

## 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 require CALHN HREC to be the Reviewing HREC Committee for a study. Please note: All Phase 1 studies are exempt from the National Mutual Acceptance scheme within South Australia. Therefore, all Phase 1 studies that are being conducted at a CALHN site must have CALHN HREC approval.

## Scope

This guideline will help to achieve the following:

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

## Definitions & Acronyms

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

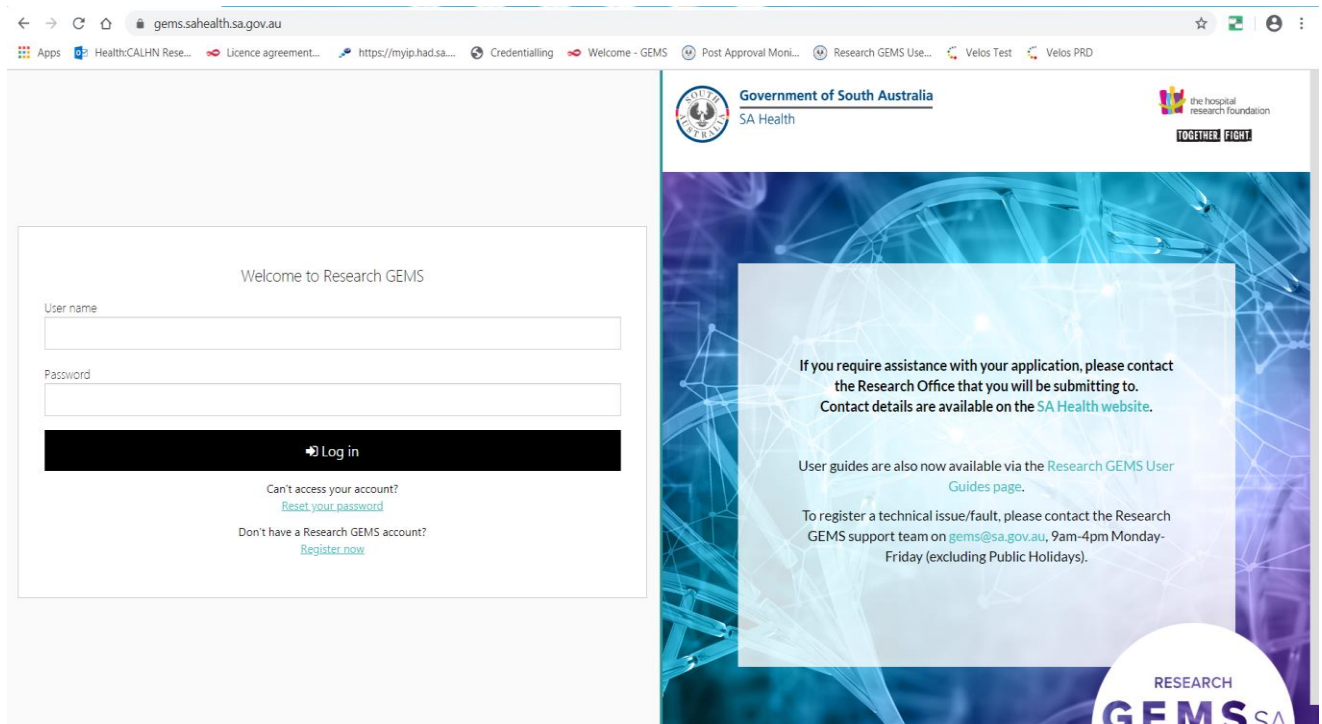
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## Procedures

### 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



The screenshot shows the Research GEMS login page. On the left, there is a login form with fields for 'User name' and 'Password', a 'Log in' button, and links for 'Reset your password' and 'Register now'. On the right, there is a large blue banner with white text providing contact information for the Research Office and user guides. The banner includes the Government of South Australia logo and the SA Health logo. The text on the banner reads: '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, 9am-4pm Monday-Friday (excluding Public Holidays).' The banner also features the 'RESEARCH GEMS SA' logo.

- 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

#### 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.

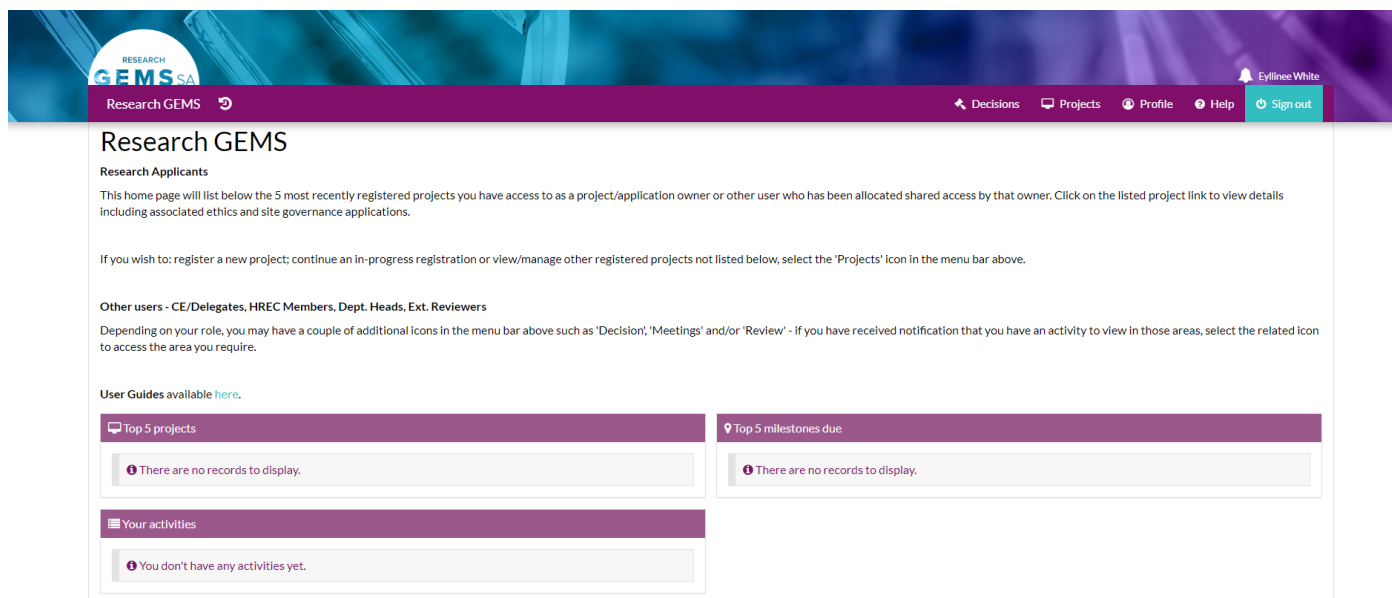
By continuing into this system, you are acknowledging that you are aware of and agree to these terms.

« Decline

✓ Agree

### 3. Registering your Project

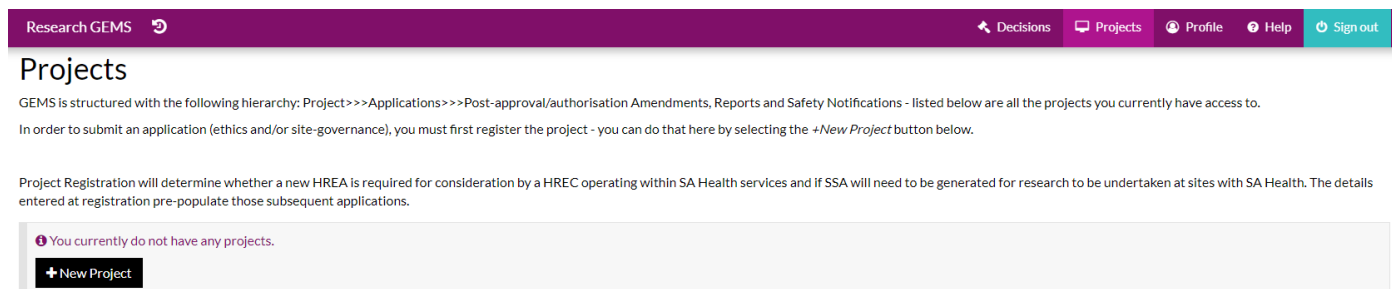
- You will now have been directed to the External Portal Homepage for Researchers / Research Personnel.



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 includes a 'Research Applicants' section with a description of the page's purpose. Below this, there are instructions for registering a new project or viewing existing ones. A section for 'Other users' lists roles like CE/Delegates, HREC Members, and Dept. Heads. There are also links to user guides. The page features three summary boxes: 'Top 5 projects' (no records), 'Top 5 milestones due' (no records), and 'Your activities' (no activities yet).

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

- 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 includes a description of the project hierarchy. Below this, there are instructions for submitting an application. A section for 'Project Registration' explains the process. At the bottom, there is a message stating 'You currently do not have any projects.' and a '+ New Project' button.

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – CALHN Ethics

### Preparing Project Registration, HREA & SSA Submission



Health  
Central Adelaide  
Local Health Network

- 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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- i. For Internal (CALHN) ethics > Select 'No'
- h. **Part B: Project Details**
  - i. Fill in details related to your project
  - ii. Enter your Short Title or Protocol first – how you want to view it later on
  - iii. > click next
- i. **Part C: Research Site(s)**
  - i. This the step where you can invite other study personnel to register and have access to the project.
  - ii. Click 'Invite to register'
  - iii. Add another user
  - iv. Enter email address (SA government or institutional email addresses)
  - v. 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
  - vi. Then click save and send
  - vii. **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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## Commercially Sponsored Clinical Trials – CALHN Ethics

### Preparing Project Registration, HREA & SSA Submission



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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 'X' 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 PI's 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 cell 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

+

-

X

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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Preparing Project Registration, HREA and SSA Submission – CALHN Ethics – Commercially Sponsored Clinical Trials

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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 \***

Central Adelaide Local Health Network ▼

**Project site \***

Royal Adelaide Hospital ▼

**Principal Investigator email (GEMS username) \* ?**

Siana.Diamond@sa.gov.au

**Principal Investigator name**

Siana Dimond

**Project centre \***

Central Adelaide Local Health Network ▼

**Project site \***

The Queen Elizabeth Hospital ▼

**Principal Investigator email (GEMS username) \* ?**

Eyllinee.BeckwithJurado@sa.gov.au

**Principal Investigator name**

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
- If you selected 'no' – enter the email address of the CPI
  - If you selected 'yes' – this prepopulates to the account holder who is currently logged in and filling out the registration

## New Project Registration

Introduction	Part D: Coordinating Principal Investigator	Preview Save Previous Next
Part A: Previous Ethics Application	<p>The Coordinating Principal Investigator (CPI) is</p> <p>a) in relation to research conducted at a single site, the investigator for that site, or;</p> <p>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</p> <p><b>Before proceeding, please note the following detail if you are not the CPI:</b> 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.</p> <p><b>If a match is found,</b> 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. <b>If no match is found,</b> 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.</p> <p><b>Invite to Register</b></p> <p>Are you the Coordinating Principal Investigator for this project? *</p> <p>The CPI is the person that holds overall responsibility for the study. They are the <b>only</b> person who has the authority to submit the Ethics application. An incorrect response here <b>WILL</b> cause the application to be Ineligible and will cause delay in processing.</p> <p>Yes <input checked="" type="radio"/> No</p> <p>CPI email (GEMS user name) * CPI name ORCID SA Health Employee Number (for SA Health staff only, if known)</p> <p>Start typing to search if you selected No above.</p>	
Part B: Project Details		
Part C: Research Site/s		
Part D: Coordinating Principal Investigator		
Part E: Upload Attachments		
Submit		

### k. Part F – Upload Attachments

- Where CALHN is the Reviewing HREC please upload the:
  - Protocol
- All other supporting documentation should be uploaded against the HREA.
- To upload documents, select the “+” button in the bottom left-hand corner
- Select what document type it is from the drop down selector
- In ‘Document Descriptor’ please insert the naming convention you prefer your document to be labelled as
- 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)
- Please note: there is a maximum file size of 20.00MB per file



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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 F: Upload Attachments**

Submit

### Part F: 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

Projects Profile Help Sign out

## Project Registration

Introduction

Part A: Previous Ethics Application

Part B: Project Details

Part C: Research Site/s

Part D: Coordinating Principal Investigator

Part F: 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:**

A HREA

SSA for each of the following SA Health sites:

Royal Adelaide Hospital, Lauren Chartier (PI)

Complete Registration

# CALHN Research Services - Research GEMS Guidelines

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- 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
- As CALHN is the Reviewing HREC – check that 'A HREA' is listed as well as an SSA to ensure you have completed the registration correctly.
- When satisfied the registration information entered is correct, click 'Complete Registration'
- 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

Decisions Projects Profile Help Sign out

## 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

- You are now able to complete your HREA and then SSA.
- Click on your project title which is in light blue and this will navigate you to your 'Applications' page for that project
  - Click on your project title which is in light blue and this will navigate you to your 'Applications' page for that project
  - HREA can now be completed by clicking on the 2021/HRE000XX application in light blue

Research GEMS

Projects Profile Help Sign out

**Project**

Project details

Applications

Contacts

Details

Documents

History

## 2021/GEM00123 - X

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	Modified date
<a href="#">2021/HRE00085</a>	x - HREA		1.00	In Progress	Lauren Chartier	24/02/2021 08:54:26 AM	24/02/2021 08:54:26 AM

Showing 1 to 1 of 1 entries

Previous 1 Next

- Note** - you can share this application with other study personnel by clicking the three dots on the left-hand side next to the application title and selecting 'Invite user to register or share application'

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Research GEMS

ProjectsProfileHelpSign out

Project

Project details

Applications

Contacts

Details

Documents

History

## 2021/GEM00123 - X

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	Modified date
▶ ⋮	Application information		1.00	In Progress	Lauren Chartier	24/02/2021 08:54:26 AM	24/02/2021 08:54:26 AM

Showing 1

Invite user to register or share application

Rename application

Delete application

◀ Previous 1 Next ▶

# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – CALHN Ethics Preparing Project Registration, HREA & SSA Submission



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## Human Research Ethics Application

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

Research GEMS
Projects
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Sign out

2021/HRE00085 - x - HREA
Preview
Save
Next

Introduction
Project Overview
Project Team
Project Team Details
(1) Lauren Chartier
(2) Lauren Chartier
Disclosure of Interests
Restrictions
Evaluations
Location
Methods
Participants
Method Specific
Participant Specific
Project Details
Risk
Benefit
Data and Privacy
Generate HREA document
Upload
HREC
Declaration
Generate HREA document

### Introduction

You are completing this HREA within GEMS for a human research project that will be considered by a HREC operating within SA Health. On that basis, it is assumed you have already made contact with the Research Office that will receive your application on behalf of the HREC you have elected to submit your application to. This can often assist with ensuring full awareness of the application requirements and preventing delays in application progress down the track.

Contact details for all SA Health HRECs and relevant Research Offices can be found via the following link:  
[SA Health Research Offices Contacts](#)

Registration of your project within GEMS has been completed and resulted in generation of this form, so many of the details already entered together with documents already uploaded will be pre-populated to assist its completion.

As you work through the HREA, check that the correct information is displayed. Also, if text has been pre-populated within a 'free-text' field, you may wish to add additional information relevant to your project.

To further assist with submission, SA HRECs accept the electronic submission of the HREA by the CPI on behalf of the project – additional declarations/signatures are not required to submit once the application is finalised.

If you are not the CPI, but will be completing the HREA on their behalf, you will need them to log into GEMS once you have finished to complete the submission.

**Before completing this application, the CPI must read the following statements and complete the acknowledgement below:**

- The HREA has been designed for ethics review of human research, as defined in the [National Statement](#).
  - The [National Statement](#) states that research is: "...widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers... Human research is research conducted with or about people, or their data or tissue".
  - The [Australian code for the responsible conduct of research \(the Code\)](#) states that research includes: "...the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings."
  - Research excludes activities that are carried out exclusively for quality improvement, quality assurance or evaluation.
  - Audit-type activities may be considered research if investigating a potential research question.
  - Non-research projects that will be published and some student internships may need ethics review, but not necessarily by an HREC.
  - Contact your institution's ethics or research office for guidance on whether your project requires ethics review.
- Adequate resources must be available to conduct this research project.
  - [National Statement](#) 1.1 (f) states that research that has merit is: "...conducted using facilities and resources appropriate for the research".
  - It is expected that adequate resources will be available for this research project. Resources may include: financial resources, human resources, equipment, facilities and in-kind support.
  - Consult with your institution's ethics or research office for further advice.
- All relevant institutional policies pertaining to the conduct of this research project should be considered and adhered to.
  - Institutions may have policies in place that relate to the conduct of research. These policies should be consulted prior to completing this application and adhered to throughout the conduct of the research.
  - Consult with your institution's ethics or research office for further advice.
  - Ensure all investigators are familiar with their institutional policies and note that if you are conducting research at multiple sites that institutional policies may differ.
- Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.
  - You must not start your research project until you have received written ethics approval and site authorisation (if appropriate).
  - This includes screening of participants and/or data collection activities.
- The HREA requires the attachment of a [Project Description/Protocol](#).
  - It is strongly recommended that you prepare the [Project Description/Protocol](#) before commencing this HREA. Advice on what to include in this document is available on the [Project Description Page](#).

Note: You cannot complete the HREA unless you acknowledge the above statements.

Do you accept and acknowledge these statements? \*

Acknowledge and Continue
Next

- Select 'Acknowledge and Continue' and 'Next' on the Introduction page

### 1. Project Overview

- Q1.1 Insert Project Title
- Q1.2 Project summary in lay terms
- Q1.3 Category(ies) of research is populated from information provided in Project Registration
- Q1.4 What type of institution research will be conducted in
- Q1.5 Who has overall ownership of the study and data obtained
- Q1.6 Insert any funding details

- ix. Q1.7 Insert anticipated start date or tick 'as soon as ethics and any other relevant approvals have been provided'
- x. Q1.8 Insert duration of study

## 2. Project Team

- i. This is where you will add in details about all Investigator(s) and Study Personnel
- ii. You can add more researchers to the Project Team by selecting the '+'
- iii. If you make a mistake and need to remove a Team member, select the person by clicking the large box next to their name and clicking '-'
- iv. After all Team members have been added you will need to provide more information for each investigator by selecting their name on the left-hand side under 'Project Team Details'

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#### Project Team

Note: For optimal performance of the HREA no more than 10 members who are directly accountable for this ethics application can be listed on this page. You may include all other team members (if need be) in your [Project Description/Protocol](#).

- [National Statement](#) 1.1 (e) states:  
 "Research that has merit is ...conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research."
- In establishing the research team you should ensure there is appropriate and sufficient expertise to undertake all the research activities.
- Ensure that you list who is undertaking the research activities and detail their expertise, qualifications and competence in the following section, (if more than 10 members, detail in your Project Description).
- Where research will involve team members who are currently unknown (e.g. a future class of students) this should be recorded in the [Project Description/Protocol](#) and the supervisor should complete this section of the HREA as the researcher/investigator.

Q1.9.1 Title <small>Optional</small>	Q1.9.2 First name *	Q1.9.3 Surname/Family name *
<input type="checkbox"/> Dr	Lauren	Chartier
<input type="checkbox"/> Miss	Siana	Dimond

+
-

- Press the '+' button to add another row for additional team members.
- Tick the check box and press the '-' button to remove a team member.
- Click and drag the grey bars to reorder the team member list.
- You can use the share feature (see [these](#) instructions) to allow other members of the research team to complete their information in the following section.

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## 3. Disclosures of Interest

- i. Select 'No' if there are no conflicts of interest to disclose
- ii. Selecting 'Yes' will prompt some additional questions related to the disclosure





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- ii. Q1.12 - selecting 'Yes' will prompt some additional questions related to the evaluations. You can also upload evidence or the outcome of this scientific evaluation, however, this is optional
- iii. Q1.13 – select 'Yes' if the project has had previous ethics review by another committee, for example the Aboriginal Human Research Ethics Committee.
- iv. You can add and remove previous ethics review details by selecting the '+' and '-'

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### Evaluations

**Q1.12 Has the scientific or academic merit of the research project been evaluated? \***

- Review of the scientific or academic merit of the research project should be robust, formal and independent of the researcher and research proponents, including any sponsors of the research.
- If the HREC considers that appropriate review of the merit of the research project has already been conducted, [National Statement 1.2](#) states that: "...the question of research merit is no longer subject to the judgment of those ethically reviewing the research."
- You should confirm any requirements regarding relevant review processes with the HREC to which you are applying.

☒ Yes
 ☐ No

**Q1.12.1 What was the review process and what was the outcome? \***

- Identify who undertook the review, the date and, where applicable, the grant scheme or funding round in which the research project was reviewed.
- If the outcome included conditions, outline what these were and how they have been or will be met.
- Provide any relevant information on any changes that have been made to the design of or plan for the project subsequent to the review.

**B** *I* U **S**    **E** **B** **B** **B** **B**    **↶** **↷** **✕** **✕** **Ω**

**Q1.12.2 Attach evidence of the outcome of the scientific or academic review process. Optional**

- Evidence may include an outcome letter or other formal correspondence received from the persons providing the review.
- Attachments are limited to 10MB in size.

[Upload New](#)

**Q1.13 Has this research project had prior ethics review? \***

- If the project has been previously reviewed it may not require re-review.
- Contact your institution's ethics or research office for guidance on whether your project requires ethics review.

☒ Yes
 ☐ No

Provide the following details for each ethics committee that has previously reviewed the application.

**Q1.13.1 Which ethics committee previously reviewed the application? \***

- Provide the full, formal title of the ethics committee or reviewing body.

Note that under the *Therapeutic Goods Act 1989* an ethics committee must be registered with the NHMRC in order to approve clinical trials undertaken as part of the Clinical Trials Notification (CTN) scheme.

**Q1.13.2 What was the outcome of the prior ethics review? \***

+
−

- i. Q1.14 – Selecting 'Yes' will ask for details of who is conducting specialist review and when this will be sought

## 6. Location

- i. Q1.15 – If single-site select 'No', if multi-site select 'Yes'
- ii. Q1.16 – If governance approval is required for other sites (not CALHN) select 'Yes'. If all study sites are CALHN sites, select 'No'

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### Location

**Q1.15 Will this research project be conducted at multiple sites? \***

- This is relevant where research activities are conducted at numerous locations that are governed by different organisations. For example, this is applicable where research is conducted at a number of different public hospitals or across numerous universities.

Yes ☒ No

**Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site? \***

- This is applicable where the research occurs at multiple centres, each with their own governance and authorisation processes (e.g. different public hospitals).
- This is not applicable where research is occurring at multiple sites but will only require a single institutional approval (e.g. a university with multiple campuses).

Yes ☒ No

## 7. Methods

- Select all methods that apply to the current study as per the descriptions provided

## 8. Participants

- Q1.18 - Select the participants involved in the study. By selecting 'Human beings', questions about recruitment will be asked. If selecting 'Human biospecimens' or 'Data associated with human beings only', no recruitment questions will be asked.
- If unsure of what to select, refer to the information provided in the table below Q1.18

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### Participants

**Q1.18 Indicate with whom or with what the research will be conducted \***

- Tick one.
- Your answer to this question will have a significant impact on the subsequent questions in this HREA. See the Methods and Participants Checklist guidance page for further information.

☐ Human beings (via active participation), including their associated biospecimens and/or data  
☐ Human biospecimens only  
☒ Data associated with human beings only (i.e. as the primary object of research)

This is a required field

As you have ticked this option, no recruitment questions will be asked. You should address any issues related to access to the data and consent to its use initially in the Consent Section and Data and Privacy Section of the HREA.

Human beings (via active participation), including their associated biospecimens and/or data.	<ul style="list-style-type: none"> <li>This refers to any research that involves the active participation of individual human beings. It includes physical and psychological investigations, face-to-face communication, being photographed, completing a questionnaire and other means that require the participation of the human mind or body.</li> <li>Select this option if you plan to collect biospecimens (for example blood samples or tissue biopsies) prospectively as only one component of a research project that involves the active participation of human beings.</li> <li>Do not select this option if coronal material is the primary component of your research.</li> </ul>
Human biospecimens only	<ul style="list-style-type: none"> <li>This refers to any research that only involves the collection and/or use of specimens derived from individual human beings. These specimens may have been taken from human beings in another context (e.g. as part of the establishment of a biobank or other research project or concurrent with a clinical procedure).</li> <li>Do not select this option if prospective collection of the biospecimens with consent or the use of biospecimens is only one component of a research project that also involves the active participation of individual human beings.</li> <li>Select this option if coronal material is the primary component of your research.</li> </ul>
Data associated with human beings only (i.e. as the primary object of research)	<ul style="list-style-type: none"> <li>This refers to any research that only involves the collection and/or use of information associated with individual human beings. This information may be obtained from an existing dataset or the research may involve the establishment of a databank or registry to collect the data. This research may involve the use of information with or without personal identifiers and it may be obtained from or associated with individuals or gathered in aggregate form.</li> <li>Select this option if human beings are being studied via an artefact such as video or photographic representations or observations taken prior to the initiation of the research project.</li> <li>Do not select this option if prospective collection of data or the use of data is only one component of a research project that also involves the active participation of individual human beings.</li> </ul>

- Q1.18.1 – If all data collected is retrospective, select 'No'
- Q1.19 – Select any of the categories of participants involved if required. This section can be left blank if none of the specified participant populations are involved

## 9. Method Specific

- The next pages will be populated according to the response provided in Q1.17 (Methods)

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### Observational research

M7.1 What type of observation will you be conducting? \*

• Details of the method that will be used should be included in the [Project Description](#).

B I U S E E E E

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M7.2 What sampling strategy will you use? \*\*

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M7.3 How will you match and follow up participants? \*\*

B I U S E E E E

≡ - ≡ - ≡ ≡ ↶ ↷ x<sub>2</sub> x<sup>2</sup> Ω

M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias? \*\*

B I U S E E E E

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## 10. Participant Specific

- The next pages will be populated according to the response provided in Q1.18 (Participants)

## 11. Recruitment

- If you have selected 'Human beings' in Q1.18 you will be asked the following general and method specific questions

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GeneralObservational Research

Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction? \*

B I U S [List Icons]

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Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing? \*

• Consider the purpose of the research, the sensitivity of the behaviour observed, the intrusiveness of the observation and whether participants will know that they have been observed.

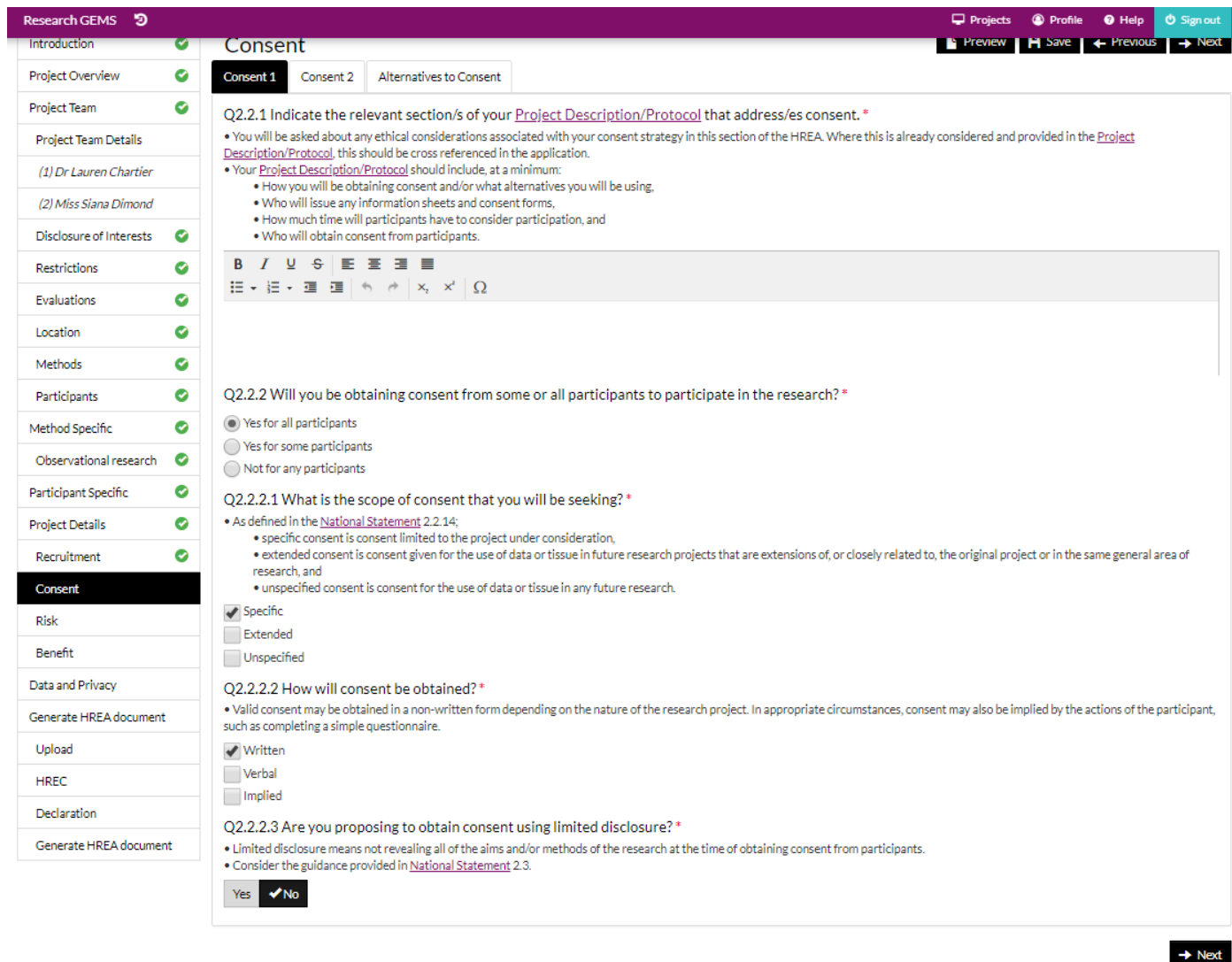
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## 12. Consent

- i. Q2.2.1 – Provide details of consent related to your study and refer to sections of the Study Protocol



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Q2.2.1 Indicate the relevant section/s of your [Project Description/Protocol](#) that address/es consent. \*

- You will be asked about any ethical considerations associated with your consent strategy in this section of the HREA. Where this is already considered and provided in the [Project Description/Protocol](#), this should be cross referenced in the application.
- Your [Project Description/Protocol](#) should include, at a minimum:
  - How you will be obtaining consent and/or what alternatives you will be using,
  - Who will issue any information sheets and consent forms,
  - How much time will participants have to consider participation, and
  - Who will obtain consent from participants.

Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research? \*

☒ Yes for all participants  
☐ Yes for some participants  
☐ Not for any participants

Q2.2.2.1 What is the scope of consent that you will be seeking? \*

- As defined in the [National Statement 2.2.14](#):
  - specific consent is consent limited to the project under consideration,
  - extended consent is consent given for the use of data or tissue in future research projects that are extensions of, or closely related to, the original project or in the same general area of research, and
  - unspecified consent is consent for the use of data or tissue in any future research.

☒ Specific  
☐ Extended  
☐ Unspecified

Q2.2.2.2 How will consent be obtained? \*

- Valid consent may be obtained in a non-written form depending on the nature of the research project. In appropriate circumstances, consent may also be implied by the actions of the participant, such as completing a simple questionnaire.

☒ Written  
☐ Verbal  
☐ Implied

Q2.2.2.3 Are you proposing to obtain consent using limited disclosure? \*

- Limited disclosure means not revealing all of the aims and/or methods of the research at the time of obtaining consent from participants.
- Consider the guidance provided in [National Statement 2.3](#).

Yes ☒ No

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- ii. Select all tabs on the top of the page to complete this section (Consent 2, Alternatives to Consent)
- iii. If you are applying for a Waiver of Consent this will be asked in the 'Alternatives to Consent Tab'

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## Consent

Consent 1 Consent 2 **Alternatives to Consent**

- The [National Statement](#) and privacy guidelines do not consider the opt-out approach to be a form of consent. For clarity, it is also not a form of, or equivalent to, implied consent. Rather, the opt-out approach and a waiver of the requirement for consent are both alternatives to consent that, in appropriate circumstances, enable the conduct of research with human beings or using their biospecimens or data without the consent of the participants.
- The practice of delayed or deferred consent is not supported by the National Statement in emergency care, intensive care research or any other type of research. This practice may also not be considered legal in some States and Territories. Additionally, validation of any form of retrospective consent is contrary to the [National Statement](#).

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all participants? \*

- [National Statement](#) 2.3.5 states:

"An opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible".

- Note that the use of an opt-out approach is not a form of consent, but is an alternative to consent.

Yes ☒ No

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants? \*

- Note that if you are not obtaining consent from an authorised representative as per [National Statement](#) 4.4.13, this does not constitute 'waiver of the requirement for consent' in the sense that is intended by [National Statement](#) 2.3.9-12.
- Note that jurisdictional legislation may differ on the subject of waiver of consent

- You have indicated at M2.3.3 that your use of the biospecimens is not consistent with the consent obtained at the time the biospecimens were collected. You may need to request a waiver of consent.

☒ Yes No

Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in [National Statement](#) 2.3.10? \*

- [National Statement](#) 2.3.10 states:

"Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

- involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
- the benefits from the research justify any risks of harm associated with not seeking consent
- it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
- there is no known or likely reason for thinking that participants would not have consented if they had been asked
- there is sufficient protection of their privacy
- there is an adequate plan to protect the confidentiality of data
- in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
- the possibility of commercial exploitation of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
- the waiver is not prohibited by State, federal, or international law."

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## Consent

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Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research? \*

Regarding the involvement of People with a cognitive impairment, an intellectual disability, or a mental illness

Consider and address this question with respect to the requirements of [National Statement](#) 4.5.5 which states:

"Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law."

Regarding the involvement of People in dependent or unequal relationships

[National Statement](#) 4.3.2 states:

"In the consent process, researchers should wherever possible invite potential participants to discuss their participation with someone who is able to support them in making their decision. Where potential participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate."

Yes ☒ No

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project? \*

Confirming or re-negotiating consent may be particularly appropriate when:

- Children or young people are involved,
- The capacity of participants changes,
- The terms of the consent change, and/or
- Action research methods are used.

☒ Yes ☐ No

Refer to the relevant section/s of your Project Description/Protocol that detail the process for confirming or re-negotiating consent at Q2.2.1.

Based on your answer to Q1.18, Q2.2.5 is not relevant to this project and has been hidden automatically by the HREA system.

Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues. \*

Include any issues related to:

- your responses to the questions above in this section on consent,
- the level of understanding of the participants,
- the inclusion of people whose primary language is other than English or other literacy issues, and
- cultural issues.

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### 13. Risk

- i. Provide information on potential risks associated with this research and how these will be mitigated referencing sections of the study protocol

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#### Risk

**General**

**Q2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your [Project Description/Protocol](#) as appropriate.**

- You may want to outline sections of your [Project Description/Protocol](#) that detail risks (e.g. "Refer to Section X of the Project Description/Protocol for information about Y risk").
- You must refer to the guidance and advice in [National Statement 2.1](#) regarding definitions of risk and how to gauge risk.
- Consider whether any of the following types of harm might occur in your research and the likelihood, severity and consequence of those harms occurring:
  - physical harm
  - psychological harm
  - disclosure of sensitive personal information
  - exposure of illegal activity
  - economic harm
  - discrimination, stigma or other social harm
  - devaluation or harassment
  - familial distress
  - harm to any member of a vulnerable population (see [National Statement](#) Section 4)
  - reputational harm
- Consider whether your research is likely to result in discomfort or inconvenience and how this might occur.
- Include risks to and burdens on participants, researchers and third parties (Individuals or groups).
- Consider the multiple levels of personal relationships that may arise during research (especially in ethnographic research or research using the participant-observation or other observational methods) and their impact upon participants, researchers and third parties.
- Consider whether there are any concerns that might be relevant to the research project regarding political or institutional sensitivities.
- Consider whether any combination of methods being used in this research might lead to additional risks.

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**Q2.3.2 Describe how these risks will be mitigated and managed.\***

- Consider the guidance and advice in [National Statement](#) Chapter 2.1 regarding managing risks.

**B** *I* U

## 14. Benefit

- i. Provide information on potential benefits associated with this research and how these will be justified and managed referencing sections of the study protocol

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






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






#### Benefit

**Q2.4.1** Describe the benefits associated with your research, referencing any relevant sections of your [Project Description/Protocol](#) as appropriate. \*

- You will be asked about any ethical considerations associated with the benefits of your research project in this section. Where this is already considered and provided in the [Project Description/Protocol](#), this should be cross referenced in the application.
- Include benefits, if any, to participants, to groups and communities, to society, to the advancement of knowledge and to researchers.
- Include any benefits accruing from the possible availability of the intervention after completion of the project.










**B** *I* U         

**Q2.4.2** Explain how the benefits of this research justify any risks or burdens associated with the research. \*

**B** *I* U         

**Q2.4.3** How will you manage participants' expectations of the perceived benefit of participating in the research? \*

- Consider both expectations of benefits that are not likely to eventuate and expectations of benefits that can reasonably be expected to eventuate, but where there may be a misperception as to the extent of those benefits. For example, therapeutic misconception in clinical research.

**B** *I* U         

## 15. Data and Privacy

- i. Data Characteristics - these questions are related to the type of data collected and used throughout the research project. i.e. Personal, health, identifiable, de-identifiable information
- ii. Select all that apply
- iii. Q3.6 – Selecting a database as a source of information will prompt Q3.6.1 relating to data custodian approval

**Q3.6.1** Has the data custodian/s, if any, agreed to provide access to the data for use in the proposed research? \*

- Approval to release data may be granted by a data custodian prior to, or subject to, ethics approval being obtained. If ethics approval is a precondition for applying for data custodian approval, select 'data custodian has not provided approval'.
- If there is no data custodian, select 'no data custodian identified'.

- ☐ Data custodian has approved access to data  
☐ Data custodian has not provided approval  
☐ No data custodian identified

- iv. Activities with Data – provide information on any sharing of data to third parties and privacy/confidentiality considerations

# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – CALHN Ethics Preparing Project Registration, HREA & SSA Submission



Health  
Central Adelaide  
Local Health Network

- v. Refer to relevant sections of the Study Protocol

## 16. Generate HREA document

- i. The HREA document can only be generated if all sections on the left-hand side have green ticks next to it
- ii. A red cross indicates that there is a blank field, or something is not completed in that section
- iii. Select 'Next'

Research GEMS

ProjectsProfileHelpSign out

### 2021/HRE00085 - x - HREA

Introduction	✓	<b>Generate HREA document</b>  To generate your HREA document: 1) Ensure that each of the page names in the left-hand menu are green. Any orange pages indicate pages that contain unanswered questions. 2) On the Upload Page, check that your Project Description/Protocol and any other relevant documents associated with conducting your research project have been uploaded. 3) Identify the HREC or ethics review body that you will send your application to. 4) Complete the declaration. 5) Generate your HREA document.
Project Overview	✓	
Project Team	✓	
Project Team Details		
(1) Dr Lauren Chartier		
(2) Miss Siana Dimond		
Disclosure of Interests	✓	
Restrictions	✓	
Evaluations	✓	

PreviewSavePreviousNext

Next

## 17. Upload

- Attach all documents related to your application** (Participant Information and Consent Form, validated questionnaires, interview guides, data collection spreadsheets etc)
- Select the type of document using the dropdown and include short description (i.e. protocol), version number and document date
- You can add and remove documents by selecting the '+' and '-'
- The Project Registration will be automatically attached
- All study documents must be uploaded, as these will flow through to the document list on the ethics approval.**

Research GEMS
Projects
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Introduction
Project Overview
Project Team
Project Team Details
(1) Dr Lauren Chartier
(2) Miss Siana Dimond
Disclosure of Interests
Restrictions
Evaluations
Location
Methods
Participants
Method Specific
Observational research
Participant Specific
Project Details
Recruitment
Consent
Risk
Benefit
Data and Privacy
Generate HREA document
Upload
HREC
Declaration

### Upload

Q4.1 Attach the [Project Description/Protocol](#) to your HREA. \*

- It is recommended that you use one of the templates provided in the HREA for your [Project Description/Protocol](#).
- Individual attachments are limited to 10 MB in size.

[Clear content selection](#)  
(tracked\_CALHN HREC MINUTES - 10 December 2020.docx) [Open](#)

Q4.2 Are there any other relevant documents associated with conducting your research project? \*

- This may include attachment of:
  - participant information and consent forms,
  - questionnaires,
  - report forms,
  - advertising materials,
  - data management plans (see [National Statement](#) Chapter 3.1),
  - ethically defensible plans for the communication of research findings or results to participants (see [National Statement](#) Chapters 3.1, 3.2 and 3.3, as appropriate, for guidance on the content of ethically defensible plans),
  - authorisations, approvals, letters of support or other clearances, and/or
  - other project-related documentation specific to your institution and/or jurisdiction.
- Consult with your institution's research/ethics office for advice on the necessary documentation.

☒ Yes ☐ No

Attach any other relevant documents associated with conducting your research project.

- Ensure that you give meaningful and unique names to your files before uploading them.
- Provide a meaningful description for each file at Q4.2.2.
- Individual attachments are limited to 10MB in size.
- The cumulative size for all attachments must not exceed 95 MB.

Document Type *	Q4.2.2 Description of attachment *	Document version *	Document date *	Q4.2.1 Upload attachment *
<input type="checkbox"/> Study Protocol	Study Potocol	1	24/02/2021	<input type="checkbox"/> Upload New

+ -

- Press the '+' button to add another row for additional team members.
- Tick the check box and press the '-' button to remove a team member.
- Click and drag the grey bars to reorder the attached documents.

Q4.2.3 Attached Project Registration form.

(029841\_Project Registration.docx.zip) [Open](#)

Next

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – CALHN Ethics

### Preparing Project Registration, HREA & SSA Submission



**Health**  
Central Adelaide  
Local Health Network

## 18. HREC

- Q4.3 and Q4.4 - Select Central Adelaide Local Health Network from the dropdown
- HREC contact details will be automatically populated
- Q4.5 – Select 'Greater than low risk review pathway' for full HREC submissions

Research GEMS

Projects Profile Help Sign out

### 2021/HRE00085 - x - HREA

Introduction

Project Overview

Project Team

Project Team Details

(1) Dr Lauren Chartier

(2) Miss Siana Dimond

Disclosure of Interests

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Methods

Participants

Method Specific

Observational research

Participant Specific

Project Details

Recruitment

Consent

#### HREC

- Indicate the institution and HREC/ethics review body to which you will submit your ethics application – only those HRECs accepting HREA via GEMS are listed.
- A HREA created in GEMS will be made available electronically to HRECs within SA Public Health Organisations – these are the only HRECs that utilise GEMS Indicate

Q4.3 Select the Organisation that hosts the HREC or other review body: \*

Central Adelaide Local Health Network

Q4.4 Select the HREC or other body to which you are applying from the list below. \*

- The HRECs and other review bodies available in the list below are filtered by the Organisation you have selected above.

Central Adelaide Local Health Network HREC

HREC or Review Body Contact Information

You may wish to seek advice from the HREC or Organisation's review body before finalising and submitting your application. Their contact information is outlined below.

Organisation  
Central Adelaide Local Health Network HREC

Contact phone number  
++61(08) 71172229

Contact email address  
Health.CALHNResearchEthics@sa.gov.au

Q4.5 Under which review pathway are you intending to submit this application? \*

- Before answering this question, consider the guidance provided by the institution to which you are applying and contact the ethics or research office for advice.

Greater than low risk review pathway

Note: The institution to which you are applying will review your application and determine the level of risk of the research project. Your answer to this question will only inform them of the intended review pathway.

Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme? \*

☐ Yes ☒ No

Preview Save Previous Next

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## 19. Declaration

- All study personnel will receive an email notification to complete this declaration page
- Select 'Certify'

Research GEMS

Projects Profile Help Sign out

### 2021/HRE00085 - x - HREA

Introduction

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Project Team Details

(1) Dr Lauren Chartier

(2) Miss Siana Dimond

Disclosure of Interests

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#### Declaration

This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.

- Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team.
- You can use the share feature to have other researchers/investigators complete their declaration within this application – see the [HREA How to Guide](#) for details.
- You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email).
- You can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature).
- Ensure you answer Q1.9.11 for each team member before completing this section.
- Electronic acceptance linked to user profile.

Q4.7 I, Dr Lauren Chartier, certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

☒ Certify

Preview Save Previous Next

Next



## 20. Generate HREA document

- i. If all information is correct and attachments are uploaded, select 'Yes' and tick 'I understand and would like to proceed'
- ii. Click 'Generate HREA document'

Research GEMS

Projects Profile Help Sign out

2021/HRE00085 - x - HREA

Introduction

Project Overview

Project Team

Project Team Details

(1) Dr Lauren Chartier

(2) Miss Siana Dimond

Disclosure of Interests

Restrictions

Evaluations

Generate HREA document

Preview

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Is your application complete and have you attached the Project Description/Protocol and any relevant supporting documents? \*

Yes

No

Once you submit the HREA, you will receive an email confirming submission and a zipped attachment containing a copy of your application and all attachments – this is for your records. GEMS will submit the application on your behalf to your nominated HREC for processing

Verify that you are ready to generate your HREA document. \*

When the below 'Generate HREA document' button is clicked your application will be finalised and will no longer be editable.

☒ I understand and would like to proceed.

Generate HREA document

## HREA Application is now submitted

1. You can download a zip file of the HREA and all attachments by selecting the blue underlined text in this box

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

2. HRE application will now appear as 'Submitted' on the Project homepage
3. SSA's applicable to the HREA will be automatically generated and appear as 2021/SSA00XXX and 'In Progress'
4. You will receive updates on your application on GEMS through email correspondence

CALHN Research Services Research GEMS Guidelines


Preparing Project Registration, HREA and SSA Submission – CALHN Ethics – Commercially Sponsored Clinical Trials

Version 1.0 dated 11-05-2021

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## Site Specific Assessment

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



Research GEMS

Decisions Projects Profile Help Sign out

Project

Project details

Applications

Contacts

Details

Documents

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](#).

[+ New Site](#)

#### Applications

[Export CSV](#) Show  entries Search:

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

Showing 1 to 2 of 2 entries

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

- 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"

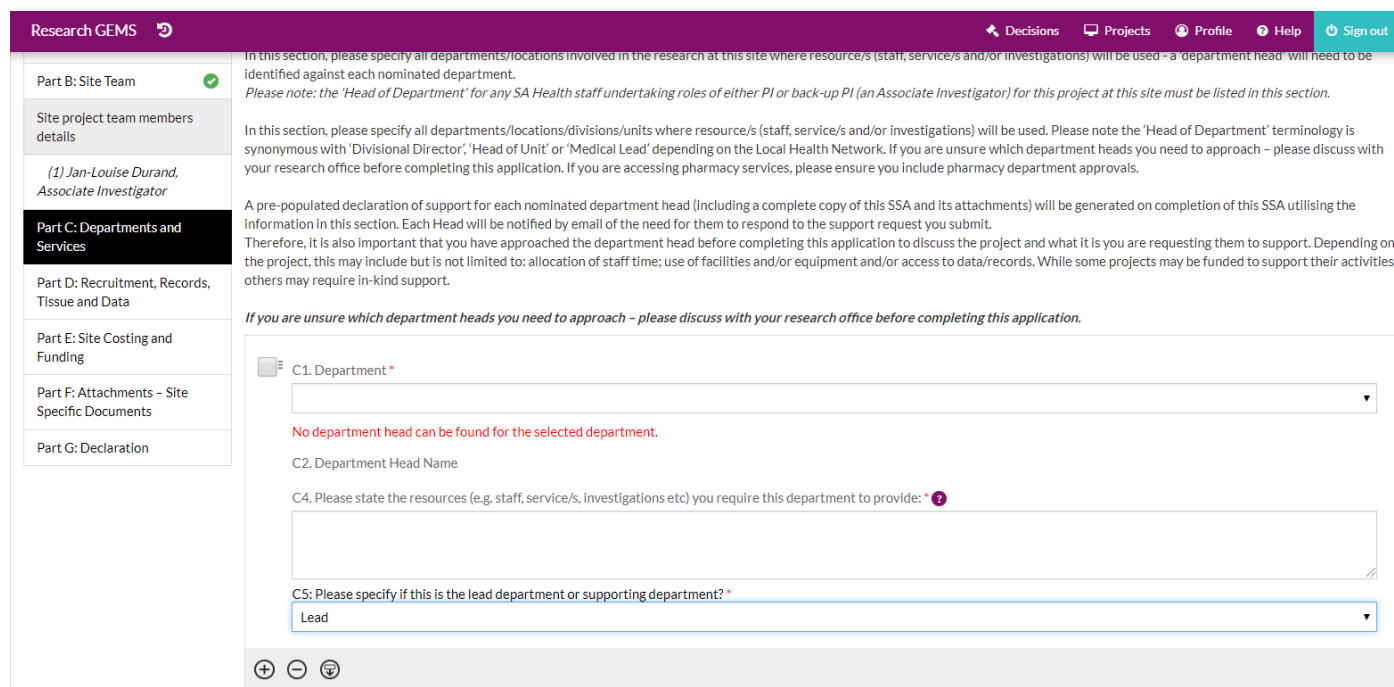
### C. Part B – Site Team

- 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 Medical Lead, Head of Department and any Supporting Departments for declarations/approvals.
- You will need to add the Medical Lead first

1. Select the drop down list and click on the appropriate Medical Lead for your stream. Medical Leads are named in the following naming convention:
    - a. RAH: Surgery 2: Medical
    - b. RAH: Surgery 2: Allied Health
    - c. RAH: Surgery 2: Nursing
  2. This will then pre-fill the name and email address of the Medical Lead.
  3. You will then need to fill in sections C4&5
  4. In section C5: select “Lead” for the Medical/Allied Health/Nursing Lead
- iii. Proceed to add the Head of Department
1. Press the “+” button to add another department
  2. Select the drop down list and click on the appropriate Head of Department for your stream. The naming conventions for Head of Departments are as follows:
    - a. RAH: Surgery 2: Ophthalmology
    - b. RAH: Surgery 2: Vascular Surgery
    - c. RAH: Surgery 2: Urology
  3. Please Note: the details of the Heads of Department were not migrated into the system as they are constantly being updated. Therefore you will need to provide the Head of Department with the declaration form and gain their approval via email or signature, then upload to the clinical trial share drive along with all other supporting documentation
  4. Then fill in section C4&5
  5. In section C5: select “Supporting” for the specific department the study will be run in.
- iv. Add any other Supporting Departments the same way as the Head of Department and gain their approval outside of the system.



**Research GEMS** [Icons]

Decisions Projects Profile Help Sign out

**Part B: Site Team** [Green checkmark]

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

- v. Naming conventions can be seen here:

# CALHN Research Services - Research GEMS Guidelines

## Commercially Sponsored Clinical Trials – CALHN Ethics

### Preparing Project Registration, HREA & SSA Submission



**Health**  
Central Adelaide  
Local Health Network

**Research GEMS** [Navigation icons]

**Part B: Site Team** [Status: Complete]

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](#)

Once you have finished, it should look like this as an example:

**Research GEMS** [Navigation icons]

(2) Rachel Chang, Associate Investigator

(3) Ayesha Salim, Associate Investigator

**Part C: Departments and Services**

Part D: Recruitment, Records, Tissue and Data [Status: Complete]

Part E: Site Costing and Funding [Status: Complete]

Part F: Attachments – Site Specific Documents [Status: Complete]

Part G: Declaration

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: Cancer: Medical

**C2. Department Head Name**  
Professor Timothy Price

**C3. Department head email address \***  
Timothy.Price@sa.gov.au

**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

**C1. Department \***

RAH: Cancer: Medical Oncology

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? \***  
Supporting

**Medical Lead is prefilled and sent to them via GEMS, fill out as follows:**

**C1. Site: Stream: Medical**

**C5. Lead (for Medical Lead)**

**Department is located here, this is just for reporting purposes, please fill out as follows:**

**C1. Site: Stream: Department**

**C5. Supporting (As you can only have 1 Lead and that is for the Medical Lead)**

**Next**

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

# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – CALHN Ethics Preparing Project Registration, HREA & SSA Submission



**Health**  
Central Adelaide  
Local Health Network

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

**Research GEMS**

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 D: Recruitment, Records, Tissue and Data**

D1. Will participants be enrolled for the research at this site? \*

Yes ☒ No

D7. Are you planning on accessing tissue samples from this site? \*

Yes ☒ No

D8 Will you be accessing pharmacy dispensing? \*

Yes ☒ No

D9. Will trial participants be exposed to ionising radiation to which they would not have been exposed to if they did not participate in the trial? \*

Yes ☒ No

D10. Will you be accessing pharmacy dispensing? \*

Yes ☒ No

D11. Do you have any agreements or contracts for this project? \*

☒ Yes

Please select an agreement type:

- Co-Principal Investigator Agreement
- Medicines Australia Clinical Trial Research Agreement - Collaborative or Cooperative Research Group
- Medicines Australia Clinical Trial Research Agreement - Contract Research Organisation
- Medicines Australia Standard Form of Indemnity - Site
- Medicines Australia Form of Indemnity - HREC only
- Master Services Agreement
- Data Transfer Agreement
- Materials Transfer Agreement
- Research Collaborative Agreement - standard
- Research Collaborative Agreement - non-standard
- Grant Agreement
- Other - please specify

## F. Part E – Site Costing and Funding

- Click 'No' to both options.

**Research GEMS**

Decisions Projects Profile Help Sign out

2021/SSA00198 - Evaluation of Processes - Royal Adelaide Hospital

Part A: Project-Wide Information ✓

Part B: Site Team ✓

Site project team members details  
(1) Eyllinee White, 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 E: Site Costing and Funding**

For complex projects such as Clinical Trials, a detailed project costing using a template may be required by the site in order to ensure that the costs of carrying out research are fully covered, and/or that the costs are transparent so that the financial implications can be assessed based on sound information.

Please contact your local research office to discuss - they may have a standard budget template to be used.

If any supporting department (e.g. Pharmacy or Pathology) has generated its own detailed budget (more detailed than the information included in any contract/agreement) that has been acknowledged and agreed to, please upload at Part F.

E1. Are there any financial costs to the site associated with the project? \*

Yes ☒ No

E2. Are there any non-financial costs (e.g. local resource allocations) associated with the project? \*

Yes ☒ No

Preview Save Previous Next

Next

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

- As documents were previously uploaded to the HREA you do not need to upload any further documents at this stage (as all documents should have been uploaded against the HREA. If you did not do this, please contact CALHN Research Services Ethics team). At this stage, please create a study folder in the Clinical Trials Share Drive under your unit and save all CVs, GCP Certificates, Study Team declarations, Head of Department approvals and study specific documents.



# CALHN Research Services - Research GEMS Guidelines Commercially Sponsored Clinical Trials – CALHN Ethics Preparing Project Registration, HREA & SSA Submission



**Health**  
Central Adelaide  
Local Health Network

- ii. Check that the documents did come across from the project registration/HREA as it should appear as below
- iii. Then click 'Next'

Research GEMS

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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 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 \*  
Ethics application decision notif

Document descriptor \*  
Approval Letter

Document version \*  
1

Document date \*  
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

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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

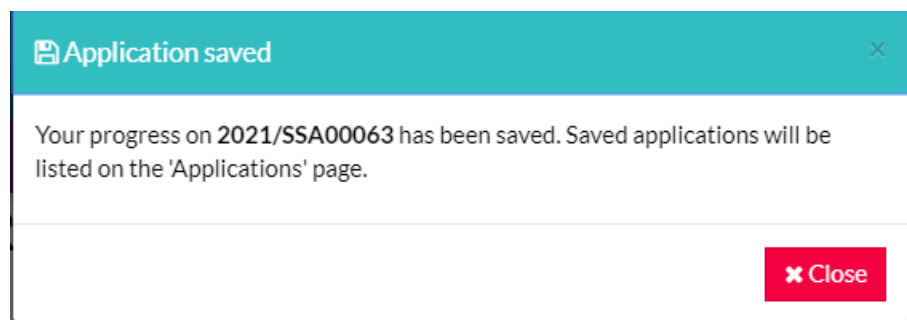
By clicking the button below I confirm that:

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.

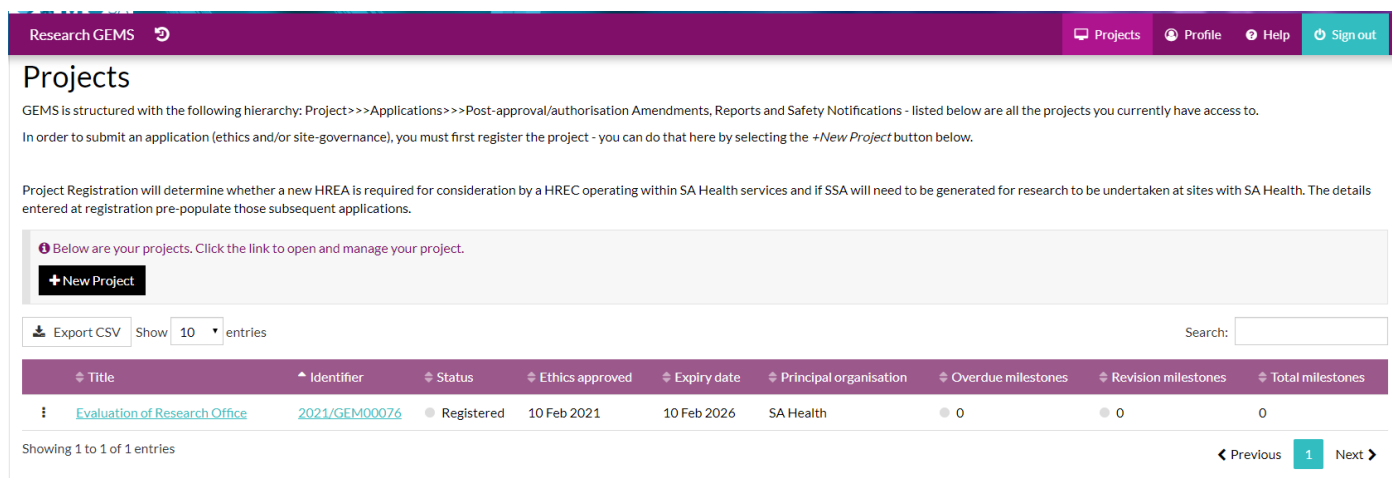
Name of Principal Investigator  
Siana Dimond  
Siana.Dimond@sa.gov.au

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





- 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



Research GEMS

Projects Profile Help Sign out

## 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="#">Evaluation of Research Office</a>	<a href="#">2021/GEM00076</a>	Registered	10 Feb 2021	10 Feb 2026	SA Health	0	0	0

Showing 1 to 1 of 1 entries


Previous 1 Next

- 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'

Research GEMS 

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:


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 Previous

viii. This will then process

Research GEMS 

Projects Profile Help Sign out


## 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'

 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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Project

Project details

Applications

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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	Eyllinee White	11/02/2021 10:22:43 AM

Showing 1 to 2 of 2 entries
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- 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

**Hints / Tips / Key Points**

**Project Registration**

<p><b>Project Registration</b></p>	<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>
<p><b>Part A: Previous Ethics Applications</b></p>	<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>
<p><b>Part B: Project Details</b></p>	<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>
<p><b>Part C: Research Site(s)</b></p>	<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>
<p><b>Part D: Coordinating Principal Investigator</b></p>	<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> <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>• 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="574 629 1244 887"> <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>

### HREA

- Fill in the HREA as per the questions asked.
- **Ensure ALL study documents are uploaded to the ‘Upload’ tab. As only, the documents uploaded will pull across to the approval letter.**

### **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 Medical Lead, Head of Department and any Supporting Departments for declarations/approvals.</li> <li>• The details of the Heads of Department/Supporting Head of Departments were not migrated into the system as they are constantly being updated. Therefore you will need to provide the Head of Department with the declaration form and gain their approval via email or signature, then upload to the clinical trial share drive along with all other supporting documentation</li> </ul>
<b>Part D: Recruitment, Records, Tissue &amp; Data</b>	<ul style="list-style-type: none"> <li>• Upload agreements to share drive.</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 No</li> <li>• Select No</li> <li>• Do not enter any details into this section</li> </ul>
<b>Part F: Attachments/Site Specific Documents</b>	<ul style="list-style-type: none"> <li>• 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>• Only the PI 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>



## Approval / Authorisation Delegation

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

Medical Lead approval will come via Research GEMS.

## 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

- 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)