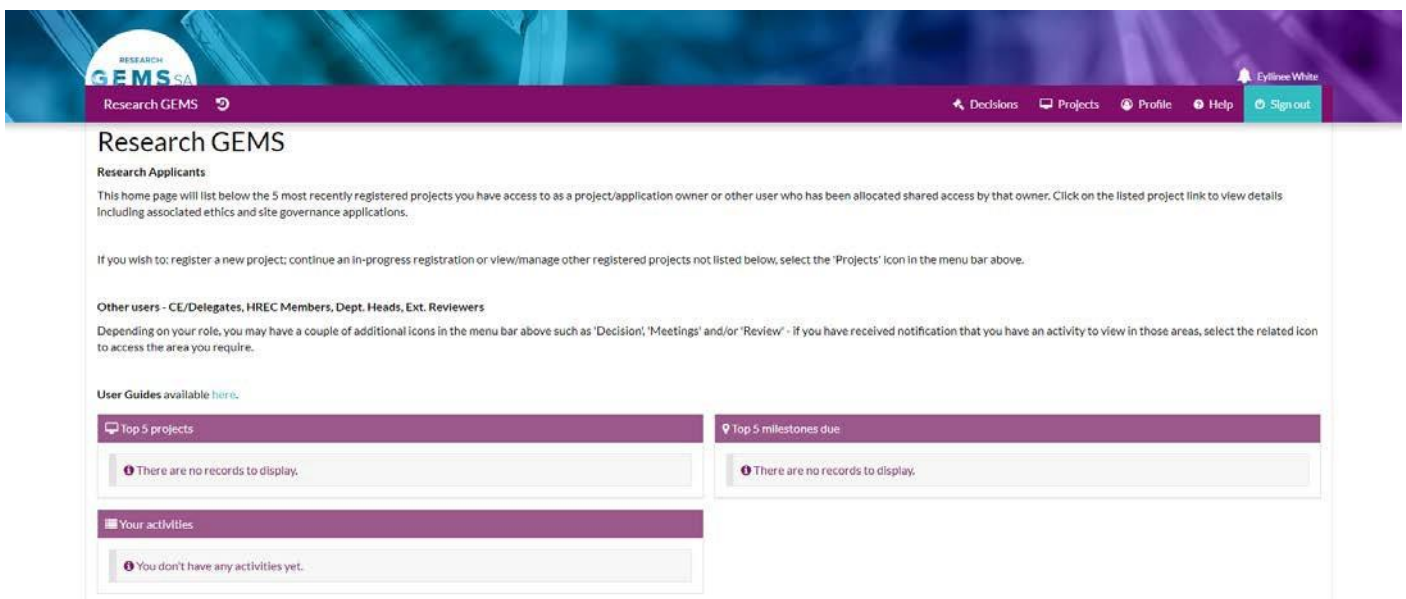
By continuing into this system, you are acknowledging that you are aware of and agree to these terms.

« Decline

✓ Agree

### 3. Registering your Project

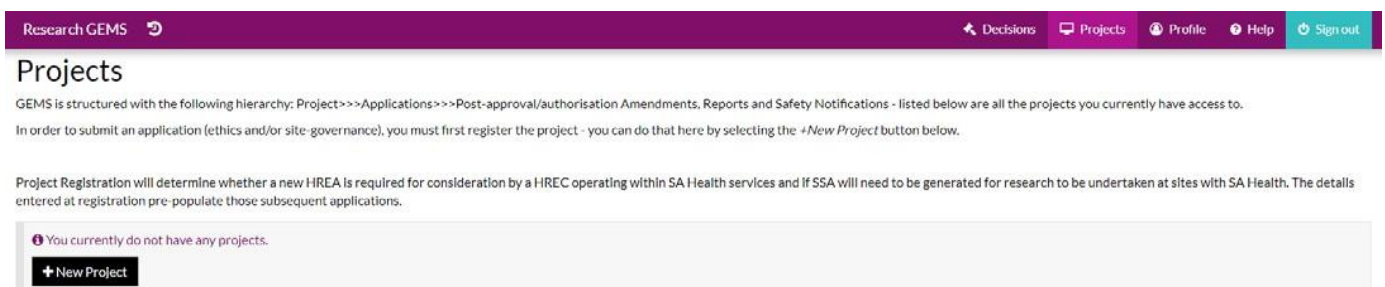
- a. You will now have been directed to the External Portal Homepage for Researchers / Research Personnel.



The screenshot shows the Research GEMS External Portal Homepage. The header includes the Research GEMS logo and a navigation bar with links for Decisions, Projects, Profile, Help, and Sign out. The main content area is titled 'Research GEMS' and contains sections for Research Applicants, Other users, and User Guides. Below these sections are two boxes: 'Top 5 projects' and 'Top 5 milestones due', both indicating 'There are no records to display.' At the bottom, there is a 'Your activities' section indicating 'You don't have any activities yet.'

- b. To register a project, navigate to the 'Projects' tab on the right hand corner

- c. Click 'New Project'



The screenshot shows the Research GEMS Projects page. The header includes the Research GEMS logo and a navigation bar with links for Decisions, Projects, Profile, Help, and Sign out. The main content area is titled 'Projects' and contains a hierarchy of Project >>> Applications >>> Post-approval/authorisation Amendments, Reports and Safety Notifications. Below this, there is a section for Project Registration, which states that a new HREA is required for consideration by a HREC operating within SA Health services and that SSA will need to be generated for research to be undertaken at sites with SA Health. At the bottom, there is a box indicating 'You currently do not have any projects.' and a '+ New Project' button.

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- d. Select 'Project Registration'

- e. This will then navigate you to the 'New Project Registration' Page on the 'Introduction' tab. Read this information, then click next.

- f. This will navigate through Tabs A-F.

- g. **Part A: Previous Ethics Application**

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Introduction	Part A: Previous Ethics Application	Preview Save Previous Next
Part A: Previous Ethics Application	<p>If an ethics application:</p> <p>Has never been previously submitted for this project to a NHMRC registered and/or certified HREC, select 'No' at question A1 - no further questions will be required in this section and you can proceed to Part B.</p> <p>Has previously had an ethics application submitted to a NHMRC registered and/or certified HREC, select 'yes' at question A1 and complete the additional questions displayed.</p> <p><b>A1 Has an application for ethics review of this project previously been submitted to a recognised HREC? *</b></p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>NOTE: SA Health now accepts Bellberry applications under a single ethical review policy, with the exception for paediatric studies.</p> <p>SA Health has current National Mutual Acceptance exclusions for Phase 0 and Phase 1 Clinical Trials. These must be reviewed by the local SA Health HREC responsible for the public health organisation where the clinical trial is taking place.</p> <p>The following details are required to identify the previous ethics application, the HREC to which it was submitted and whether it was submitted under the NMA arrangements which exist between a number of public health jurisdictions nationally. Outcomes or status of that previous application may be requested.</p> <p><b>A2 Ethics application ID *</b></p> <p>External Ethics</p> <p><b>A3 HREC Name *</b></p> <p>Austin Health Human Research Ethics Committee</p> <p><b>A4 HREC Code</b></p> <p>EC00204</p> <p><b>A5 Was/Is application being reviewed under the NMA scheme *</b></p> <p>Yes</p> <p><b>A6 Outcome or status *</b></p> <p>Approved</p> <p><b>A7 Date of written decision notification (email or letter) *</b></p> <p>11/02/2021</p>	
Part B: Project Details		
Part C: Research Site/s		
Part D: Coordinating Principal Investigator		
Part E: Upload Attachments		
Submit		

- For Internal (CALHN) ethics > Select 'No'
- For External ethics (under NMA) > Select 'Yes'
- Fill in External HREC details using text and drop down selector(s)

#### h. Part B: Project Details

- Fill in details related to your project
- Enter your Short Title or Protocol first – how you want to view it later on
- > click next

#### i. Part C: Research Site(s)

- This the step where you can invite other study personnel to register and have access to the project.
- Click 'Invite to register'
- Add another user
- Enter email address (SA government or institutional email addresses)
- Select what access they should have
  - Share with view access – will allow the user to view but not edit the project
  - Share with edit access – will allow the user to be able to make changes to the project
- Then click save and send
- Note:** If you make a mistake of adding someone, you can click the red trash can on the right-hand side to delete the invited user



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Local Health Network

Research GEMS

Decisions Projects Profile Help Sign out

## New Project Registration

Introduction

Part A: Previous Ethics Application

Part B: Project Details

**Part C: Research Site/s**

Part D: Coordinating Principal Investigator

Part E: Upload Attachments

Submit

### Part C: Research Site/s

In the tabbed sections below, you will be required to nominate the sites at which you intend to undertake the activities for the project you are registering. Depending on the details of your project, you may need to enter sites under more than one tab.

You can add a site under the required tab/s by selecting the '+' icon. For locations with SA Health, you will then select the relevant Centre/s and their associated site/s from pre-populated drop-down lists. For locations not operated by either government organisation, you will provide details as indicated.

If you wish to delete a site that you have listed below, select the tick box next to the Project Centre label and then select '-' in the gold bar below the section.

Before proceeding, please note: All PIs named in this section must have a GEMS user profile before you will be able to complete registration - as you enter the PI email address, GEMS will search for a match with a registered user.

If a match is found, their email address will display for you to select and their full name will be added below. As you progress, GEMS will prepopulate registration and subsequent applications with relevant details from their profile as required.

If no match is found, leave the PI email blank and select 'Invite to Register'. This will open a dialogue box for you to add the PIs username (email address) and, when you save the dialogue box to close, your PI will receive an invite to register in GEMS at the email address you've entered. Once they can confirm they have registered their profile, come back and complete your registration. In the meantime, select the next section to complete from the menu down the left-side of the page

Invite to Register

You must add at least one site in the below table.

If you are unsure of the Project Centre use this call to search SA site names in GEMS. Once you select the Project Site the Project Centre will appear. Use this information to complete the table below.

Royal Adelaide Hospital

Central Adelaide Local Health Network

SA Health

Other health jurisdictions or organisations

**Nominate the project site/s within SA Health and a Principal Investigator for each site**

A research project may be conducted at one or more sites within one or more Centres within SA Health.

A 'Centre' may be a Local Health Network (LHN), a Specialty Health Network, a Pillar organisation, an affiliated health organisation or other health organisation operated by SA Health. A Site Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (PI) is the person responsible either individually or as a leader of the researchers at a site, for the conduct of research at that site. In a single site research project or when a project does not require the appointment of a SA Health principal investigator, the coordinating principal investigator may also be the principal investigator. The PI is the only person who has the authority to submit the Site application. An incorrect response here may cause the application to be ineligible and will cause delay in processing.

If you are unsure of the names of the Centre or Site/s your project will be conducted at, please discuss with your local research office. An incorrect selection here can delay your application process.

Project centre \*

Project site \*

Principal Investigator email (GEMS username) \*

Principal Investigator name

+

-

?

Next

Invite user to register & manage access

The list of users currently assigned to this form are listed below

There are currently no users assigned to this form.

Add another user

Save and send Cancel

Invite user to register & manage access

The list of users currently assigned to this form are listed below

Send	Name	Username	Access status	Modify access
		Siana.Dimond@sa.gov.au	No current access	<div>Share with view access</div> <div>Share with view access</div> <div>Share with edit access</div>

User Siana.Dimond@sa.gov.au is found. A notification will be sent to this email address and the user will be able to access this application

Add another user

Save and send Cancel

- viii. Select the site you will be conducting the research at, when you begin to type the site should appear in the drop down selector box. This will then pre-fill the local health network next to the site name,

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- ix. Then fill in the 'Nominate the project site/s within SA Health and a PI for each site' section

Royal Adelaide Hospital Central Adelaide Local Health Network

**SA Health** Other health jurisdictions or organisations

**Nominate the project site/s within SA Health and a Principal Investigator for each site**  
A research project may be conducted at one or more sites within one or more Centres within SA Health. A 'Centre' may be a Local Health Network (LHN), a Specialty Health Network, a Pillar organisation, an affiliated health organisation or other health organisation operated by SA Health. A Site Specific Assessment (SSA) will be generated for each site nominated.

A Principal Investigator (PI) is the person responsible either individually or as a leader of the researchers at a site, for the conduct of research at that site. In a single site research project or when a project does not require the appointment of a SA Health principal investigator, the coordinating principal investigator may also be the principal investigator. The PI is the only person who has the authority to submit the Site application. An incorrect response here may cause the application to be ineligible and will cause delay in processing.

If you are unsure of the names of the Centre or Site/s your project will be conducted at, **please discuss with your local research office. An incorrect selection here can delay your application process.**

**Project centre \*** **Project site \***

Central Adelaide Local Health Network Royal Adelaide Hospital

Principal Investigator email (GEMS username) \* 2 Principal Investigator name

Siana.Diamond@sa.gov.au Siana Dimond

**Project centre \*** **Project site \***

Central Adelaide Local Health Network The Queen Elizabeth Hospital

Principal Investigator email (GEMS username) \* 2 Principal Investigator name

Eyllinee.BeckwithJurado@sa.gov.au Eyllinee White

+ - ☺

- x. To add multiple sites, select the "+" button in the bottom left-hand corner
- xi. You must always add your site and the PI in this section to be able to create an SSA
- xii. Then click next once you have finalised your sites and PI's
- j. **Part D – Coordinating Principal Investigator**
- i. Click 'yes' if you are the CPI or 'no' if not the CPI
1. If you selected 'no' – enter the email address of the CPI
  2. If it is external ethics, then enter the site PI's email address. Do not enter the CPI for all sites otherwise, they will have to make an account and sign off.
  3. If you selected 'yes' – this prepopulates to the account holder who is currently logged in and filling out the registration

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## New Project Registration

Introduction
Part A: Previous Ethics Application
Part B: Project Details
Part C: Research Site/s
**Part D: Coordinating Principal Investigator**
Part E: Upload Attachments
Submit

### Part D: Coordinating Principal Investigator

The Coordinating Principal Investigator (CPI) is

a) in relation to research conducted at a single site, the investigator for that site, or;

b) in relation to research conducted at more than one site, the individual, whether or not they are an investigator at any particular site, who takes primary responsibility for the conduct of the research

**Before proceeding, please note the following detail if you are not the CPI:** The CPI named in this section must have a GEMS user profile before you will be able to complete registration - as you enter the CPI email address, GEMS will search for a match with a registered user.

**If a match is found,** their email address will display for you to select and their full name will be added below. As you progress, GEMS will prepopulate registration and subsequent applications with relevant details from their profile as required. **If no match is found,** leave the CPI email blank and select 'Invite to Register'. This will open a dialogue box for you to add their username (email address) and, when you save the dialogue box to close, your CPI will receive an invite to register in GEMS at the email address you've entered. Once they can confirm they have registered their profile, come back and complete your registration. In the meantime, select the next section to complete from the menu down the left-side of the page.

**Invite to Register**

Are you the Coordinating Principal Investigator for this project? \*

The CPI is the person that holds overall responsibility for the study. They are the **only** person who has the authority to submit the Ethics application. An incorrect response here **WILL** cause the application to be Ineligible and will cause delay in processing.

Yes ☒ No ☐

CPI email (GEMS user name) \*

CPI name

ORCID

SA Health Employee Number (for SA Health staff only, if known)

Start typing to search if you selected No above.

**Next**

#### k. Part F – Upload Attachments

- i. If the reviewing HREC is an external HREC please only upload these documents:
  1. HREA
  2. HREC Approval Letter
  3. Protocol
- ii. All other supporting documentation should be uploaded to the Clinical Trials Share Drive to your specific clinical trial unit folder.
- iii. To upload documents, select the “+” button in the bottom left-hand corner
- iv. Select what document type it is from the drop down selector
- v. In ‘Document Descriptor’ please insert the naming convention you prefer your document to be labelled as
- vi. Fill in, ‘Version Number’ (please put N/A if there is none) and then the date of the document (please do not enter a random date as this will follow through your application)
- vii. Please note: there is a maximum file size of 20.00MB per file



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**Part E: Upload Attachments**

Submit

### Part E: Upload Attachments

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

This section has been included at Project Registration to ensure consistent naming of frequently required documents. All documents uploaded here will be automatically added to any subsequent ethics and/or site-specific application, as appropriate.

For those registrations which require upload of a previously submitted (external) ethics application

- Ethics approval letter (If available) Type = Ethics application decision notification, Version = 0, Date = Ethics approval date
- Approved documents can be individually uploaded or as a .zip file.
- If uploading individual documents Type = best available description, Version = as listed in approval letter (if none then 0), Date = as listed on approval letter (if none then today's date)
- If uploading as a .zip Type = Ethics application (HREA or other), Version = 0, Date = Ethics approval date letter please ensure all attachments included with the original application are included in that upload.

For those registrations which will submit to a SA HREC

- REGISTER ANY document you intend to submit to the HREC now. You can upload a draft document, documents can be updated, added and removed when completing the HREA.
- Type = best available description, Version = as listed on the document - usually the footer (if none or still draft then 0), Date = as listed on the document - usually the footer (if none then today's date)
- site-specific documents are not required to be uploaded here - only project-wide, master documents. Site-specific documents will be requested when completing the relevant site application form.

**FOR ALL REGISTRATIONS**

- Document descriptor should be in the following format: "short description of doc type-brief unique descriptor" (PISCF-Intervention, IB-DrugName) 20 characters max
- Maximum document size is 20MB (larger documents can be converted to a .zip)
- Total upload can not exceed 95MB. If your application exceeds this limit consider converting files to .zip or contact the research office managing the application for alternate document submission process.
- Uploading the same document multiple times e.g. Protocol at F1 and F2 may cause the system to crash.

Document type - please select from the list *	Document descriptor - your name for the file *	Document version *	Document date *
<div> <div>+</div> <div>-</div> </div>			

**Required documents not yet attached**

These documents have been identified as required to finalise your registration. As they are attached, they will be removed from the list.

Ethics application (HREA or other)

Ethics application decision notification

Next

- viii. Then upload the document by selecting "Select upload new" > Choose the file > Select the file > Open > Start Upload
- ix. Then click the (+) button to add upload additional documents via the same method
- x. Click 'Next' once all the documents have been uploaded

## I. Submit

Research GEMS

Decisions Projects Profile Help Sign out

## New Project Registration

Introduction

Part A: Previous Ethics Application

Part B: Project Details

Part C: Research Site/s

Part D: Coordinating Principal Investigator

Part E: Upload Attachments

**Submit**

### Submit

When you select the Complete Registration button below, GEMS will check whether your registration is complete and if so, will generate subsequent applications depending on your responses to the registration questions.

If a HREA is listed below, this will be generated prior to any Site/SSA applications that might be required for site governance at SA Health site - SSA/s in this instance will be generated on submission of the HREA.

If no HREA is required and a Site/SSA is to be generated for a SA Health site, the SSA will be generated immediately.

**PROJECT REGISTRATION CANNOT BE CHANGED ONCE IT IS SUBMITTED.**

BEFORE YOU CLICK "COMPLETE REGISTRATION" MAKE SURE YOU CAN SEE EACH TYPE OF APPLICATION YOU EXPECT TO BE CREATED IN GEMS.

If you are submitting a HREA to a SA HREC you should see "A HREA" below.

If you are submitting to a SA site EACH site selected under the SA tab at Part B should be listed below.

If you do not see the information expected below please refer to the [Research GEMS User Guides for completing Project Registration](#)

**The following applications will be generated:**

SSA for each of the following SA Health sites:

Royal Adelaide Hospital, Siana Dimond (PI)

The Queen Elizabeth Hospital, Eyllinee White (PI)

Complete Registration

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- i. Please double check your project registration is correct before you submit it, as you **can't** make edits to it once it has been submitted
- ii. When satisfied the registration information entered is correct, click 'Complete Registration'
- iii. Following submission, you will be returned to the Projects page, and your project will be viewable in a list and the status will display as 'In Progress'

Research GEMS

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## Projects

GEMS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation Amendments, Reports and Safety Notifications - listed below are all the projects you currently have access to.

In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by selecting the *+New Project* button below.

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within SA Health services and if SSA will need to be generated for research to be undertaken at sites with SA Health. The details entered at registration pre-populate those subsequent applications.

Below are your projects. Click the link to open and manage your project.

+ New Project

Export CSV

Show 10 entries

Search:

Title	Identifier	Status	Ethics approved	Expiry date	Principal organisation	Overdue milestones	Revision milestones	Total milestones
<a href="#">029926 - Project Registration</a>		In Progress				0	0	0

Showing 1 to 1 of 1 entries

[< Previous](#)
[1](#)
[Next >](#)

- iv. You are now able to create your SSA.
- v. Click on your project title which is in light blue and this will navigate you to your 'Applications' page for that project
- vi. **Please note:** All sites that you have added will be displayed and their progress status

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## Site Specific Assessment

- A. Once you have submitted the project registration, you can proceed to creating the SSA/filing in information
- Please note:** the coordinator/research personnel can add information to the SSA, however only the PI will be able to submit the SSA

The screenshot shows the Research GEMS web application. The top navigation bar includes links for Decisions, Projects, Profile, Help, and Sign out. The left sidebar contains a 'Project' icon and a list of menu items: Project details, Applications (selected), Contacts, Details, Documents, and History. The main content area is titled '2021/GEM00076 - EVALUATION OF RESEARCH OFFICE'. It contains instructions on how to find project details, the status of applications, and how to access Post Approval Forms. A '+ New Site' button is visible. Below this is the 'Applications' section, which includes an 'Export CSV' button, a 'Show 10 entries' dropdown, and a search bar. A table lists two applications:

Identifier	Title	Comments	Version	Status	Owner	Created date
2021/SSA00063	Evaluation of Research Office - Royal Ad...		1.00	In Progress	Siana Dimond	11/02/2021 10:22:39 AM
2021/SSA00064	Evaluation of Research Office - The Que...		1.00	In Progress	Eylinee White	11/02/2021 10:22:43 AM

Showing 1 to 2 of 2 entries

- Click on your identifier number (e.g. 2021/SSA000XX)
- This will then prompt you to fill in the SSA

## B. Part A – Project Wide Information

- Most of this section is pre-filled from the Project Registration
- Please check the details to ensure they are correct
- Please note: If this is a clinical trial, please use the items 'Clinical Trial Phase – Phase X' do not use the class phases.
- Then proceed to click "Next"

## C. Part B – Site Team

- This is where you will add in details about your Investigator(s)
- Please ensure you enter the correct phone number (not the hospital switch board number), position, employer and department
- Please Note:** Employer must be CALHN and not RAH/TQEH
- In B7 – You can add 1 administrative staff to receive correspondence about the study (this should be the main study coordinator)
- In B8 – Add site team members (associate investigators)
- Provide the details requested then click 'Next'
- The next tabs will be about the Investigators/Study Team you have added, please fill in these details and click "Next" once complete

## D. Part C – Departments & Services

- This is where you will add the Lead Department
  - Select the drop down list and click on the appropriate Department for your project: **Example:** RAH: Cancer: Haematology



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2. Please leave C2 and C3 blank
- ii. Add any other Supporting Departments the same way as above and obtain their approval outside of GEMS.

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**Part B: Site Team** ✓

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

**Part C: Departments and Services**

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

In this section, please specify all departments/locations involved in the research at this site where resource/s (staff, service/s and/or investigations) will be used – a 'department head' will need to be identified against each nominated department.  
Please note: the 'Head of Department' for any SA Health staff undertaking roles of either PI or back-up PI (an Associate Investigator) for this project at this site must be listed in this section.

In this section, please specify all departments/locations/divisions/units where resource/s (staff, service/s and/or investigations) will be used. Please note the 'Head of Department' terminology is synonymous with 'Divisional Director', 'Head of Unit' or 'Medical Lead' depending on the Local Health Network. If you are unsure which department heads you need to approach – please discuss with your research office before completing this application. If you are accessing pharmacy services, please ensure you include pharmacy department approvals.

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit. Therefore, it is also important that you have approached the department head before completing this application to discuss the project and what it is you are requesting them to support. Depending on the project, this may include but is not limited to: allocation of staff time; use of facilities and/or equipment and/or access to data/records. While some projects may be funded to support their activities, others may require in-kind support.

If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.

C1. Department \*

No department head can be found for the selected department.

C2. Department Head Name

C4. Please state the resources (e.g. staff, service/s, investigations etc) you require this department to provide: \*

C5: Please specify if this is the lead department or supporting department? \*

Lead

- iii. Naming conventions can be seen here:

Research GEMS

Decisions Projects Profile Help Sign out

**Part B: Site Team** ✓

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

**Part C: Departments and Services**

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

In this section, please specify all departments/locations involved in the research at this site where resource/s (staff, service/s and/or investigations) will be used – a 'department head' will need to be identified against each nominated department.  
Please note: the 'Head of Department' for any SA Health staff undertaking roles of either PI or back-up PI (an Associate Investigator) for this project at this site must be listed in this section.

In this section, please specify all departments/locations/divisions/units where resource/s (staff, service/s and/or investigations) will be used. Please note the 'Head of Department' terminology is synonymous with 'Divisional Director', 'Head of Unit' or 'Medical Lead' depending on the Local Health Network. If you are unsure which department heads you need to approach – please discuss with your research office before completing this application. If you are accessing pharmacy services, please ensure you include pharmacy department approvals.

A pre-populated declaration of support for each nominated department head (including a complete copy of this SSA and its attachments) will be generated on completion of this SSA utilising the information in this section. Each Head will be notified by email of the need for them to respond to the support request you submit. Therefore, it is also important that you have approached the department head before completing this application to discuss the project and what it is you are requesting them to support. Depending on the project, this may include but is not limited to: allocation of staff time; use of facilities and/or equipment and/or access to data/records. While some projects may be funded to support their activities, others may require in-kind support.

If you are unsure which department heads you need to approach – please discuss with your research office before completing this application.

C1. Department \*

RAH: Acute and Urgent Care: Geriatrics

Glenside: Mental Health: Inpatient Mental Health

Hampstead: Neuroscience & Rehabilitation: General Rehabilitation

Hampstead: Neuroscience & Rehabilitation: SA Brain Injury Rehabilitation Service

Hampstead: Neuroscience & Rehabilitation: SA Spinal Cord Injury Services

RAH: Mental Health: Allied Health

RAH: Acute & Urgent Care: Allied Health

RAH: Acute & Urgent Care: Medical

RAH: Acute & Urgent Care: Nursing

RAH: Acute and Urgent Care: Acute Assessment Unit(s)

RAH: Acute and Urgent Care: Burns Service

RAH: Acute and Urgent Care: Emergency Department

RAH: Acute and Urgent Care: General Medicine

RAH: Acute and Urgent Care: Geriatrics

RAH: Acute and Urgent Care: Patient Flow & RAH/TQEH Afterhours

RAH: Acute and Urgent Care: Trauma Service

RAH: Cancer: Adolescents & Young Adults

RAH: Cancer: Allied Health

RAH: Cancer: Haematology

RAH: Cancer: Medical

User Guides SA Health Internet Hospital Research Foundation



# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



#### E. Part D – Recruitment, Records, Tissue & Data

- Answer questions 'Yes' or 'No' from D1 to D11
- For D11, "Do you have any agreements or contracts for this project?" please select "NO"

#### F. Part E – Site Costing and Funding

- Click 'Yes' or 'No' as applicable.

#### G. Part F – Attachments/Site Specific Documents

- As documents were previously uploaded to the project registration (e.g. HREA, HREC Approval and Protocol) you do not need to upload any further documents at this stage. However, you should at this stage create the study folder in the Clinical

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



**Health**  
Central Adelaide  
Local Health Network

- Trials Share Drive and save all supporting documentation in it (with declarations)
- ii. Check that the documents did come across from the project registration as it should appear as below
- iii. Then click 'Next'

Research GEMS

Decisions Projects Profile Help Sign out

### 2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

Part A: Project-Wide Information ✓  
Part B: Site Team ✓  
Site project team members details  
(1) Jan-Louise Durand, Associate Investigator  
Part C: Departments and Services ✓  
Part D: Recruitment, Records, Tissue and Data ✓  
Part E: Site Costing and Funding ✓  
**Part F: Attachments – Site Specific Documents**  
Part G: Declaration

#### Part F: Attachments – Site Specific Documents

Document Title: Hrea-1-10-FEB-2021

Document type: Ethics application (HREA or other) [Clear content selection \(GEMS steps.docx\)](#) [Open](#)

Document type *	Document descriptor *	Document version *	Document date *
Ethics application decision notifi	Approval Letter	1	10/02/2021

[Clear content selection \(Research GEMS.docx\)](#) [Open](#)

Maximum file size is 20.00 MB

[Next](#)

#### H. Part G – Declaration

- i. As the PI has to submit the SSA, if you are not the PI completing the SSA you will need to save the application by clicking 'Save' in the top right-hand corner. You will then need to notify the PI that the SSA is ready to be submitted (the PI's email address is on the declaration page – please ensure this is the same email address for their GEMS login)

Research GEMS

Decisions Projects Profile Help Sign out

### 2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

Part A: Project-Wide Information ✓  
Part B: Site Team ✓  
Site project team members details  
(1) Jan-Louise Durand, Associate Investigator  
Part C: Departments and Services ✓  
Part D: Recruitment, Records, Tissue and Data ✓  
Part E: Site Costing and Funding ✓  
Part F: Attachments – Site Specific Documents ✓  
**Part G: Declaration**

#### Part G: Declaration

G1 Declaration by the Principal Investigator responsible for the site

By clicking the button below I confirm that:

- the information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site;
- all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any emergencies and contingencies related to the research that may arise;
- I will ensure all team members receive any additional relevant training as required;
- I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Office and, that this will not be before evidence is received by them (provided by me) of ethics approval by an appropriate Human Research Ethics Committee (HREC);
- I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the Responsible Conduct of Research (as amended) and, where applicable, Note for Guidance on Good Clinical Practice.
- If authorised to undertake this project at Royal Adelaide Hospital (this site),
  - I will inform the Research Office if the research project ceases before the expected date;
  - I will discontinue the research at this site if the HREC withdraws ethical approval;
  - I will adhere to the conditions of authorisation stipulated by the authorising authority at this site including any monitoring/reporting requirements;
  - I will discontinue the research at this site if the authorising authority withdraws authorisation;
- I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit and monitoring purposes, AND
- I understand that information relating to this research, and about me as an investigator, will be held within SA Health information systems and other local data collections. This information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cwth) and relevant laws in the States and Territories of Australia.

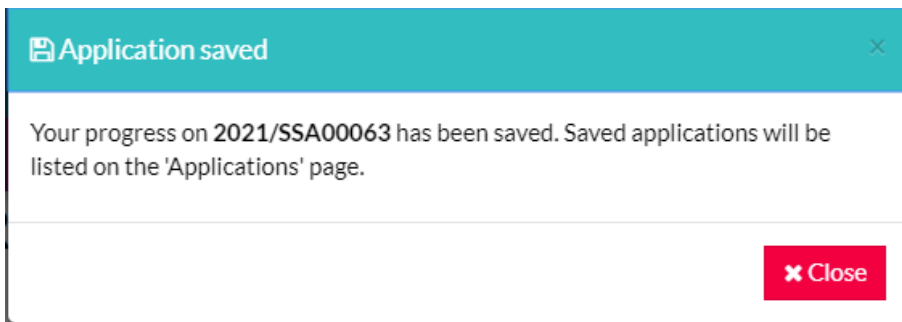
Name of Principal Investigator  
Siana Dimond  
Siana.Dimond@sa.gov.au

- ii. Once you hit save, a pop up box will appear which states the below:

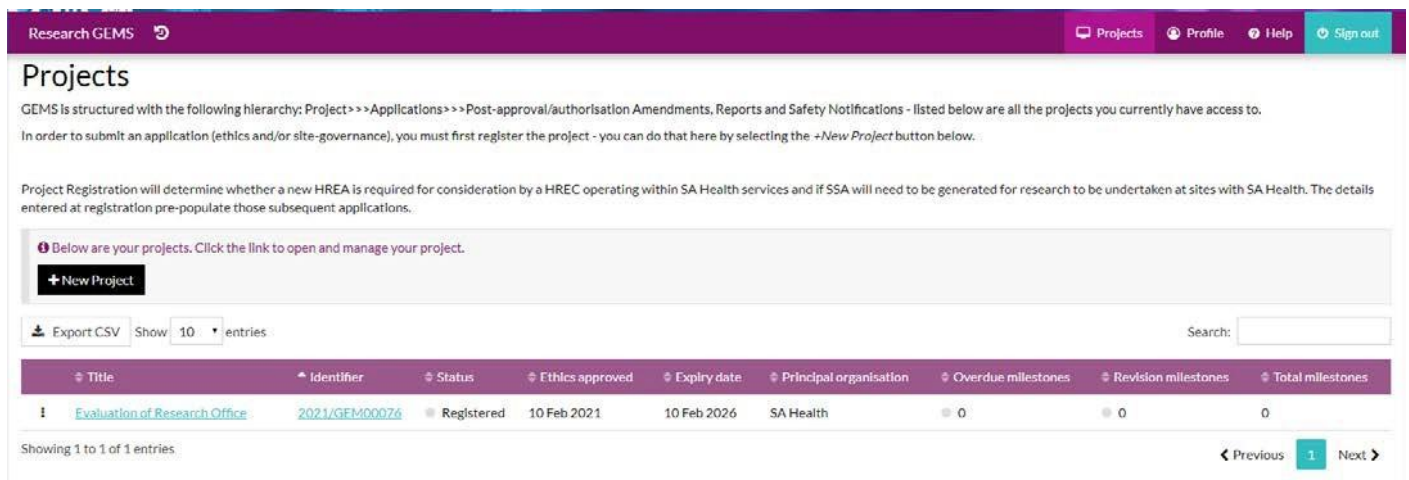
# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



- iii. The project should then appear in the PI's project list when they log in. To access the projects section, click 'Projects' on top right-hand corner



- iv. Once PI has logged in, they need click on the 'Title' (Project that is applicable for the submission)
- v. Then click SSA application that you are the PI for (your/their site)
- vi. Click the blue Identifier title of your application – this will only let you choose your own site to submit. You will not be able to submit other PI's SSA's
- vii. This will then take the PI directly to Section G – Declaration, where the PI needs to select 'Complete SSA'

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



**Health**  
Central Adelaide  
Local Health Network

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2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

Part A: Project-Wide Information

Part B: Site Team

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

Part G: Declaration

G1 Declaration by the Principal Investigator responsible for the site  
By clicking the button below I confirm that:  
1. the information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site;  
2. all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any emergencies and contingencies related to the research that may arise;  
3. I will ensure all team members receive any additional relevant training as required;  
4. I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Office and, that this will not be before evidence is received by them (provided by me) of ethics approval by an appropriate Human Research Ethics Committee (HREC);  
5. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the Responsible Conduct of Research (as amended) and, where applicable, Note for Guidance on Good Clinical Practice.  
6. If authorised to undertake this project at Royal Adelaide Hospital (this site),  
a. I will inform the Research Office if the research project ceases before the expected date;  
b. I will discontinue the research at this site if the HREC withdraws ethical approval;  
c. I will adhere to the conditions of authorisation stipulated by the authorising authority at this site including any monitoring/reporting requirements;  
d. I will discontinue the research at this site if the authorising authority withdraws authorisation;  
7. I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit and monitoring purposes, AND  
8. I understand that information relating to this research, and about me as an investigator, will be held within SA Health information systems and other local data collections. This information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cwth) and relevant laws in the States and Territories of Australia.

Name of Principal Investigator  
Siana Dimond  
Siana.Dimond@sa.gov.au

Complete SSA

Preview
Save
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viii. This will then process

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2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

GEMS is creating your documents in the background, this may take a few minutes. Please don't refresh or navigate away from this page.

Please Wait


ix. A pop-up box will appear (as below) then click 'Next'



# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission

 Application submission


Select the application attachments you wish to download:

[All application forms and attachments \(.zip\)](#)

*This package of files contains your application content, attachments, and other files supporting your application.*

> Next

- x. Another pop-up box will appear to let you know the project has successfully been submitted > click close

 Application submission

The application **2021/SSA00063** has been successfully generated.

Your application has been successfully submitted. Thank you for your application. To continue please click the close button.

< Back

✕ Close

- xi. The status of the project should then change from 'In Progress' to 'Submitted'

Research GEMS

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History

## 2021/GEM00076 - EVALUATION OF RESEARCH OFFICE

Details relating to your Project can be found on this page.

Once the status of an Ethics or Governance application is Approved/Authorised, various Amendments may need to be raised to support your application.

Click on the 3 vertical dots next to the relevant study, and select Project Information to access the available Post Approval Forms for your application.

For further information on other functions, such as adding new sites or sharing your application, please refer to the [Research GEMS User Guides](#).

### Applications

Export CSV
Show 10 entries
Search:

Identifier	Title	Comments	Version	Status	Owner	Created date
2021/SSA00063	Evaluation of Research Office		1.00	Submitted	Siana Dimond	11/02/2021 10:22:39 AM
2021/SSA00064	Evaluation of Research Office - The Qu...		1.00	In Progress	Eylinee White	11/02/2021 10:22:43 AM

Showing 1 to 2 of 2 entries

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1
Next

**CALHN Research Services - Research GEMS Guidelines  
Commercially Sponsored Clinical Trials – NMA Ethics  
Preparing Project Registration and SSA Submission**



**Health**  
Central Adelaide  
Local Health Network

- xii. Please email [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au) to notify CALHN Research Services that your application has been submitted and is ready for processing

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



## Hints / Tips / Key Points

### Project Registration

<b>Project Registration</b>	<p><u>Login/Register:</u></p> <ul style="list-style-type: none"> <li>• <a href="https://gems.sahealth.sa.gov.au/">https://gems.sahealth.sa.gov.au/</a></li> </ul> <p><u>Projects Page:</u></p> <ul style="list-style-type: none"> <li>• View all projects that you have created or are assigned to you</li> <li>• Add new project</li> <li>• The first step in initiating your human research project in GEMS is to register it. By completing a project registration, GEMS will identify if a Human Research Ethics Application (HREA) or Site Application (SSA), or both, are required.</li> <li>• Before you begin your application ensure that you have your project details, research site information, PI details and documentation ready.</li> </ul>
<b>Part A: Previous Ethics Applications</b>	<p><u>External Ethics Approval</u></p> <ul style="list-style-type: none"> <li>• Once submitted GEMs will create a SSA application for each SA Health site added</li> </ul> <p><u>Internal Ethics Approval (CALHN HREC)</u></p> <ul style="list-style-type: none"> <li>• The project has not been previously submitted to a recognised HREC (in GEMS)</li> <li>• Once submitted GEMs will create a HREA application and a SSA application for each SA Health site added</li> </ul>
<b>Part B: Project Details</b>	<ul style="list-style-type: none"> <li>• Ensure everything is entered precisely. <u>After submission you will not be able to edit your project registration.</u></li> </ul>
<b>Part C: Research Site(s)</b>	<ul style="list-style-type: none"> <li>• The Owner/PI has the responsibility for the study at the site and is the only person who can submit the Site/SSA Application. This responsibility cannot be delegated to another role or user.</li> <li>• The person who created Project Registration (if different to the PI) is allocated automatic shared – edit access to the site application and is also able to share the application with other users.</li> <li>• Ability to share application, “Invite to Register”- Select the level of access you are requesting for the user. If the email address is recognised as a registered GEMS account a message will pop up and you will be guided to Share.</li> <li>• Add all SA Health Sites for your project</li> <li>• If you miss a site and submit the project registration, you must add it as a site amendment. <ul style="list-style-type: none"> <li>◦ <u>Do not use the “New Site” button above “Applications”.</u> If you use this method, you will have to withdraw the SSA created and re-submit using the site amendment method</li> </ul> </li> </ul>
<b>Part D: Coordinating Principal Investigator</b>	<ul style="list-style-type: none"> <li>• If you are the CPI, select ‘yes’.</li> <li>• If you are not the CPI, select ‘no’ and enter the email address of the CPI. If the CPI is listed in GEMS their email address will appear for selection. If the CPI is not listed in GEMS, you will need to invite them to register before you can complete registration.</li> </ul>

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



	<ul style="list-style-type: none"> <li>If you do not assign the correct the CPI, this will have a flow on effect and will delay your application</li> </ul>
<p><b>Part F: Upload Attachments</b></p>	<ul style="list-style-type: none"> <li>For external ethics: <ul style="list-style-type: none"> <li>Upload External HREC approval letter, HREA and protocol.</li> </ul> </li> <li>Please note: GEMs will not allow the project to be submitted if the documents have not been uploaded <ul style="list-style-type: none"> <li>The supporting documentation is uploaded to the Clinical Trials Share Drive</li> </ul> </li> <li>Please note: there is a maximum file size of 20.00MB to upload per file</li> </ul>
<p><b>Submit</b></p>	<ul style="list-style-type: none"> <li>Before you “Complete Registration” ensure all documents have been uploaded and all sites have been added</li> <li>On this page you can see the applications that will be generated from your project registration</li> </ul> <div data-bbox="574 786 1246 1046"> <p>The following applications will be generated:</p> <p><i>SSA for each of the following SA Health sites:</i></p> <p>Royal Adelaide Hospital, Siana Dimond (PI)</p> <p>The Queen Elizabeth Hospital, Eyllinee White (PI)</p> </div>



# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



#### SSA Application

<b>SSA Application</b>	The coordinator/research personnel can add information to the SSA, however only the PI will be able to submit the SSA
<b>Part A: Project Wide Information</b>	<ul style="list-style-type: none"> <li>This section will be prefilled- the information will be taken from your project registration</li> <li>Ensure all the details are correct</li> </ul>
<b>Part B: Site Team</b>	<ul style="list-style-type: none"> <li>Add site team members and administrative staff. Please add staff in who will also be actioning post-approval monitoring</li> <li>For all clinical trials, please nominate one associate investigator (AI) who will act as a back-up/substitute for the site PI if they are not able to be contacted. You will not be able to proceed to the next step without adding an AI.</li> <li>Please note: You must add in an AI to progress forward with the site application. You can select the PI again if there is none.</li> </ul>
<b>Part C: Departments &amp; Services</b>	<ul style="list-style-type: none"> <li>This is where you will add the Department and any Supporting Departments.</li> <li>These approvals will need to be obtained outside of GEMS via email</li> </ul>
<b>Part D: Recruitment, Records, Tissue &amp; Data</b>	<ul style="list-style-type: none"> <li>Send agreements via email to <a href="mailto:Health.CALHNClinicalTrials@sa.gov.au">Health.CALHNClinicalTrials@sa.gov.au</a></li> <li>Under "Agreement Location" please select "No"</li> </ul>
<b>Part E: Site Costing &amp; Funding</b>	<ul style="list-style-type: none"> <li>Select "Yes" or "No" as applicable</li> </ul>
<b>Part F: Attachments/Site Specific Documents</b>	<ul style="list-style-type: none"> <li>The HREA, HREC Approval and Protocol should be automatically attached from the Project Registration. Check that the documents are attached.</li> <li>Create a study folder in the Clinical Trials Share Drive and save any supporting documents and declarations to folder</li> </ul>
<b>Part G: Declaration</b>	<ul style="list-style-type: none"> <li>The PI or delegate will be able to submit the SSA</li> <li>PI's will not be able to submit SSA's assigned to another PI</li> </ul>

# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – NMA Ethics Preparing Project Registration and SSA Submission



## Approval / Authorisation Delegation

You will need to provide the Head of Department declaration in your supporting documents (uploaded to the share drive).

## Correspondence

Email template to notify CALHN Research Services once completed application has been submitted via Research GEMS:

Dear CALHN Research Services,

Site Unit Name (e.g. RAH Medical Oncology) has now submitted a SSA for the below study:

<b>Project Title:</b>	XXX
<b>Protocol:</b>	XXXX
<b>Principal Investigator:</b>	XXX
<b>Program Directory:</b>	XXX
<b>HREC Reference Number:</b>	202X/HREXXXXX or External HREC Number
<b>SSA Reference Number:</b>	202X/SSAXXXXX
<b>CALHN Reference Number:</b>	MYIPXXXXX

You can find the supporting documentation located here: <provide link to share drive>

<insert email signature>

\*ensure telephone number is on this email in case we need to call you

## Links & Resources

For more resources and general information about Research GEMS please visit the SA Health website where information is continually being updated:

<https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/research+gems/research+gems+user+guides>

Resources include:

- **General User guides**
  - Creating and managing a user account
  - Updating username and password
  - Status definitions and glossary
- **Researcher User guides**
  - Project Registration
    - Project Registration guide
    - Sharing access to a project
    - Withdrawing an application
    - Guidance for COVID-19 data collection
  - Ethics Applications
    - Resubmitting an ineligible application
    - Downloading your ethics application

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – NMA Ethics

### Preparing Project Registration and SSA Submission



- Ethics Post Monitoring Approvals (Amendments, Safety and Progress Reports)
  - Completing and submitting an ethics amendment
  - Responding to an amendment information request
  - Submitting an annual progress or final report (milestone)
  - Submitting a clinical safety report
- Governance Application
  - Resubmitting an ineligible application
  - Creating a new site application
  - Completing, requesting and submitting Head of Department Support
  - Head of Department – Not supported
  - Completing the site application part C: department and services guide
- Governance: Post-approval (amendments, local safety reports, progress reports)
  - Completing and submitting a site amendment
  - Responding to a site information request
  - Submitting a governance milestone
  - Submitting a clinical trial safety report

## Contact Details

For all technical errors/issues and feedback, please contact the Research GEMS Project team at:  
[gems@sa.gov.au](mailto:gems@sa.gov.au)

For all study related questions in regards, please contact CALHN Research Services:  
[Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au) or [Health.CALHNResearchGovernance@sa.gov.au](mailto:Health.CALHNResearchGovernance@sa.gov.au)