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

Overview

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

Scope

This guideline will help to achieve the following:

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

Definitions & Acronyms

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

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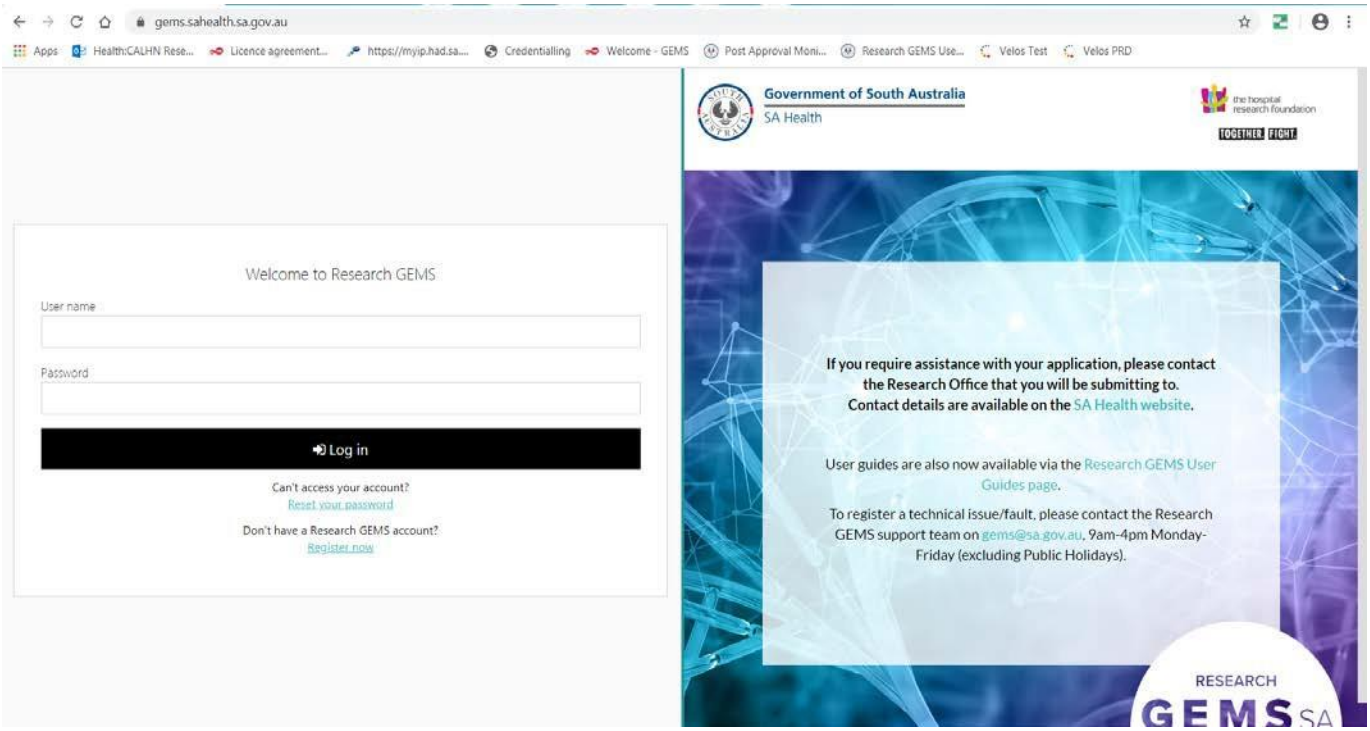
Procedures

Registering a Project

1. Go to the GEMS Website located here <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

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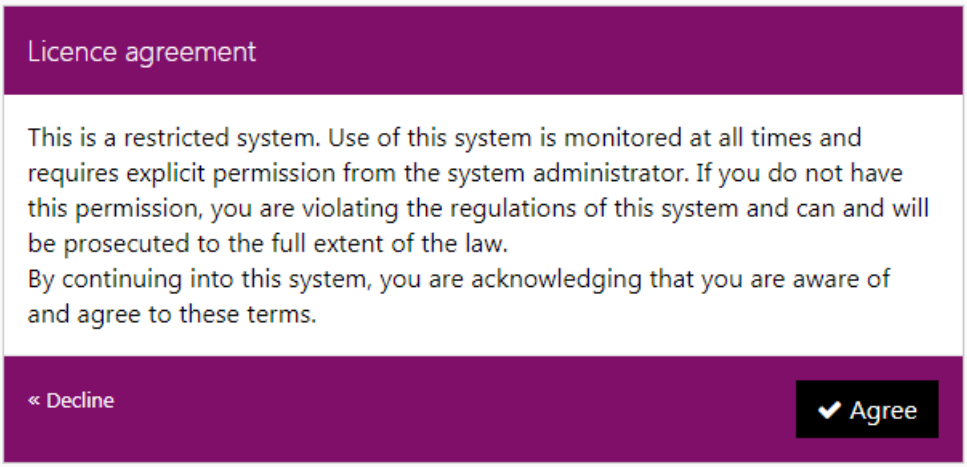
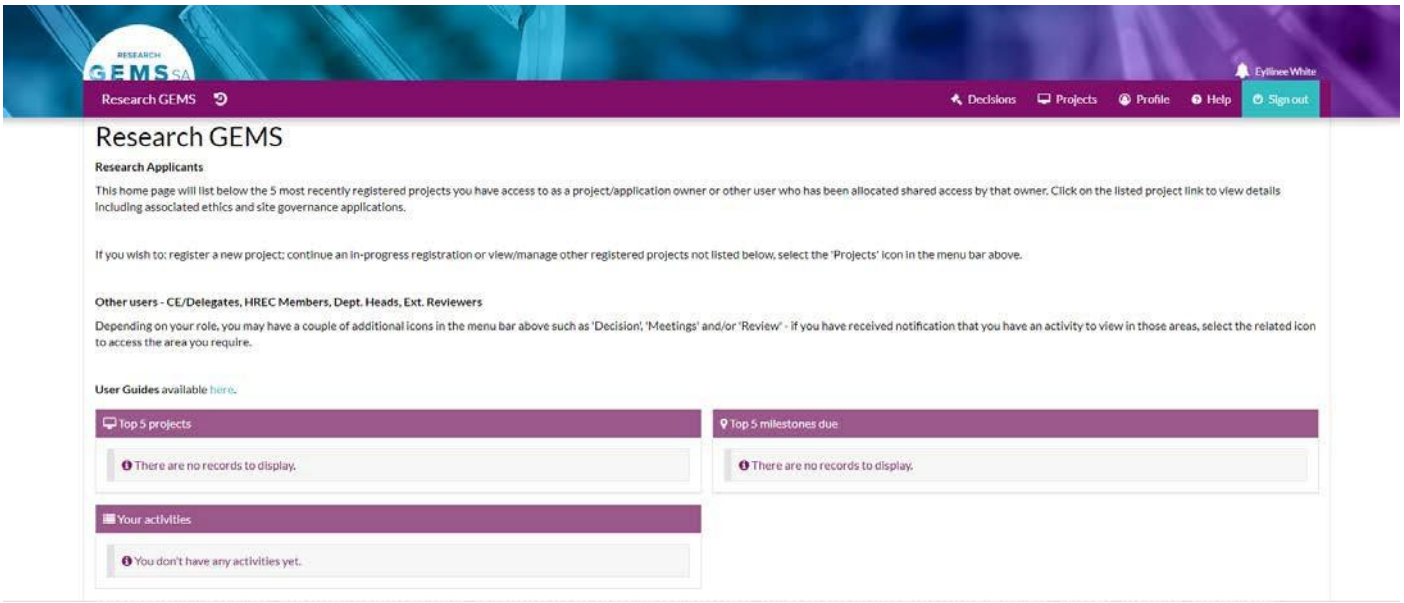
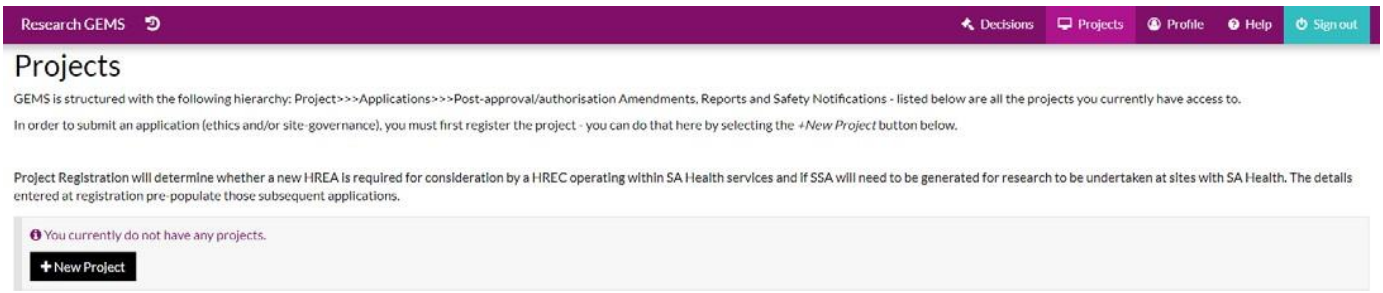


3. Registering your Project
    a. You will now have been directed to the External Portal Homepage for Researchers / Research Personnel.

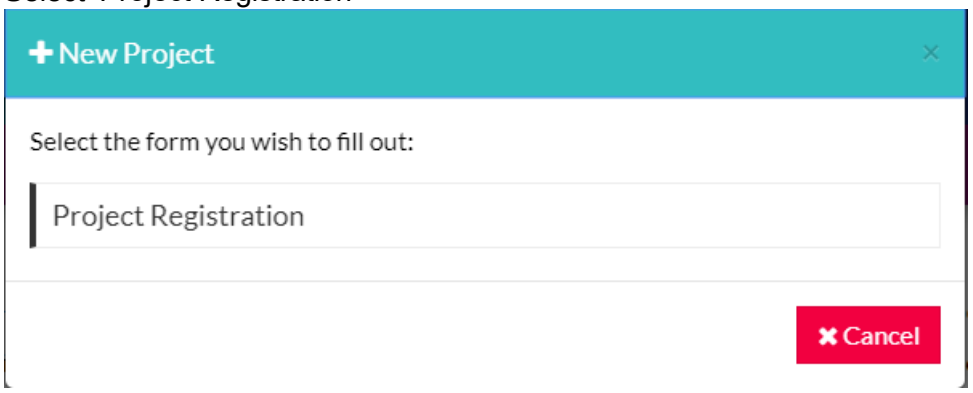


    b. To register a project, navigate to the 'Projects' tab on the right hand corner

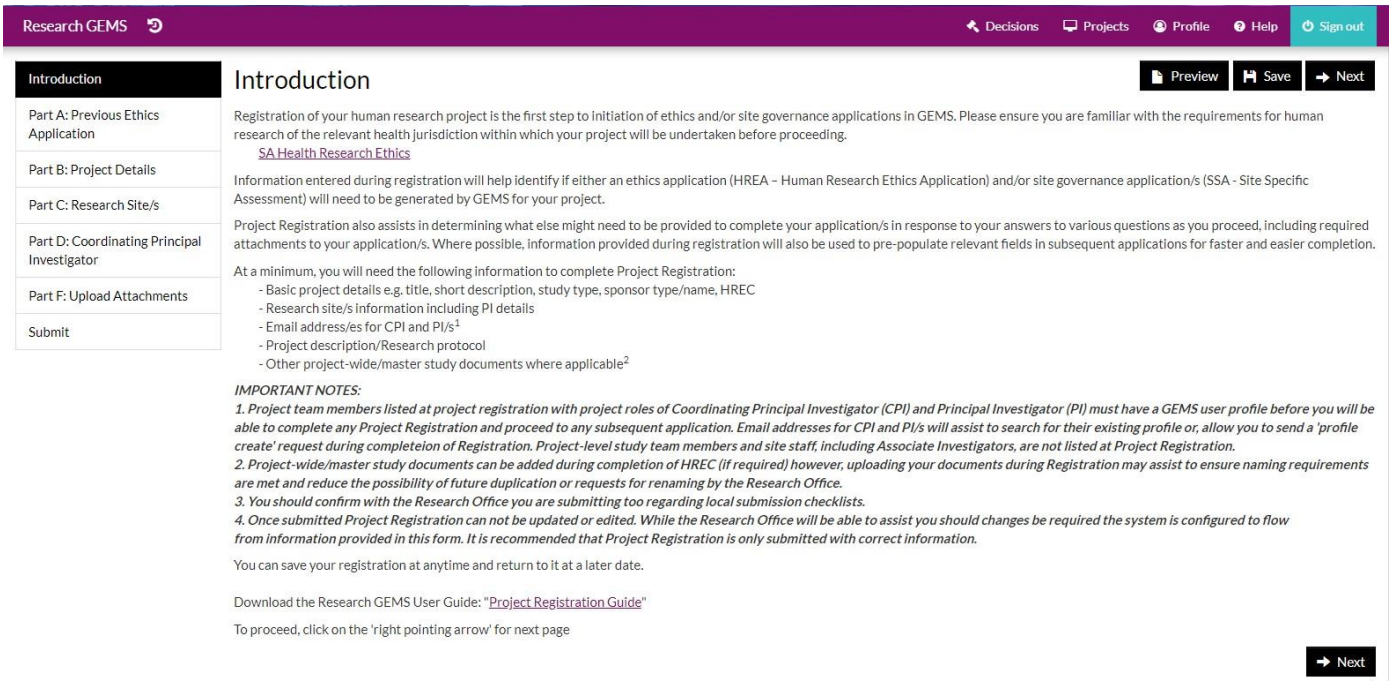
    c. Click 'New Project'



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**

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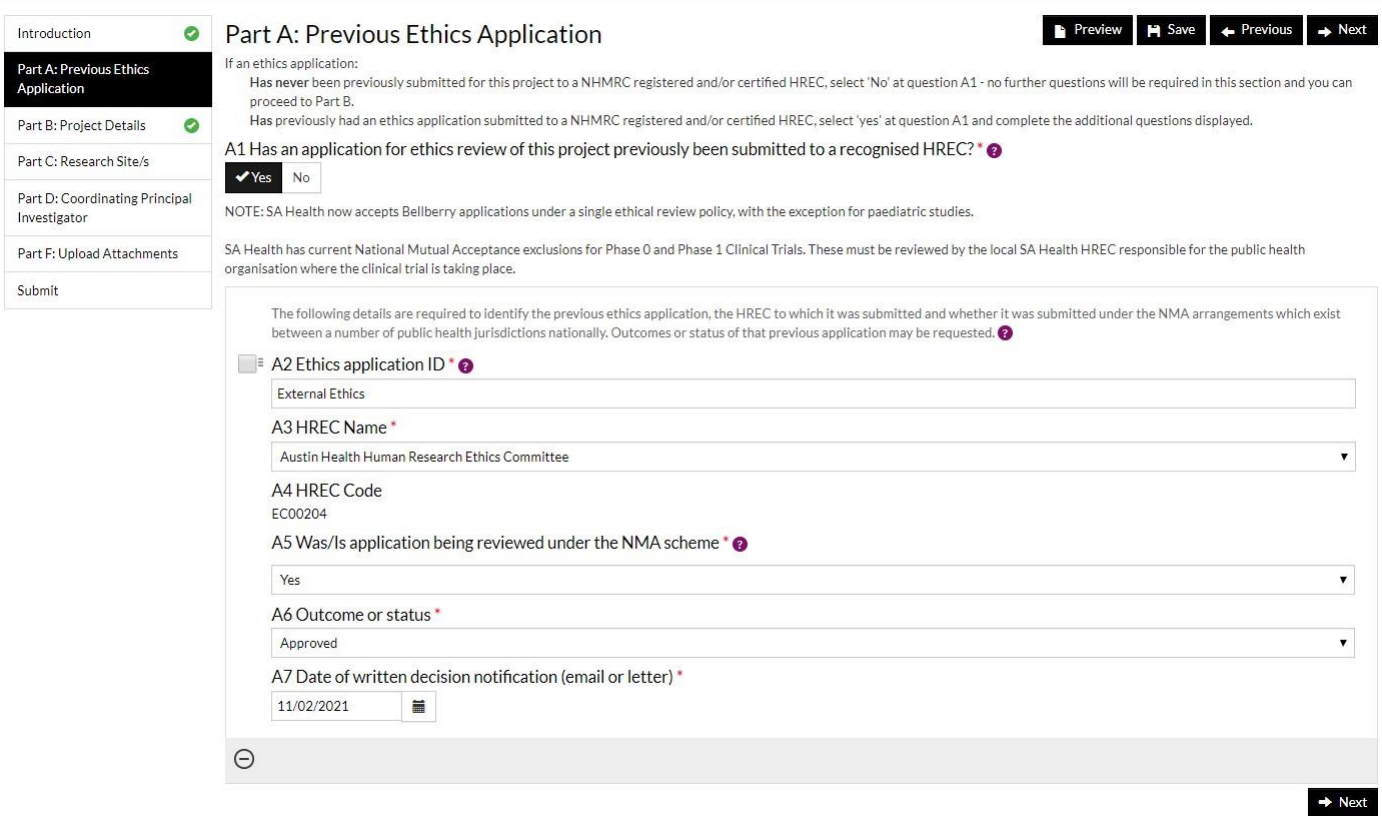

i. For Internal (CALHN) ethics > Select 'No'
ii. For External ethics (under NMA) > Select 'Yes'
iii. Fill in External HREC details using text and drop down selector(s)

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

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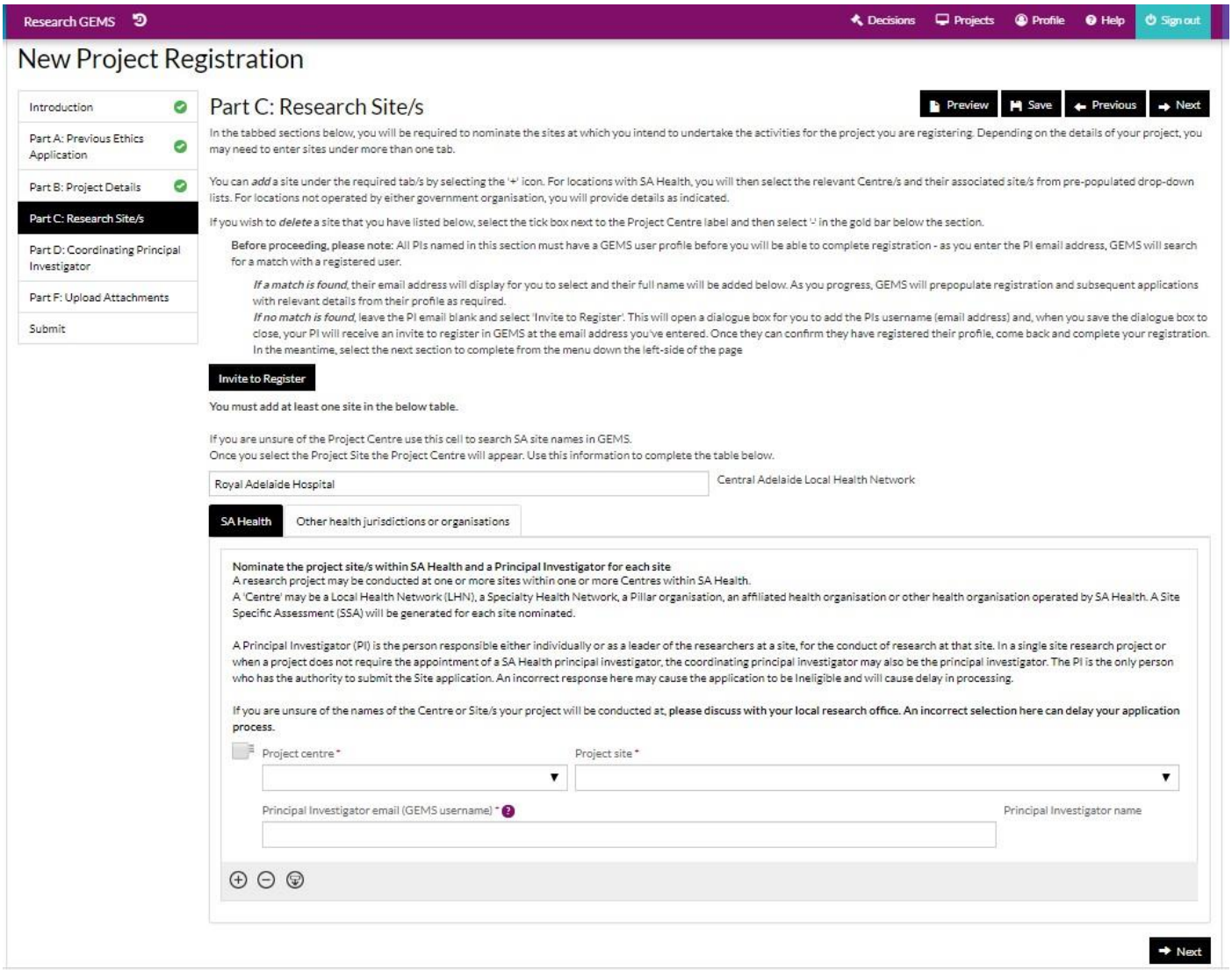
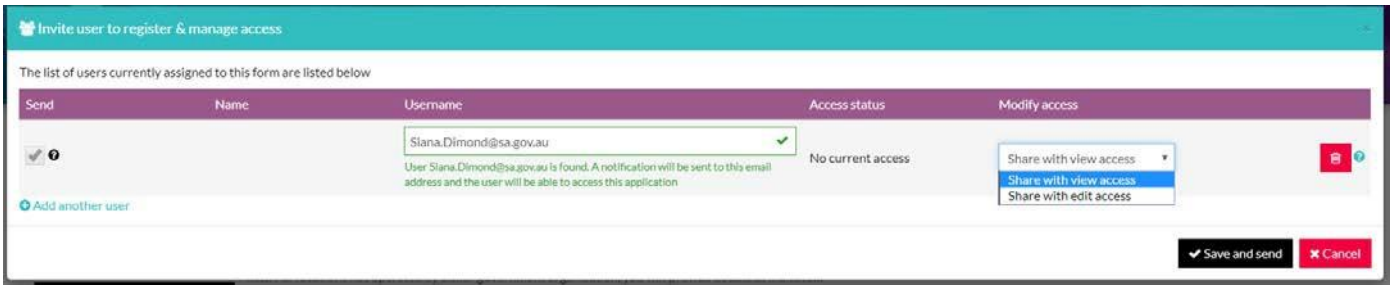
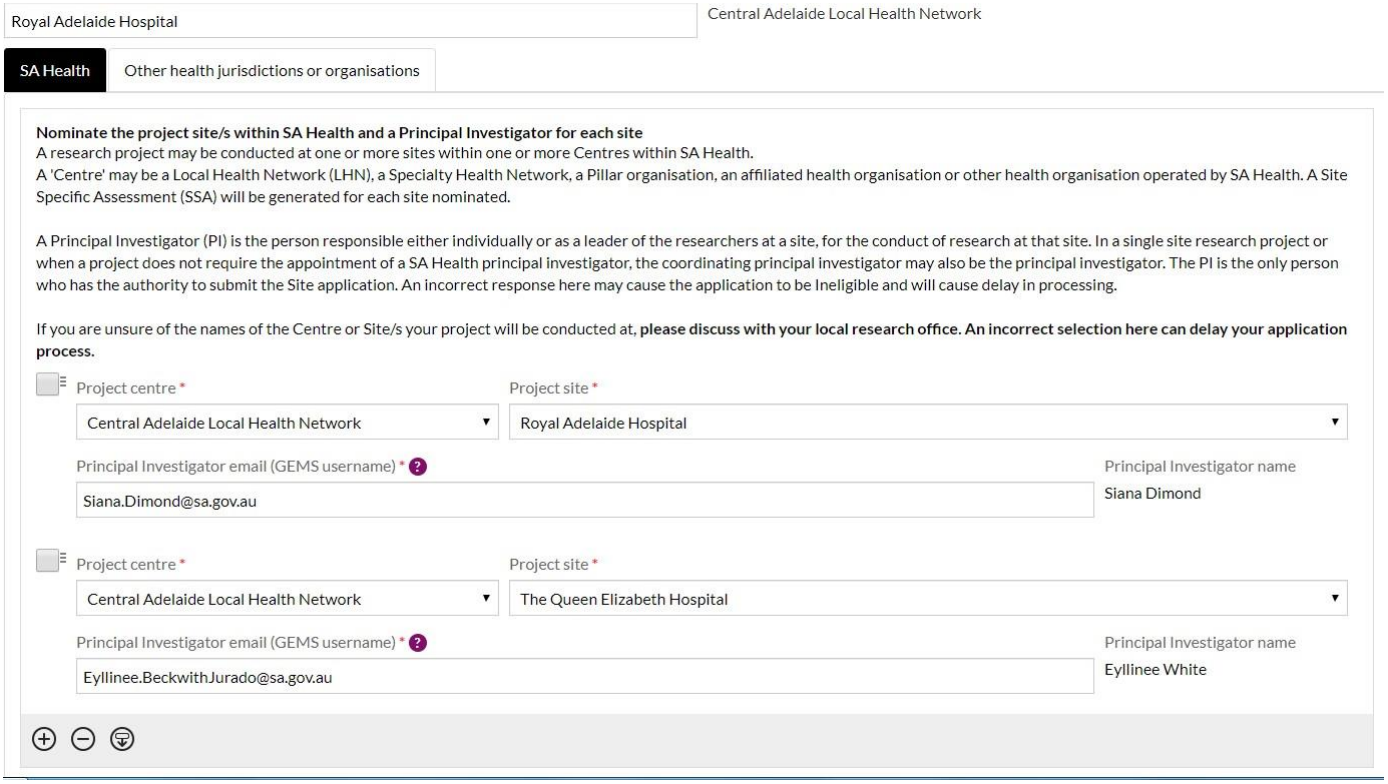




viii. Select the site you will be conducting the research at, when you begin to type the site should appear in the drop down selector box. This will then pre-fill the local health network next to the site name,

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



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. <u>If it is external ethics, then enter the site PI's email address</u>. Do not enter the CPI for all sites otherwise, they will have to make an account and sign off.
      3. If you selected 'yes' – this prepopulates to the account holder who is currently logged in and filling out the registration

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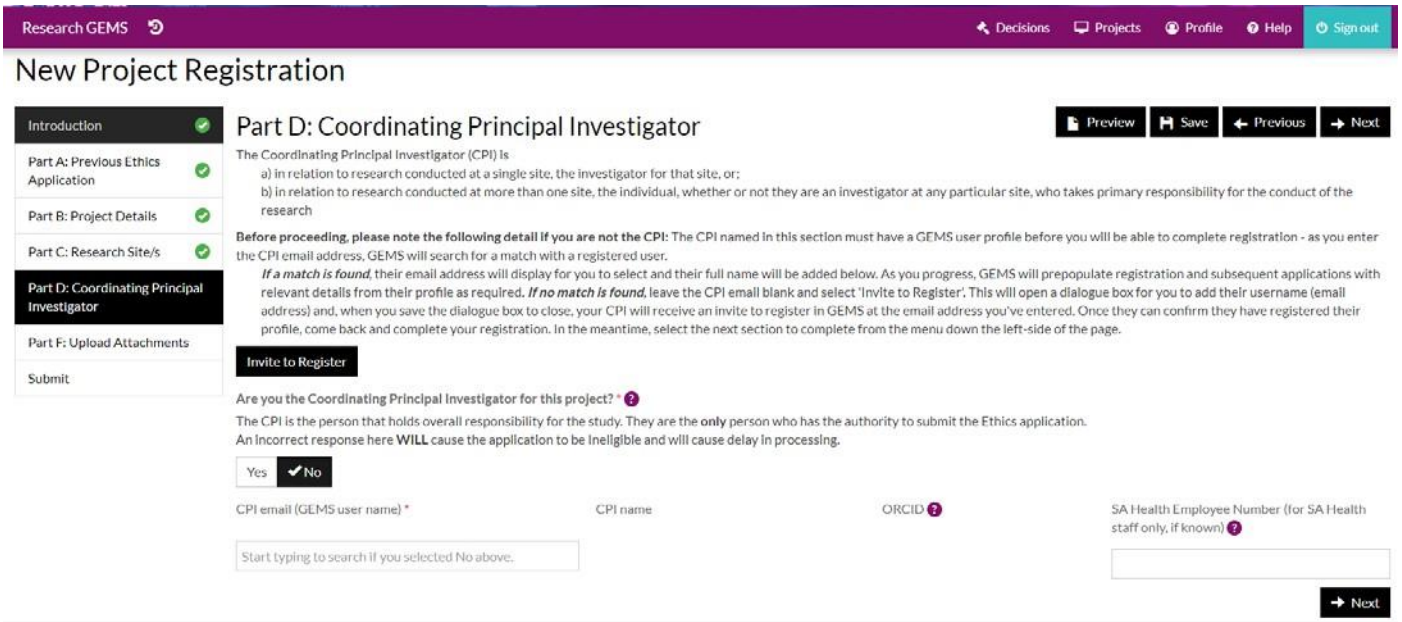

k. **Part F – Upload Attachments**

i. If the reviewing HREC is an external HREC please only upload these documents:
   1. HREA
   2. HREC Approval Letter
   3. Protocol

ii. All other supporting documentation should be uploaded to the Clinical Trials Share Drive to your specific clinical trial unit folder.

iii. To upload documents, select the "+" button in the bottom left-hand corner

iv. Select what document type it is from the drop down selector

v. In 'Document Descriptor' please insert the naming convention you prefer your document to be labelled as

vi. Fill in, 'Version Number' (please put N/A if there is none) and then the date of the document (please do not enter a random date as this will follow through your application)

vii. Please note: there is a maximum file size of 20.00MB per file

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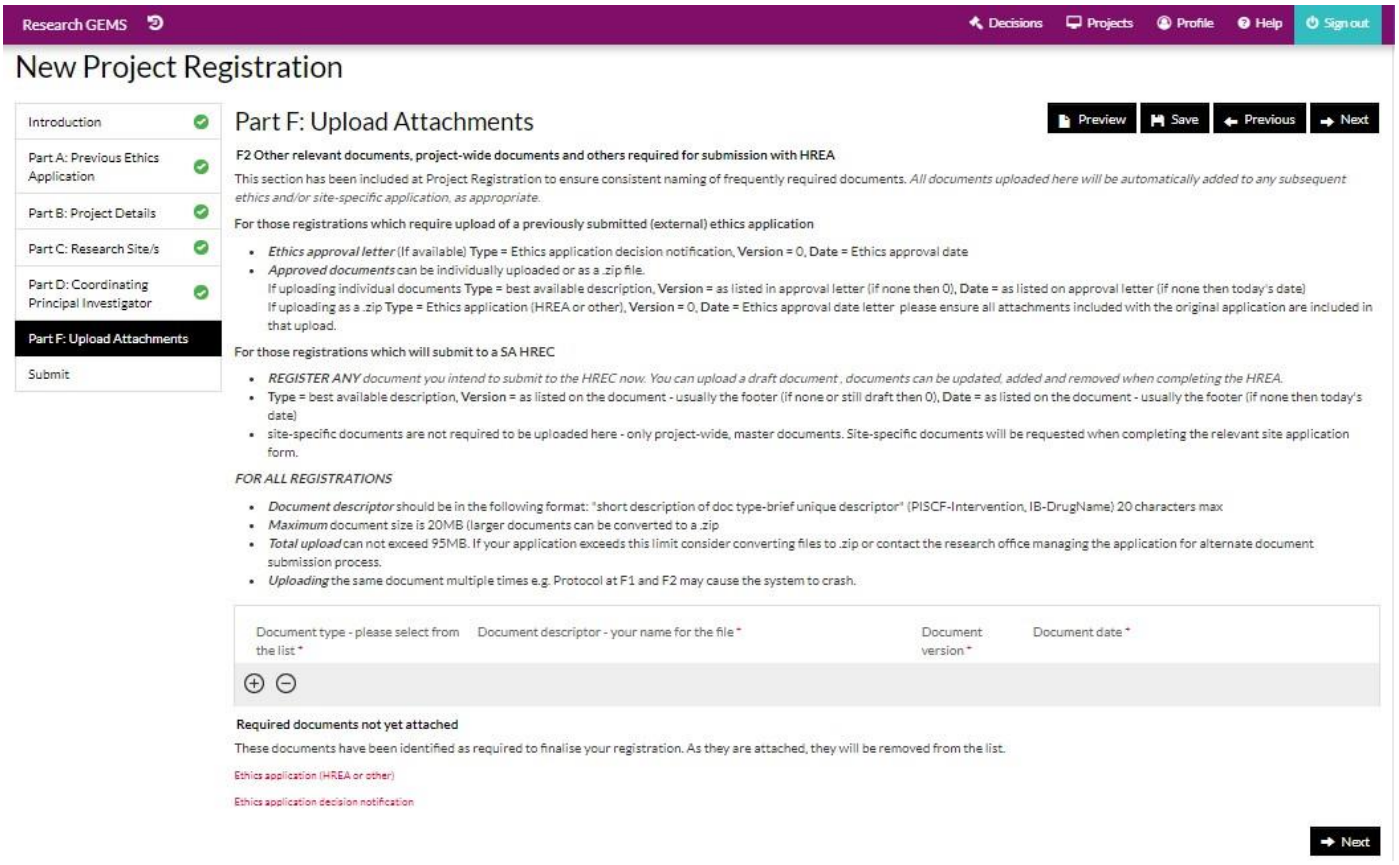
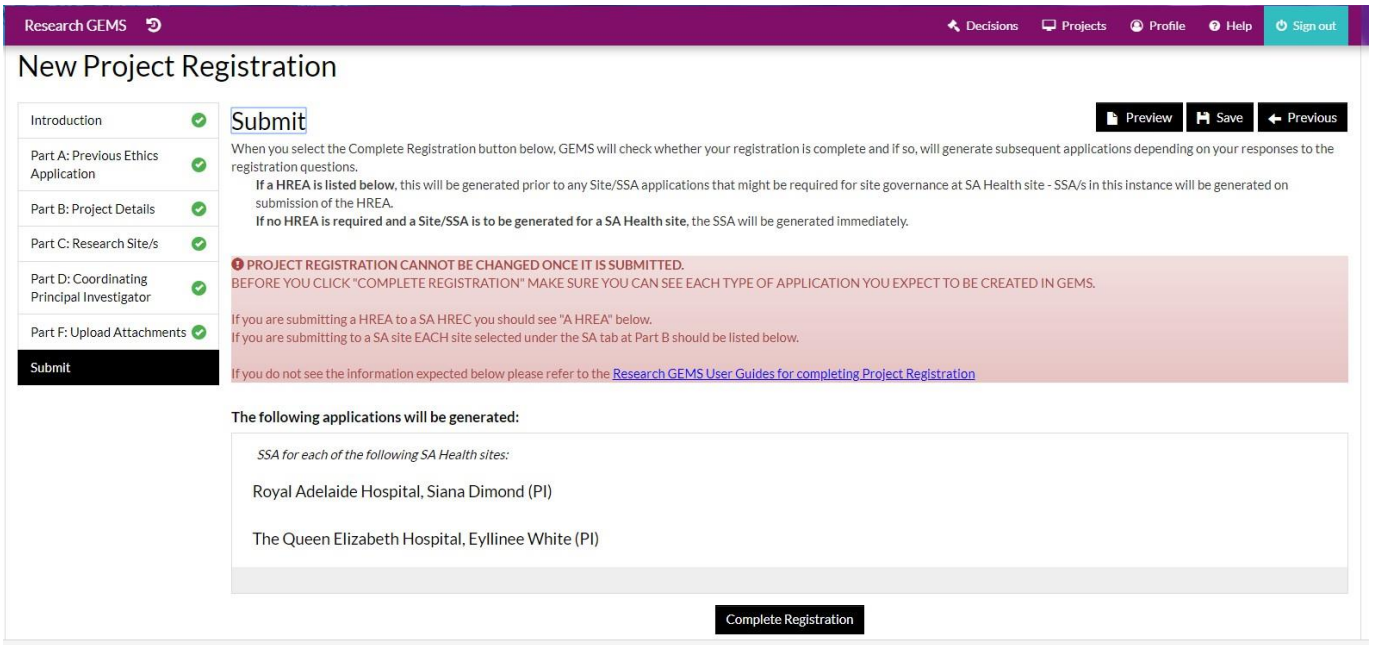


viii. Then upload the document by selecting "Select upload new" > Choose the file > Select the file > Open > Start Upload

ix. Then click the (+) button to add upload additional documents via the same method

x. Click 'Next' once all the documents have been uploaded

l. **Submit**



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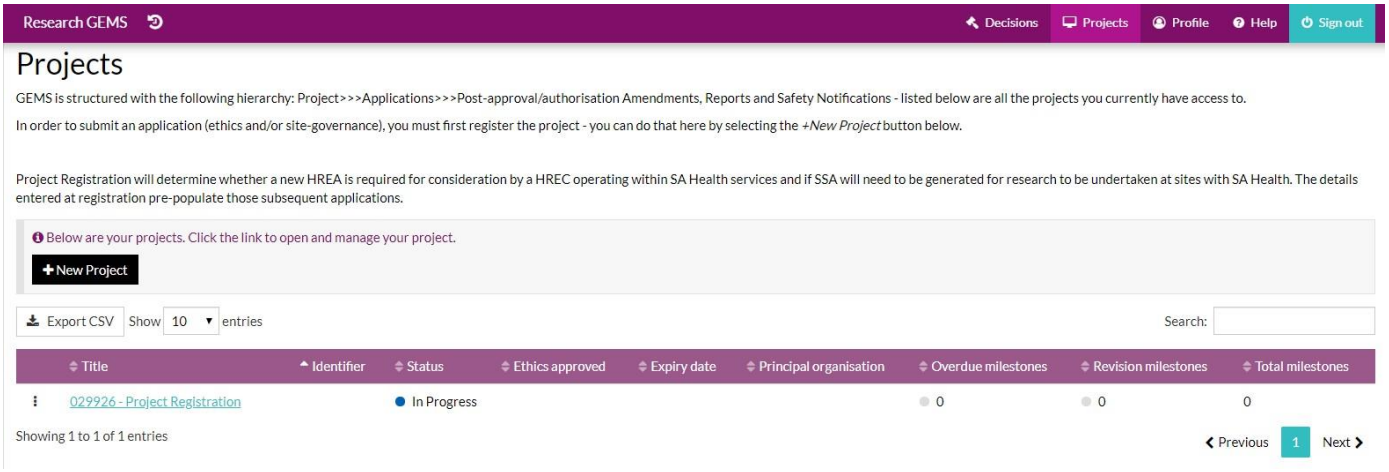
i. Please double check your project registration is correct before you submit it, as you **can't** make edits to it once it has been submitted
ii. When satisfied the registration information entered is correct, click 'Complete Registration'
iii. Following submission, you will be returned to the Projects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



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

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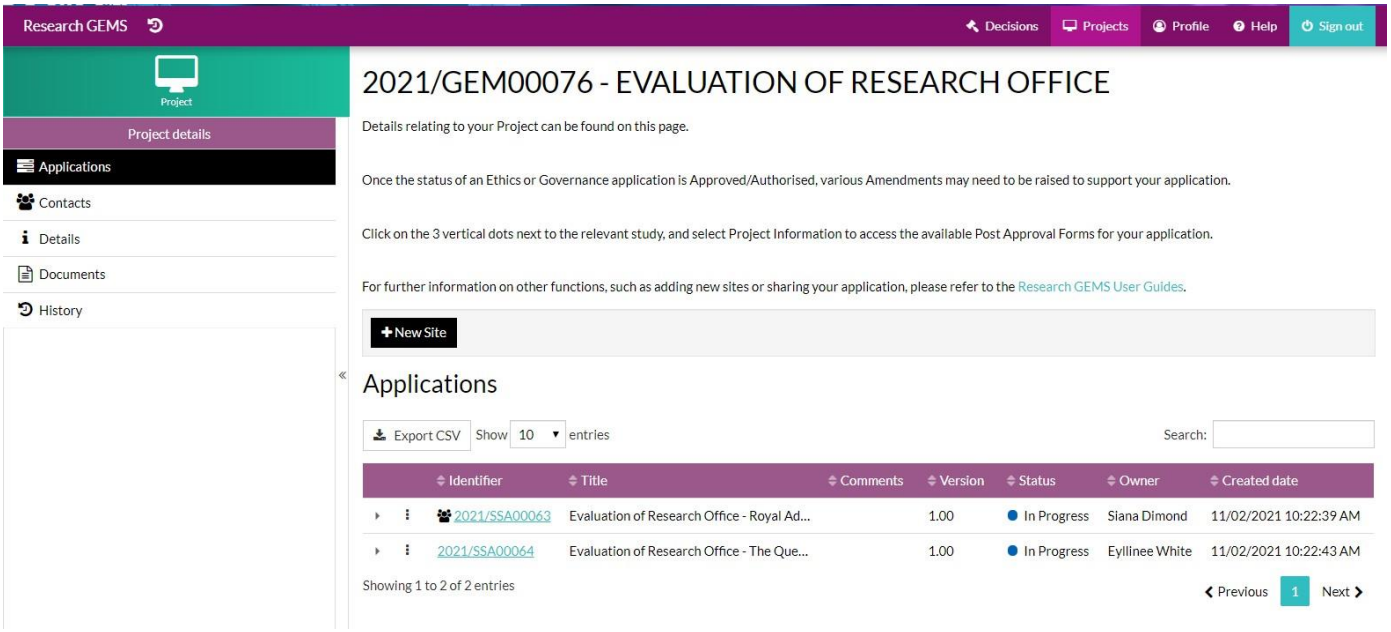
Site Specific Assessment

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

i. **Please note:** the coordinator/research personnel can add information to the SSA, however only the PI will be able to submit the SSA



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/TQEH
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

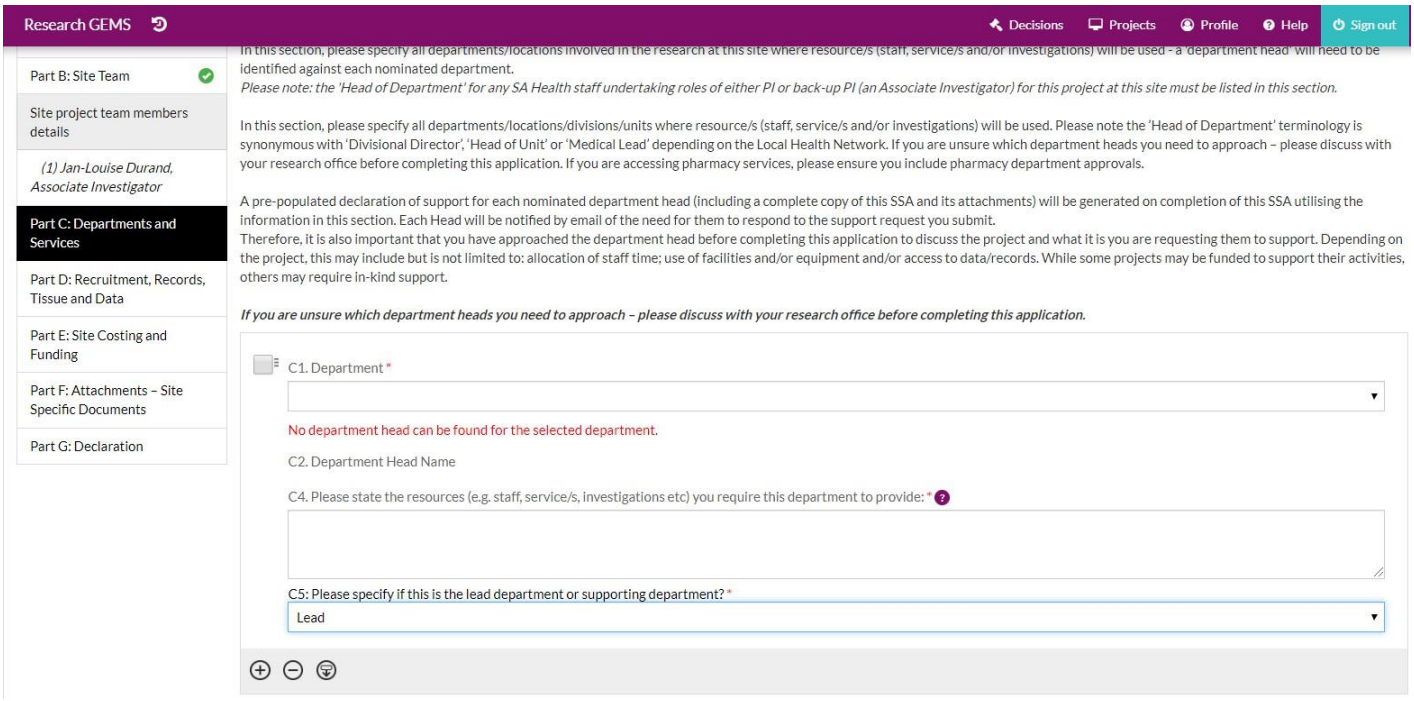
D. Part C – Departments & Services

i. This is where you will add the Lead Department

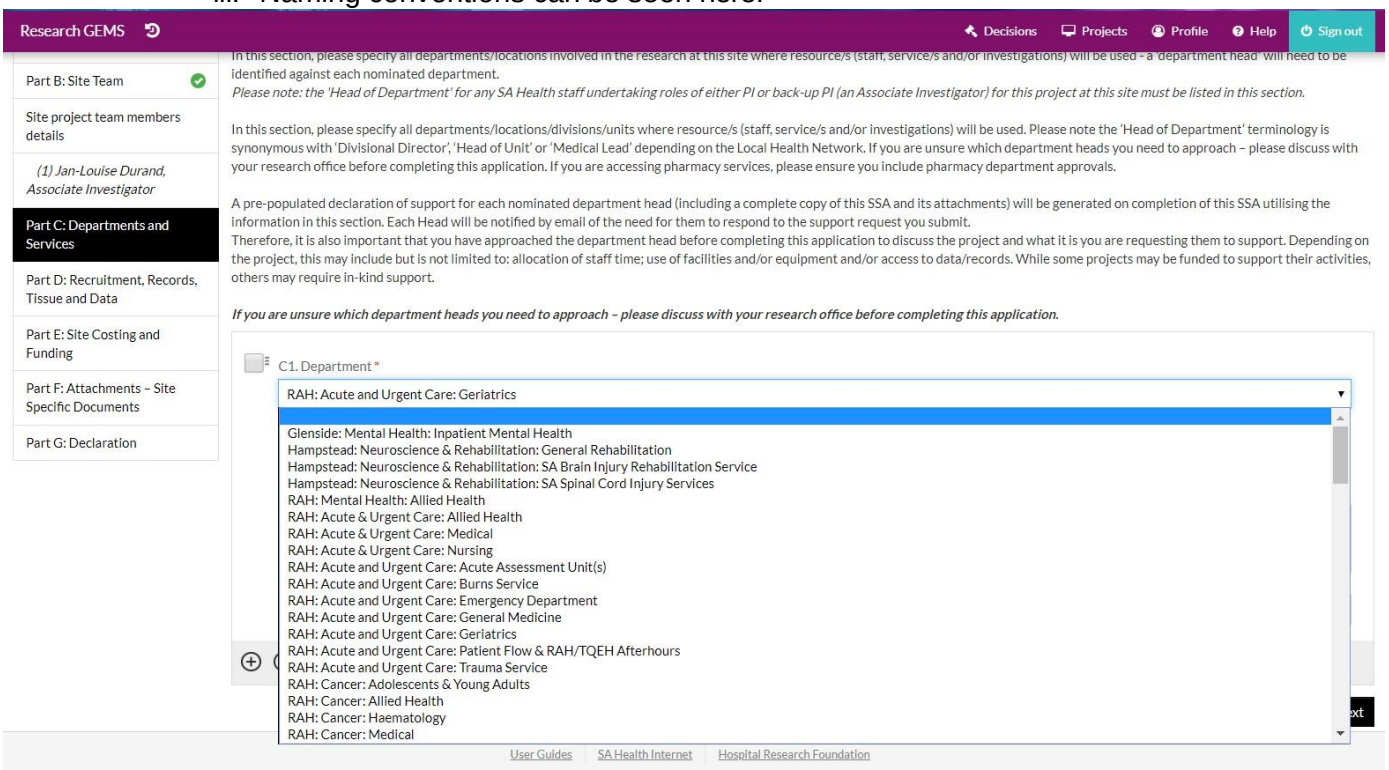
1. Select the drop down list and click on the appropriate Department for your project: **Example:** RAH: Cancer: Haematology

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.



iii. Naming conventions can be seen here:



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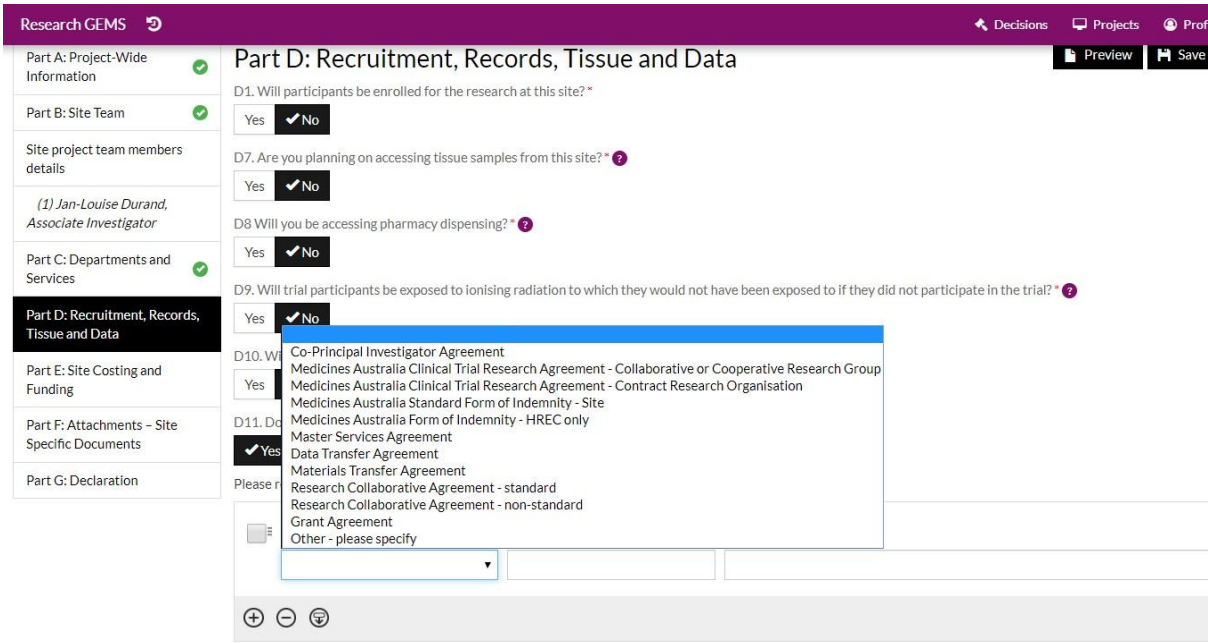
E. Part D – Recruitment, Records, Tissue & Data

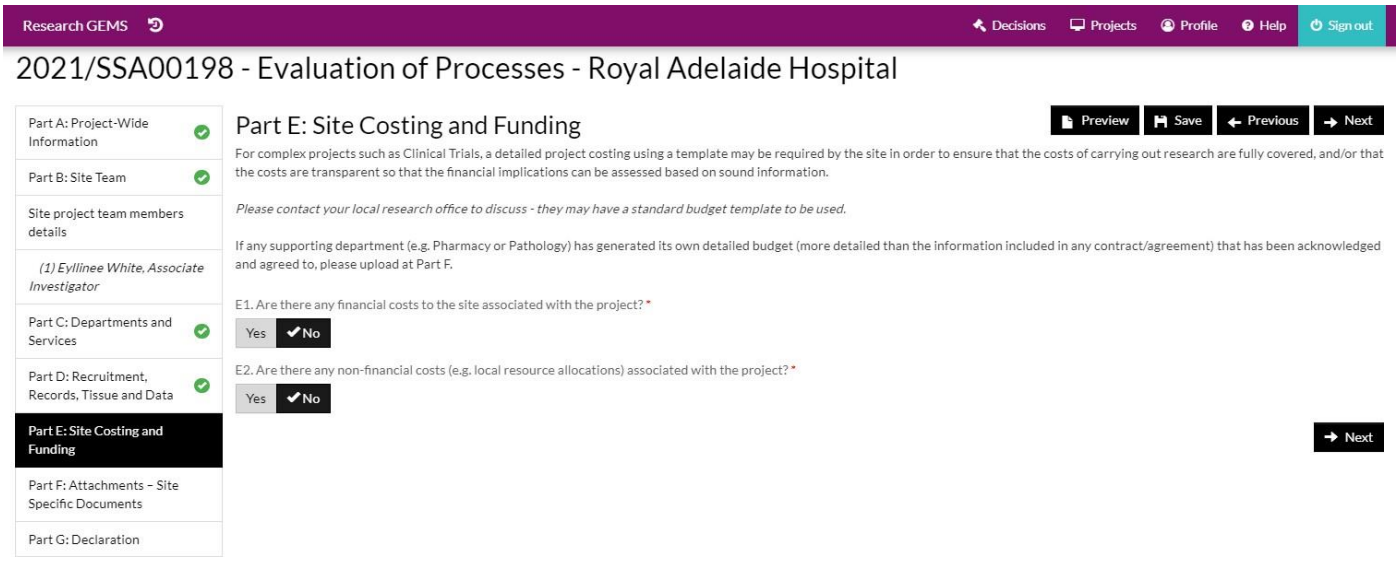
i. Answer questions 'Yes' or 'No' from D1 to D11

ii. For D11, "Do you have any agreements or contracts for this project?" please select "NO"



F. Part E – Site Costing and Funding

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



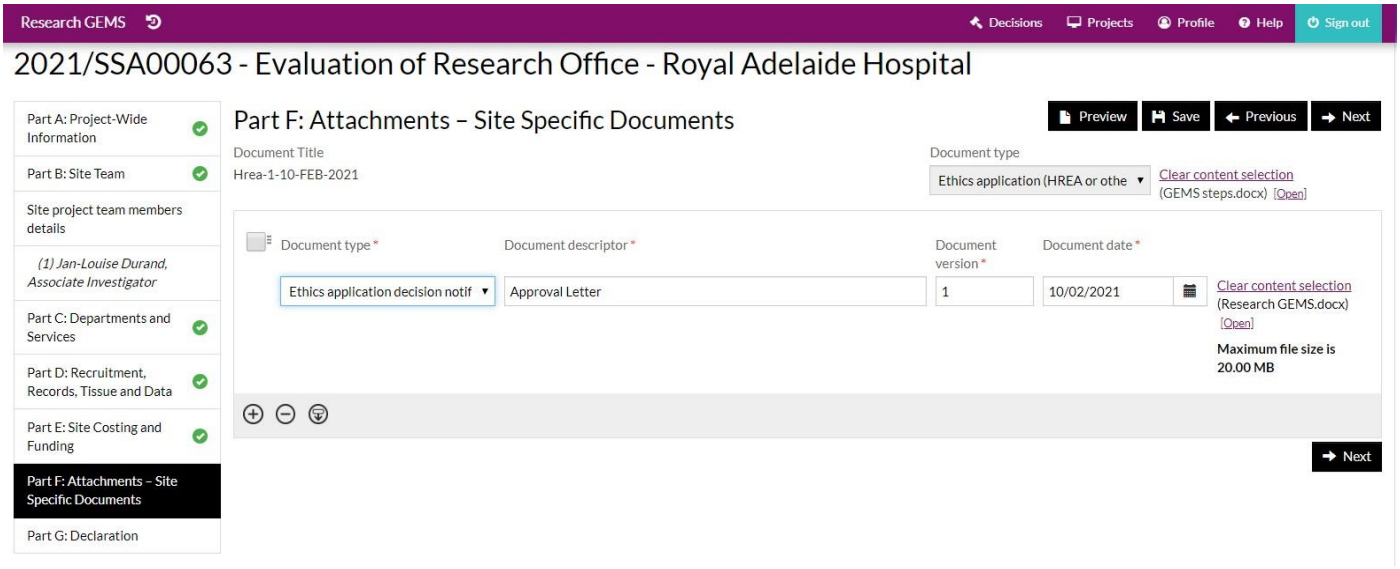
G. Part F – Attachments/Site Specific Documents

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)

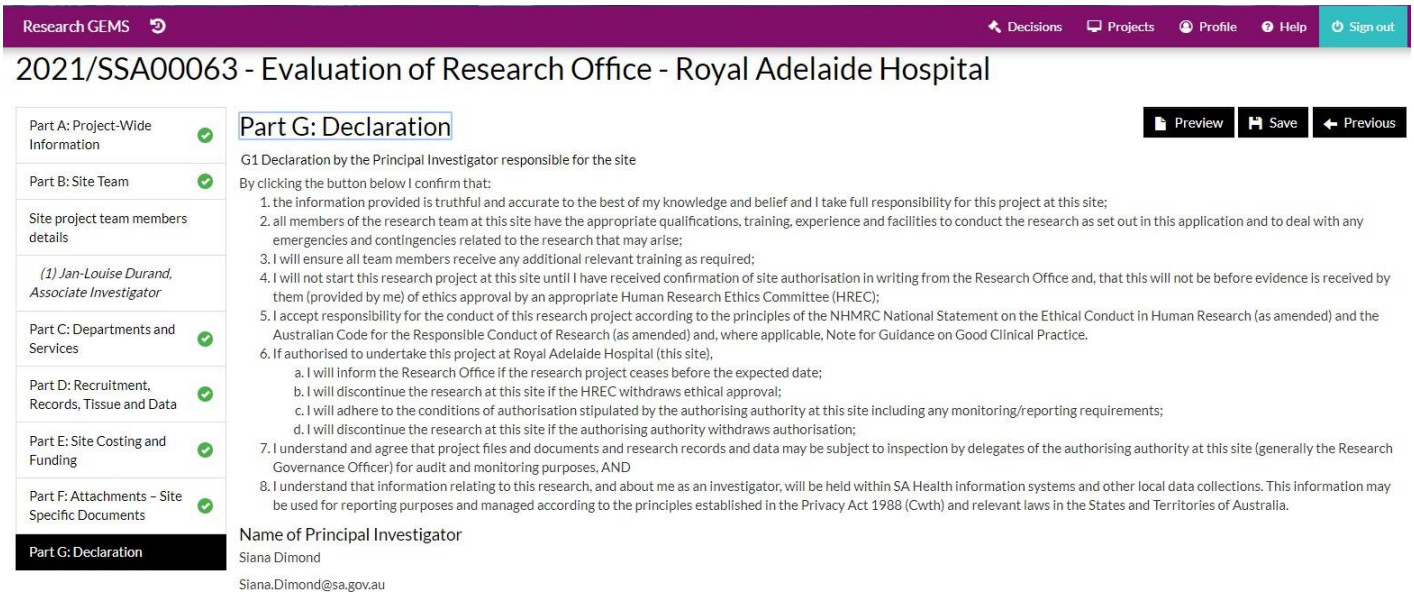
ii. Check that the documents did come across from the project registration as it should appear as below

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:

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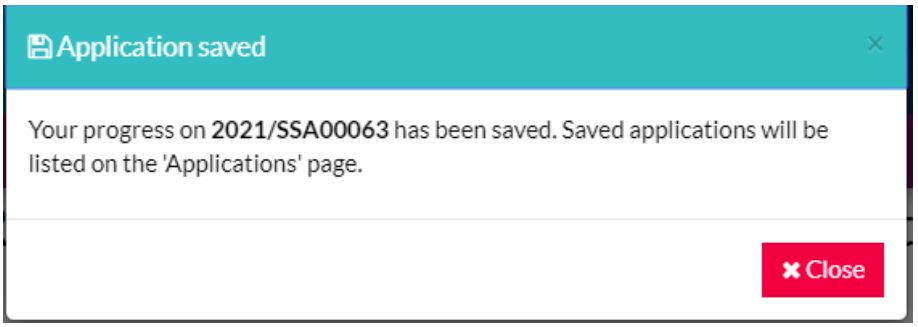
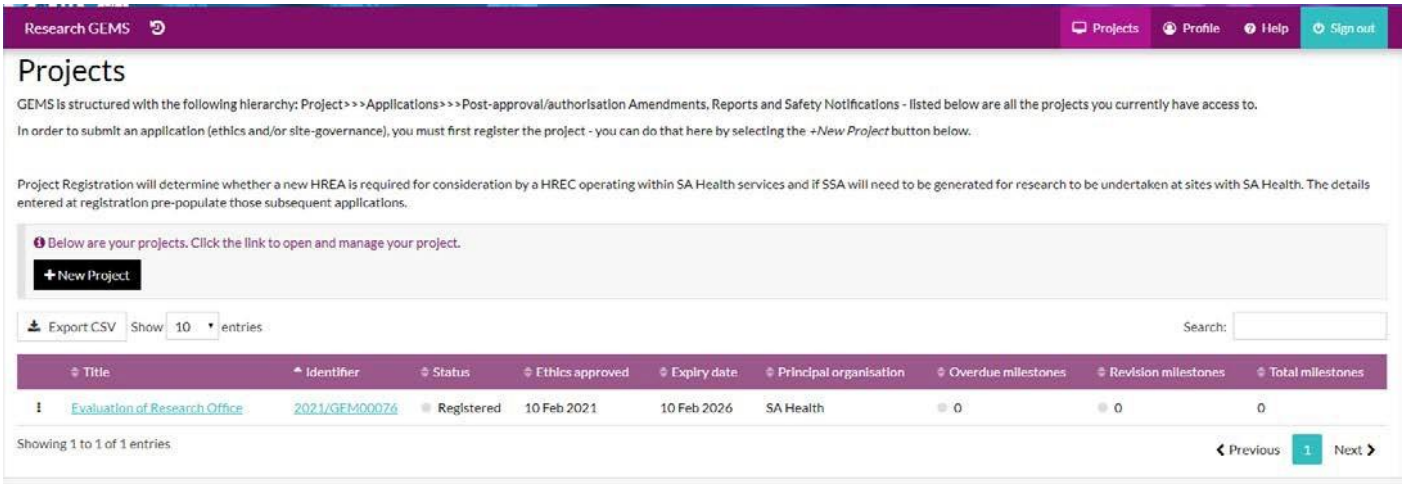
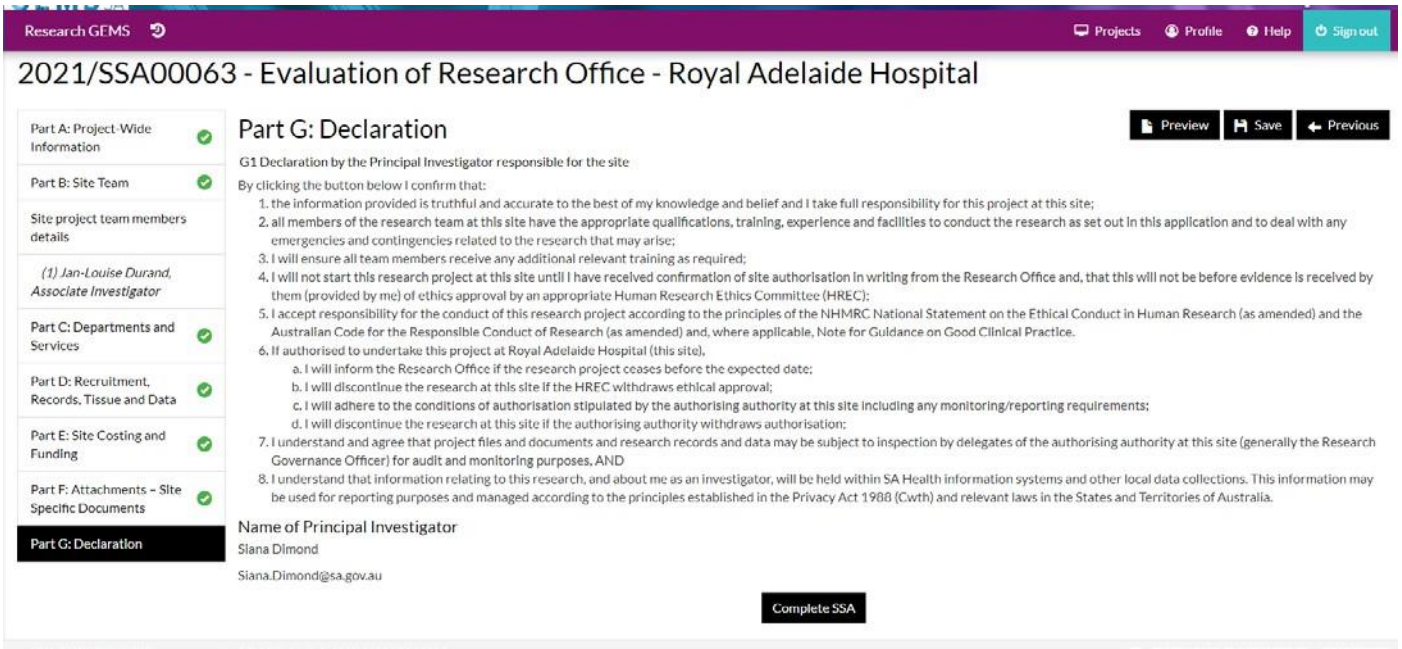


iii. The project should then appear in the PI's project list when they log in. To access the projects section, click 'Projects' on top right-hand corner



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'



viii. This will then process

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

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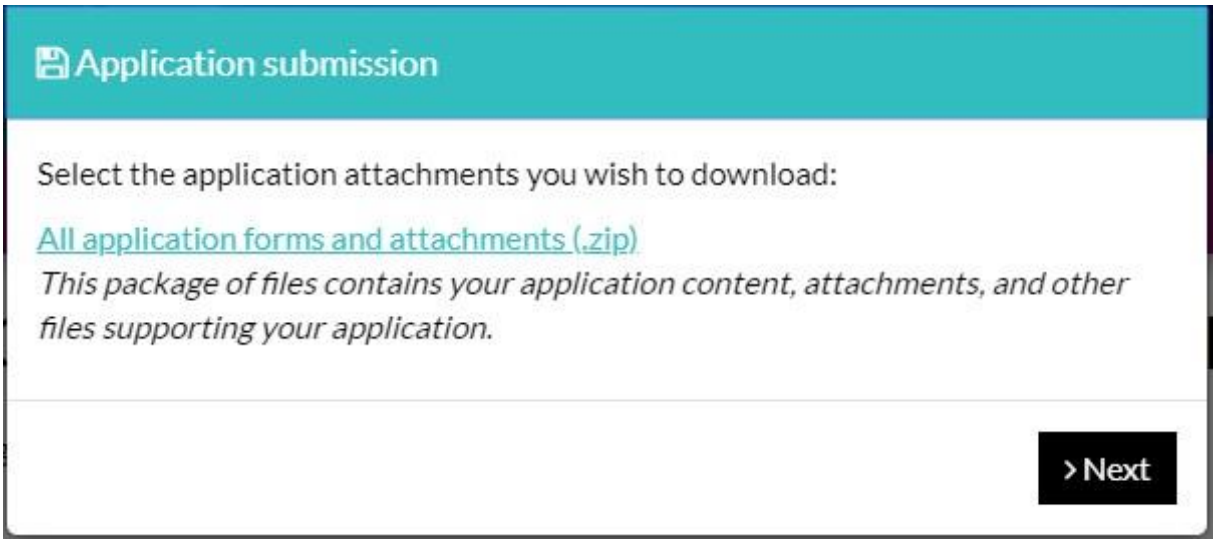
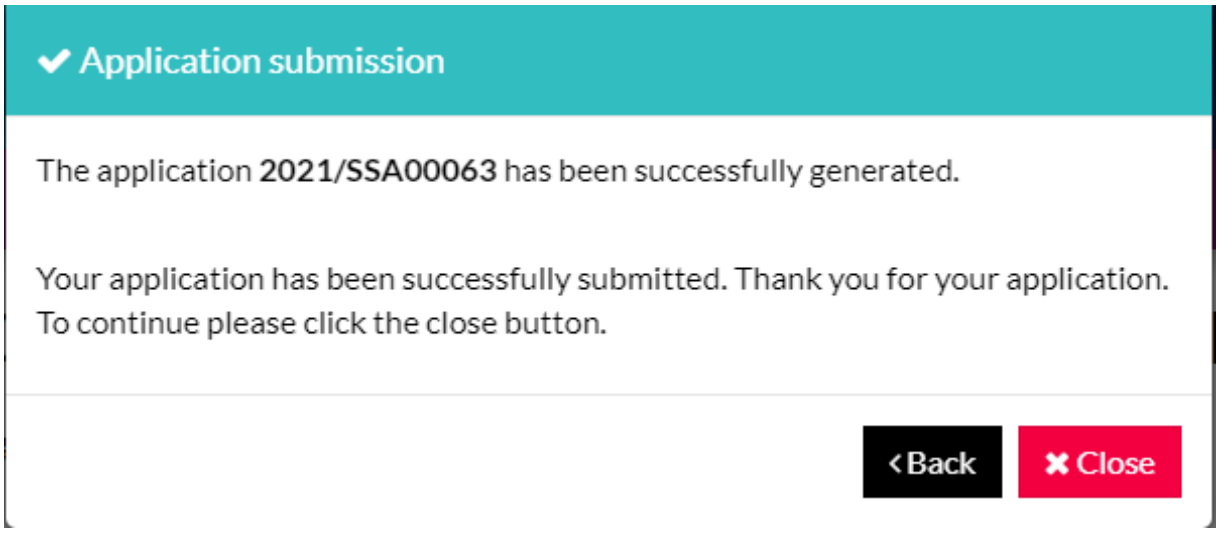


x. Another pop-up box will appear to let you know the project has successfully been submitted > click close



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

xii. Please email Health.CALHNClinicalTrials@sa.gov.au to notify CALHN Research Services that your application has been submitted and is ready for processing

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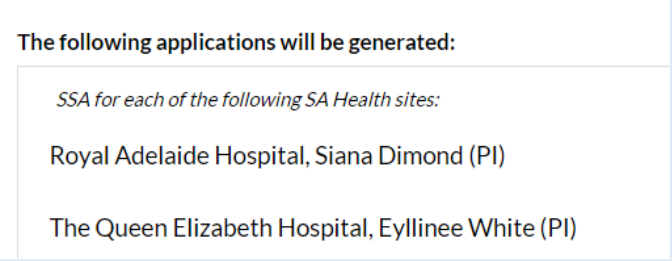
Hints / Tips / Key Points

Project Registration

Project Registration	Login/Register: • https://gems.sahealth.sa.gov.au/ Projects Page: • 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.
Part A: Previous Ethics Applications	External Ethics Approval • Once submitted GEMs will create a SSA application for each SA Health site added Internal Ethics Approval (CALHN HREC) • 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
Part B: Project Details	• Ensure everything is entered precisely. After submission you will not be able to edit your project registration.
Part C: Research Site(s)	• 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. ○ Do not use the "New Site" button above "Applications". If you use this method, you will have to withdraw the SSA created and re-submit using the site amendment method
Part D: Coordinating Principal Investigator	• 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.

	• If you do not assign the correct the CPI, this will have a flow on effect and will delay your application

Part F: Upload Attachments	• For external ethics:
	  ○ 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
	  ○ 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

Submit	• 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 

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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	• This section will be prefilled- the information will be taken from your project registration • Ensure all the details are correct
Part B: Site Team	• 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	• 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	• Send agreements via email to Health.CALHNClinicalTrials@sa.gov.au • Under “Agreement Location” please select “No”
Part E: Site Costing & Funding	• Select “Yes” or “No” as applicable
Part F: Attachments/Site Specific Documents	• 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	• 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:

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

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