

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

Overview

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

Scope

This guideline will help to achieve the following:

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

Definitions & Acronyms

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

Quick Links

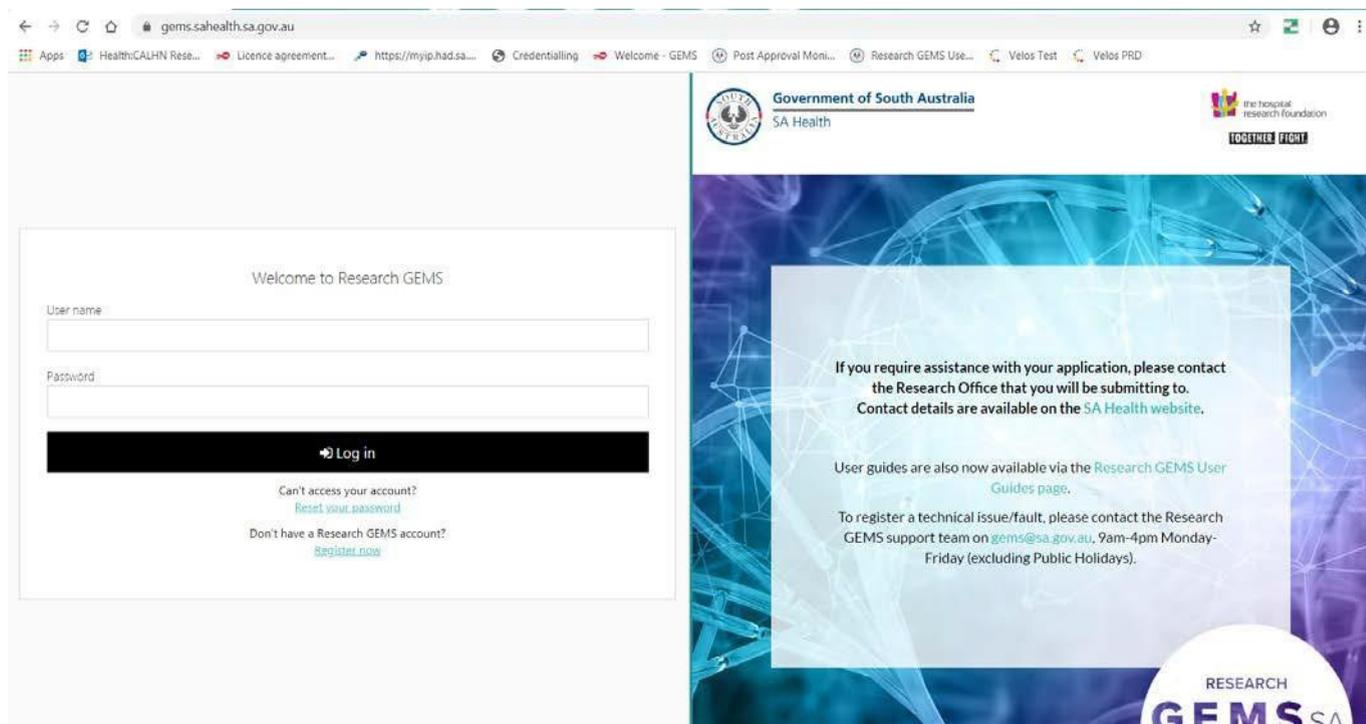
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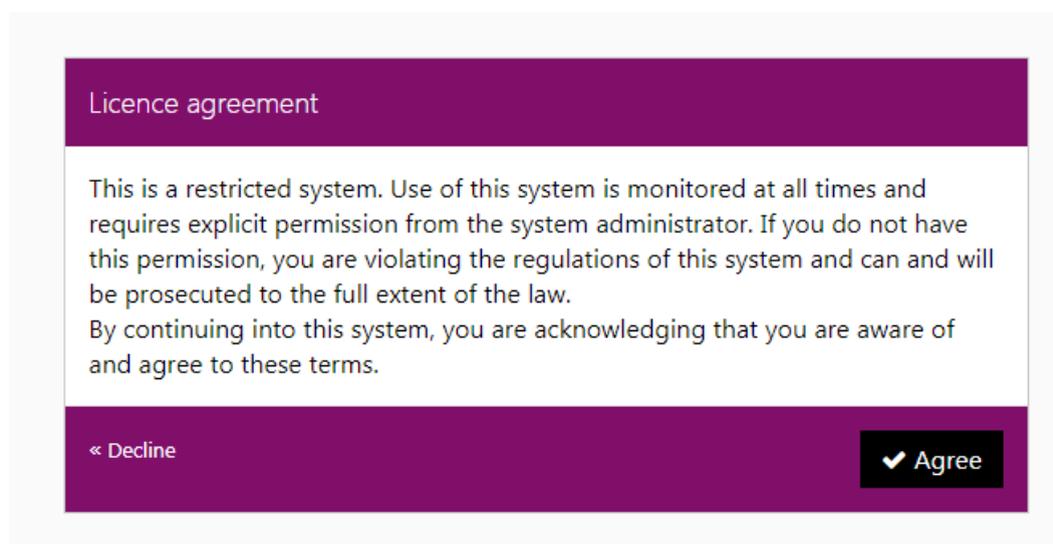
Procedures

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

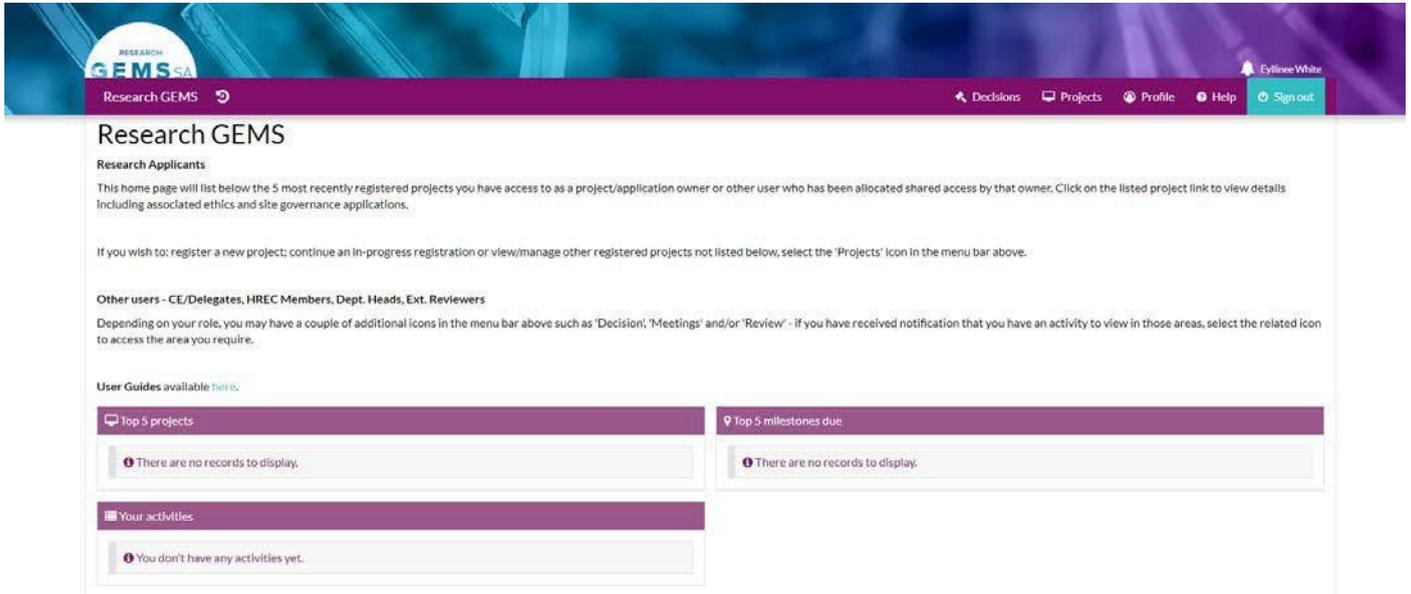


- a. If your account is set up, login with your username and password
 - i. If you have received an email but have not yet logged in before, click 'Reset your password' and enter the email address the original email went to
- b. If your account is not set up
 - i. Try logging in with your SA Health government 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



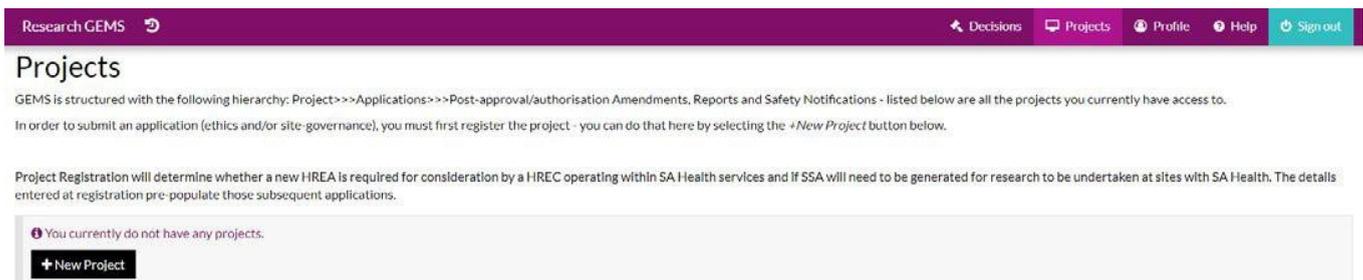
3. Registering your Project

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

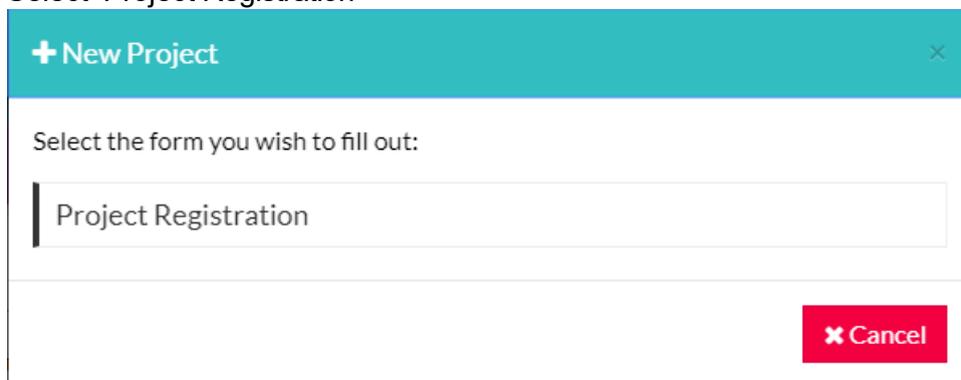


- b. To register a project, navigate to the 'Projects' tab on the right hand corner

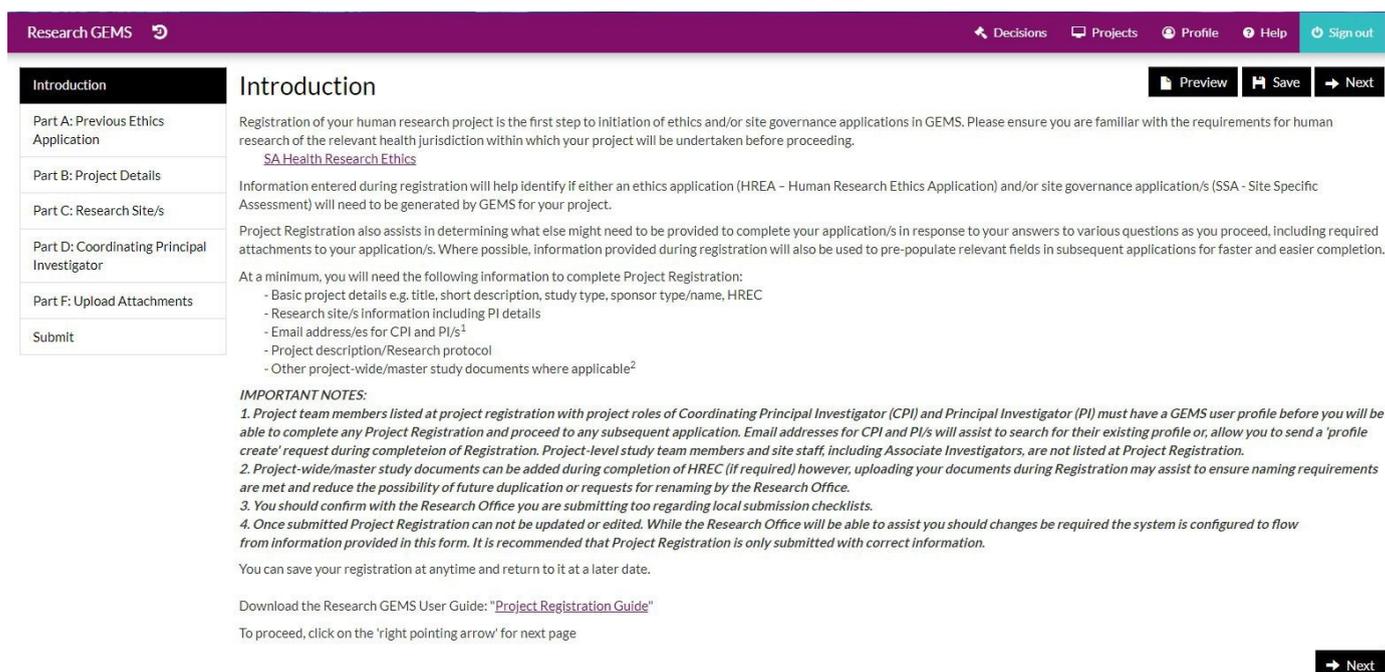
- c. Click 'New Project'



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

- 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 A: Previous Ethics Application

Preview Save Previous Next

If an ethics application:
 Has never been previously submitted for this project to a NHMRC registered and/or certified HREC, select 'No' at question A1 - no further questions will be required in this section and you can proceed to Part B.
 Has previously had an ethics application submitted to a NHMRC registered and/or certified HREC, select 'yes' at question A1 and complete the additional questions displayed.

A1 Has an application for ethics review of this project previously been submitted to a recognised HREC? * ?

Yes No

NOTE: SA Health now accepts Bellberry applications under a single ethical review policy, with the exception for paediatric studies.

SA Health has current National Mutual Acceptance exclusions for Phase 0 and Phase 1 Clinical Trials. These must be reviewed by the local SA Health HREC responsible for the public health organisation where the clinical trial is taking place.

The following details are required to identify the previous ethics application, the HREC to which it was submitted and whether it was submitted under the NMA arrangements which exist between a number of public health jurisdictions nationally. Outcomes or status of that previous application may be requested. ?

A2 Ethics application ID * ?

External Ethics

A3 HREC Name *

Austin Health Human Research Ethics Committee

A4 HREC Code

EC00204

A5 Was/Is application being reviewed under the NMA scheme * ?

Yes

A6 Outcome or status *

Approved

A7 Date of written decision notification (email or letter) *

11/02/2021

Next

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

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
 1. Share with view access – will allow the user to view but not edit the project
 2. 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

New Project Registration

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

Part C: Research Site/s

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

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

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

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

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

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

Invite to Register

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

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

SA Health

Other health jurisdictions or organisations

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

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

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

Project centre *

Project site *

Principal Investigator email (GEMS username) *

Principal Investigator name

+
-
⌵

Next

Invite user to register & manage access

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

There are currently no users assigned to this form.

[Add another user](#)

Save and send
Cancel

Invite user to register & manage access

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

Send	Name	Username	Access status	Modify access
✉		Slana.Dimondi@sa.gov.au ✔	No current access	<div style="border: 1px solid #ccc; padding: 2px; display: inline-block;"> Share with view access Share with view access Share with edit access </div>

User Slana.Dimondi@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,

- 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.

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

Project centre * Project site *

Central Adelaide Local Health Network Royal Adelaide Hospital

Principal Investigator email (GEMS username) * ? Siana.Dimond@sa.gov.au Principal Investigator name Siana Dimond

Project centre * Project site *

Central Adelaide Local Health Network 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
1. If you selected 'no' – enter the email address of the CPI
 2. If it is external ethics, then enter the site PI's email address. Do not enter the CPI for all sites otherwise, they will have to make an account and sign off.
 3. If you selected 'yes' – this prepopulates to the account holder who is currently logged in and filling out the registration

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 D: Coordinating Principal Investigator

The Coordinating Principal Investigator (CPI) is

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

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

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

Invite to Register

Preview Save Previous Next

Are you the Coordinating Principal Investigator for this project? ?

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

Yes No

CPI email (GEMS user name) *

CPI name

ORCID ?

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

Next

k. Part F – Upload Attachments

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

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 style="display: flex; justify-content: center; gap: 10px;"> + - </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

- 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:

SSA for each of the following SA Health sites:

Royal Adelaide Hospital, Siana Dimond (PI)

The Queen Elizabeth Hospital, Eyllinee White (PI)

Complete Registration

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

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

Site Specific Assessment

- A. Once you have submitted the project registration, you can proceed to creating the SSA/filing in information
 - i. **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

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
2021/SSA00063	Evaluation of Research Office - Royal Ad...		1.00	In Progress	Siana Dimond	11/02/2021 10:22:39 AM
2021/SSA00064	Evaluation of Research Office - The Que...		1.00	In Progress	Eyllinee White	11/02/2021 10:22:43 AM

Showing 1 to 2 of 2 entries [Previous](#) [1](#) [Next](#)

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

B. Part A – Project Wide Information

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

C. Part B – Site Team

- i. This is where you will add in details about your Investigator(s)
- ii. Please ensure you enter the correct phone number (not the hospital switch board number), position, employer and department
- iii. **Please Note:** Employer must be CALHN and not RAH/TQE
- iv. In B7 – You can add 1 administrative staff to receive correspondence about the study (this should be the main study coordinator)
- v. In B8 – Add site team members (associate investigators)
- vi. Provide the details requested then click ‘Next’
- vii. 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

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

Haematology

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

Research GEMS

Decisions Projects Profile Help Sign out

Part B: Site Team ✓

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

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

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

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

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

C1. Department *

No department head can be found for the selected department.

C2. Department Head Name

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

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

Lead

- iii. Naming conventions can be seen here:

Research GEMS

Decisions Projects Profile Help Sign out

Part B: Site Team ✓

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

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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.

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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

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

- i. Answer questions ‘Yes’ or ‘No’ from D1 to D11
- ii. 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 No

Please specify:

- 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

- i. Click ‘Yes’ or ‘No’ as applicable.

Research GEMS

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

Next

G. Part F – Attachments/Site Specific Documents

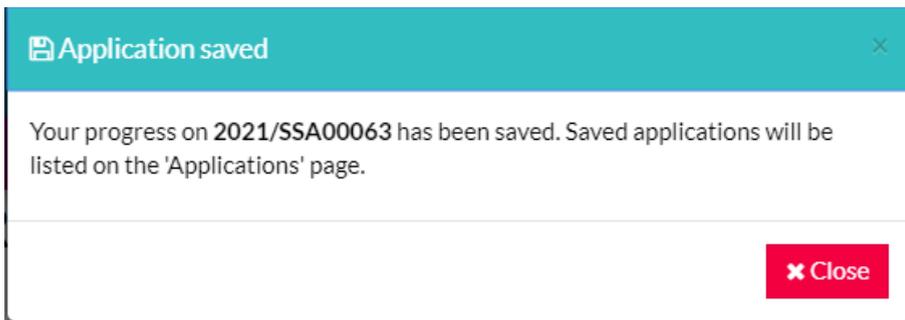
- i. As documents were previously uploaded to the project registration (e.g. HREA, HREC Approval and Protocol) you do not need to upload any further documents at this stage. However, you should at this stage create the study folder in the Clinical

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

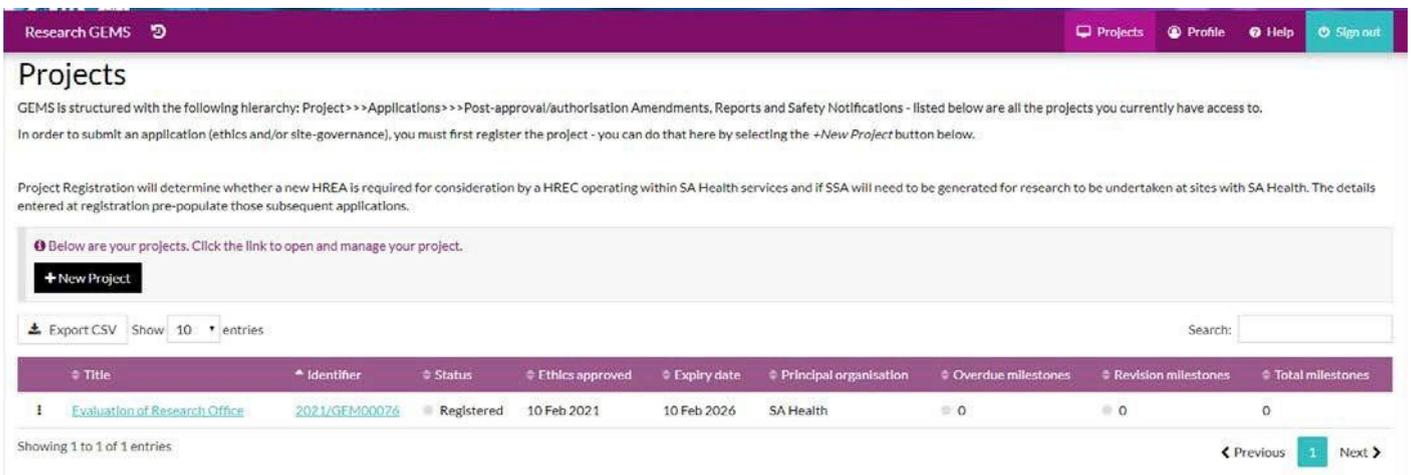
H. Part G – Declaration

- 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)

- 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



- 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**

Preview Save Previous

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

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

Projects Profile Help Sign out

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	Siانا Dimond	11/02/2021 10:22:39 AM
2021/SSA00064	Evaluation of Research Office - The Qu...		1.00	In Progress	Eylinee White	11/02/2021 10:22:43 AM

Showing 1 to 2 of 2 entries

Previous 1 Next

- xii. Please email 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>Project Registration</p>	<p><u>Login/Register:</u></p> <ul style="list-style-type: none"> • https://gems.sahealth.sa.gov.au/ <p><u>Projects Page:</u></p> <ul style="list-style-type: none"> • View all projects that you have created or are assigned to you • Add new project • 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. • Before you begin your application ensure that you have your project details, research site information, PI details and documentation ready.
<p>Part A: Previous Ethics Applications</p>	<p><u>External Ethics Approval</u></p> <ul style="list-style-type: none"> • Once submitted GEMs will create a SSA application for each SA Health site added <p><u>Internal Ethics Approval (CALHN HREC)</u></p> <ul style="list-style-type: none"> • The project has not been previously submitted to a recognised HREC (in GEMS) • Once submitted GEMs will create a HREA application and a SSA application for each SA Health site added
<p>Part B: Project Details</p>	<ul style="list-style-type: none"> • Ensure everything is entered precisely. <u>After submission you will not be able to edit your project registration.</u>
<p>Part C: Research Site(s)</p>	<ul style="list-style-type: none"> • 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. • 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. • 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. • Add all SA Health Sites for your project • If you miss a site and submit the project registration, you must add it as a site amendment. <ul style="list-style-type: none"> ◦ <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
<p>Part D: Coordinating Principal Investigator</p>	<ul style="list-style-type: none"> • If you are the CPI, select ‘yes’. • 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.

	<ul style="list-style-type: none"> • If you do not assign the correct the CPI, this will have a flow on effect and will delay your application
<p>Part F: Upload Attachments</p>	<ul style="list-style-type: none"> • For external ethics: <ul style="list-style-type: none"> ○ Upload External HREC approval letter, HREA and protocol. • Please note: GEMs will not allow the project to be submitted if the documents have not been uploaded <ul style="list-style-type: none"> ○ The supporting documentation is uploaded to the Clinical Trials Share Drive • Please note: there is a maximum file size of 20.00MB to upload per file
<p>Submit</p>	<ul style="list-style-type: none"> • Before you “Complete Registration” ensure all documents have been uploaded and all sites have been added • On this page you can see the applications that will be generated from your project registration <div data-bbox="571 786 1243 1043" style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <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>

SSA Application

SSA Application	The coordinator/research personnel can add information to the SSA, however only the PI will be able to submit the SSA
Part A: Project Wide Information	<ul style="list-style-type: none"> This section will be prefilled- the information will be taken from your project registration Ensure all the details are correct
Part B: Site Team	<ul style="list-style-type: none"> Add site team members and administrative staff. Please add staff in who will also be actioning post-approval monitoring 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. 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.
Part C: Departments & Services	<ul style="list-style-type: none"> This is where you will add the Department and any Supporting Departments. These approvals will need to be obtained outside of GEMS via email
Part D: Recruitment, Records, Tissue & Data	<ul style="list-style-type: none"> Send agreements via email to Health.CALHNClinicalTrials@sa.gov.au Under "Agreement Location" please select "No"
Part E: Site Costing & Funding	<ul style="list-style-type: none"> Select "Yes" or "No" as applicable
Part F: Attachments/Site Specific Documents	<ul style="list-style-type: none"> The HREA, HREC Approval and Protocol should be automatically attached from the Project Registration. Check that the documents are attached. Create a study folder in the Clinical Trials Share Drive and save any supporting documents and declarations to folder
Part G: Declaration	<ul style="list-style-type: none"> The PI or delegate will be able to submit the SSA PI's will not be able to submit SSA's assigned to another PI

Approval / Authorisation Delegation

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

Correspondence

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

Dear CALHN Research Services,

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

Project Title:	XXX
Protocol:	XXXX
Principal Investigator:	XXX
Program Directory:	XXX
HREC Reference Number:	202X/HREXXXXX or External HREC Number
SSA Reference Number:	202X/SSAXXXXX
CALHN Reference Number:	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: [What](#)

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

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