

Overview

This guideline will provide the necessary information for researchers to submit their Project Registration and Ethics Applications for Investigator Initiated Studies via Research GEMS.

Scope

This guideline will help to achieve the following:

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

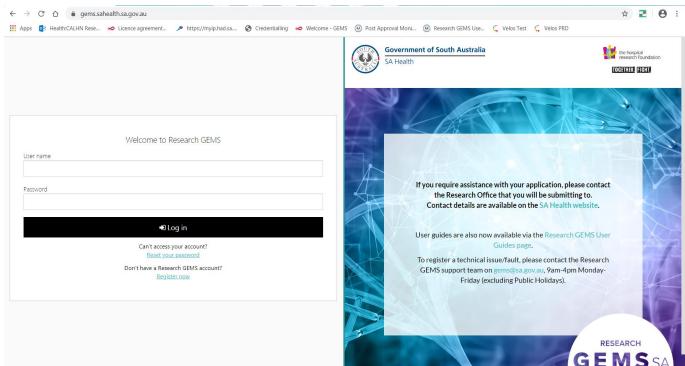
Definitions & Acronyms

- GEMS Governance and Ethics Management System
- HREA Human Research Ethics Application
- SSA Site Specific Assessment or 'Site' Application
- Project Study
- CPI Coordinating Principal Investigator
- PI Principal Investigator

Procedures

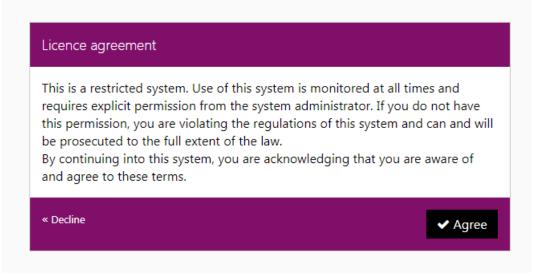
Registering a Project

- Go to the GEMS Website located <u>here</u> https://gems.sahealth.sa.gov.au/>
- 2. Login/Register Account



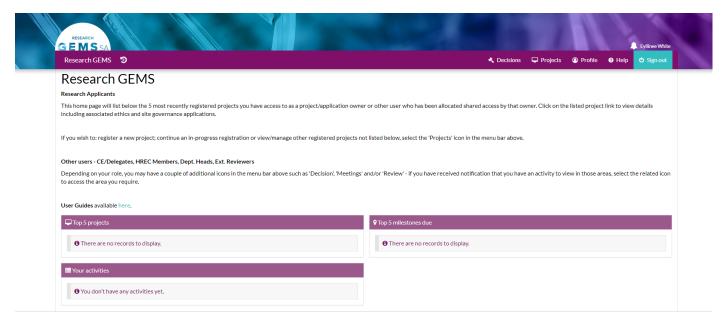


- a. If your account is set up, login with your username and password
 - i. If you have received an email but have not yet logged in before, click 'Reset your password' and enter the email address the original email went to
- b. If your account is not set up
 - i. Try logging in with your SA Health government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



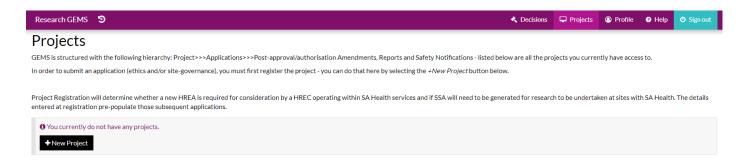
3. Registering your Project

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

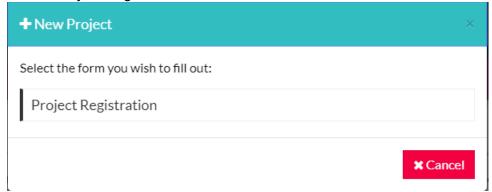


- b. To register a project, navigate to the 'Projects' tab on the right hand corner
- c. Click 'New Project'

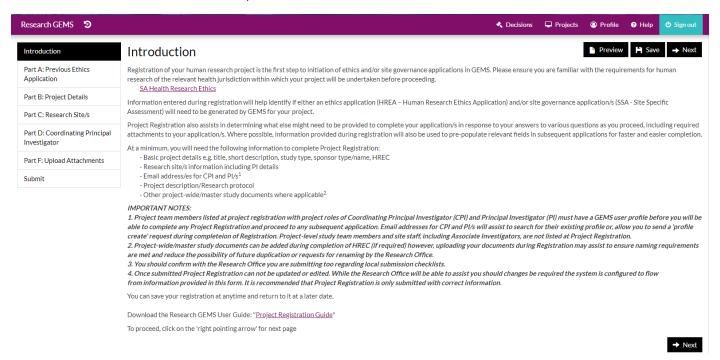




d. Select 'Project Registration'

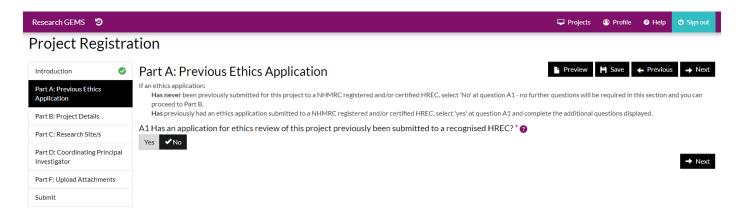


e. This will then navigate you to the 'New Project Registration' Page on the 'Introduction' tab. Read this information, then click next.

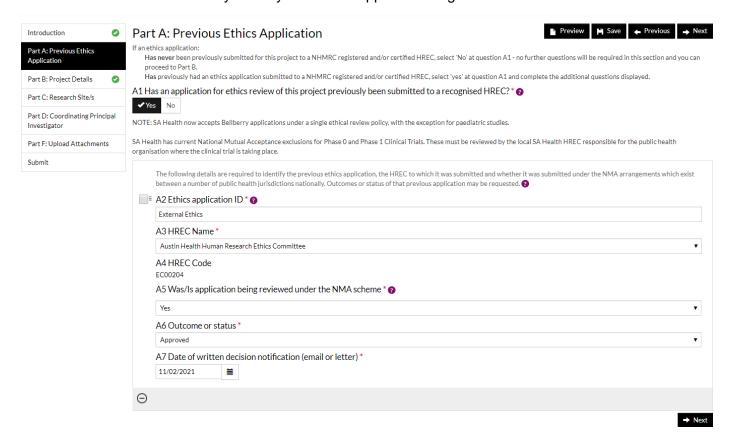


- f. This will navigate through Tabs A-F.
- g. Part A: Previous Ethics Application





i. If the study already has ethics approval listing the relevant CALHN site > Select 'Yes'

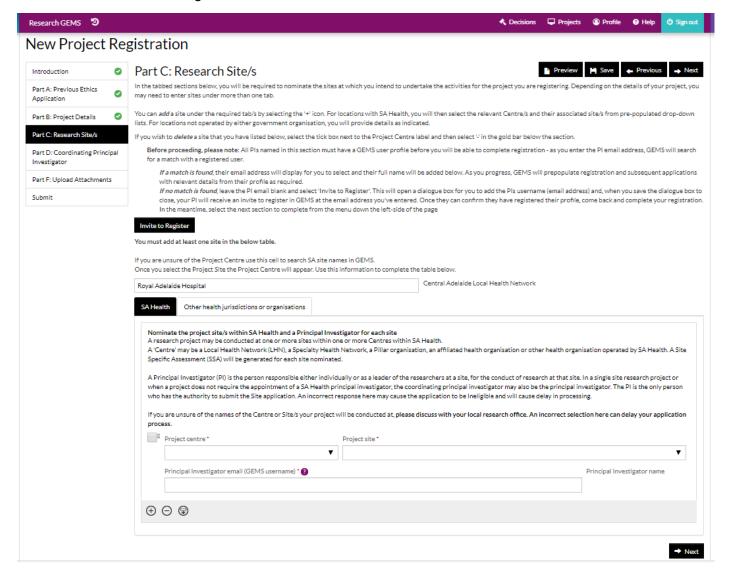


ii. For new ethics applications to be reviewed by the CALHN HREC > Select 'No'

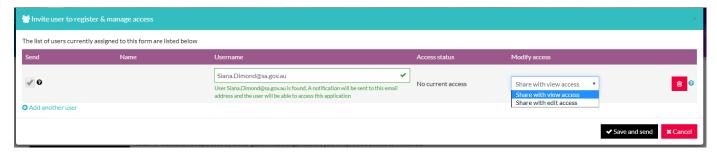
- h. Part B: Project Details
 - i. Fill in details related to your project > click next
- i. Part C: Research Site(s)
 - This the step where you can invite other study personnel to register and have access to the project.
 - ii. Click 'Invite to register'
 - iii. Add another user
 - iv. Enter email address (SA government or institutional email addresses)



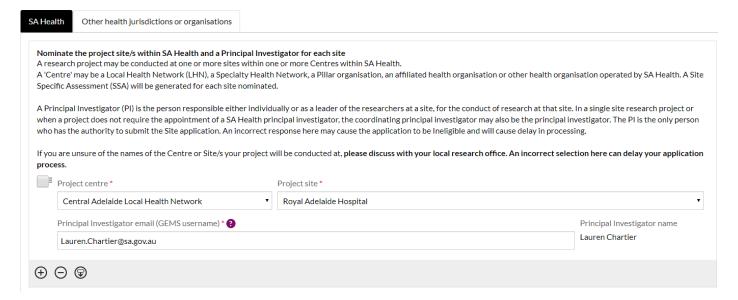
- v. Select what access they should have
 - 1. Share with view access will allow the user to view but not edit the project
 - 2. Share with edit access will allow the user to be able to make changes to the project
- vi. Then click save and send
- vii. **Note:** If you make a mistake of adding someone, you can click the red trash can on the right-hand side to delete the invited user





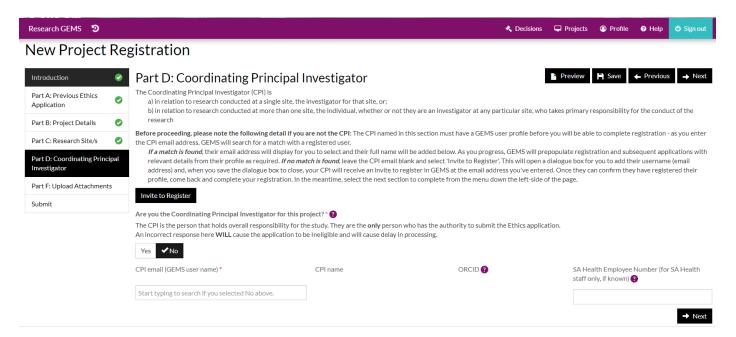


- viii. Select the site you will be conducting the research at, when you begin to type the site should appear in the drop-down selector box. This will then pre-fill the local health network next to the site name.
- ix. Then fill in the 'Nominate the project site/s within SA Health and a PI for each site' 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 any SSA's related to this application
- 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 you selected 'yes' this prepopulates to the account holder who is currently logged in and filling out the registration
 - Note Only the CPI can submit the Project Registration and Ethics applications

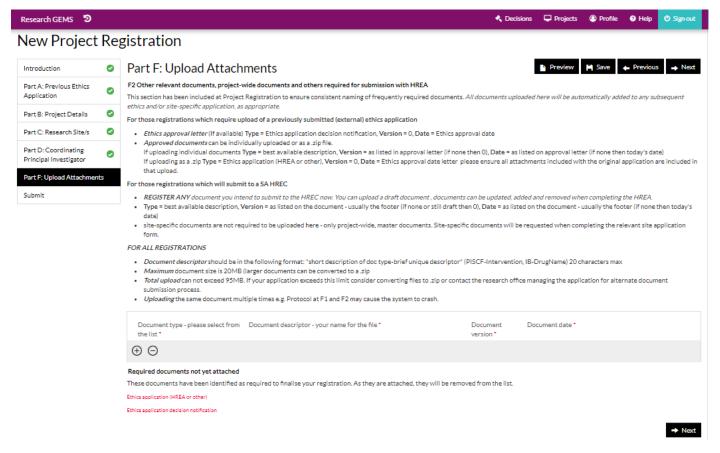




k. Part F - Upload Attachments

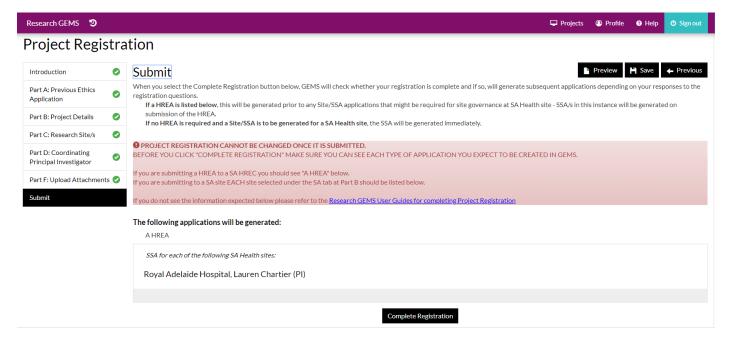
- i. To upload documents, select the "+" button in the bottom left-hand corner
- ii. Select what document type it is from the drop-down selector
- In 'Document Descriptor' please insert the naming convention you prefer your document to be labelled as
- iv. Fill in, 'Version Number' (please put N/A if there is none) and then the date of the document (please do not enter a random date as this will follow through your application)
- v. Please note: there is a maximum file size of 20.00MB per file





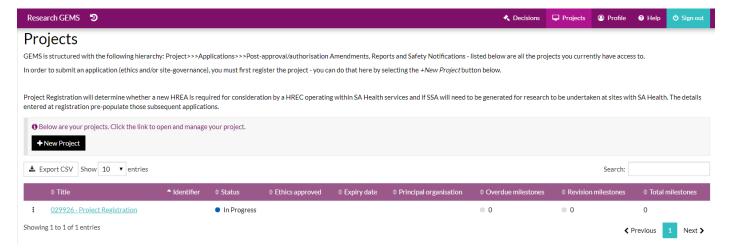
- vi. Then upload the document by selecting "Select upload new" > Choose the file > Select the file > Open > Start Upload
- vii. Then click the (+) button to add upload additional documents via the same method
- viii. Click 'Next' once all the documents have been uploaded

I. Submit

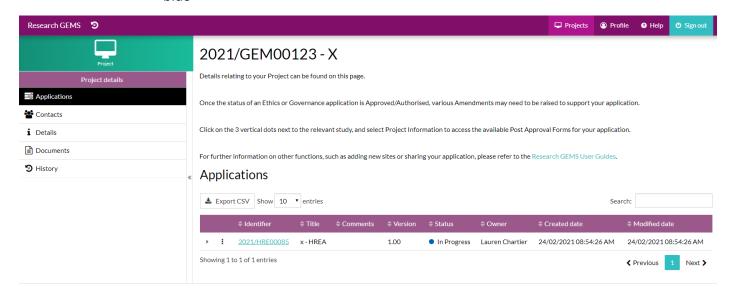




- i. Please double check your project registration is correct before you submit it, as you cannot make edits to it once it has been submitted
- ii. When satisfied the registration information entered is correct, click 'Complete Registration'
- iii. Following submission, you will be returned to the Projects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

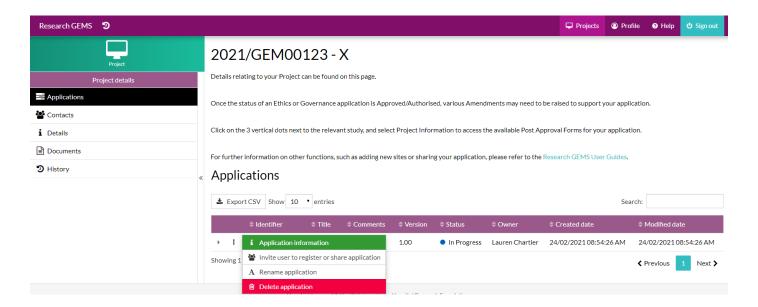


- iv. You are now able to complete your HREA
- v. Click on your project title which is in light blue and this will navigate you to your 'Applications' page for that project
- vi. HREA can now be completed by clicking on the 2021/HRE000XX application in light blue



vii. **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'

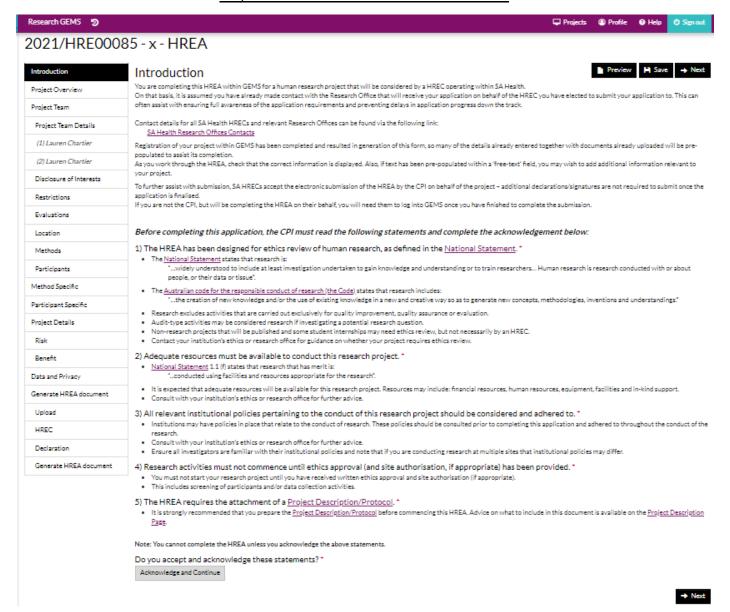






Human Research Ethics Application

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



ii. Select 'Acknowledge and Continue' and 'Next' on the Introduction page

1. Project Overview

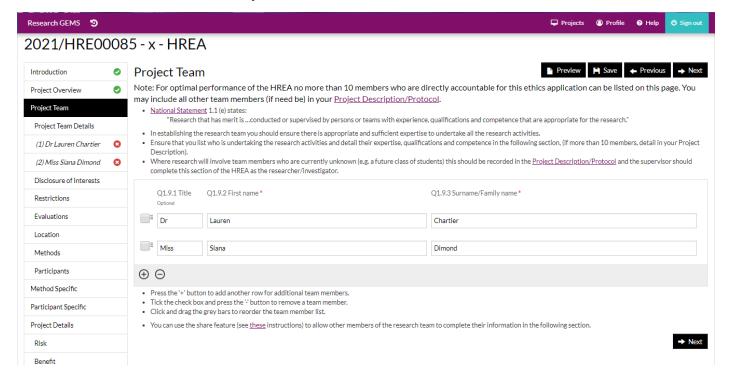
- iii. Q1.1 Insert Project Title
- iv. Q1.2 Project summary in lay terms
- v. Q1.3 Category/ies of research is populated from information provided in Project Registration
- vi. Q1.4 What type of institution research will be conducted in
- vii. Q1.5 Who has overall ownership of the study and data obtained



- viii. 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

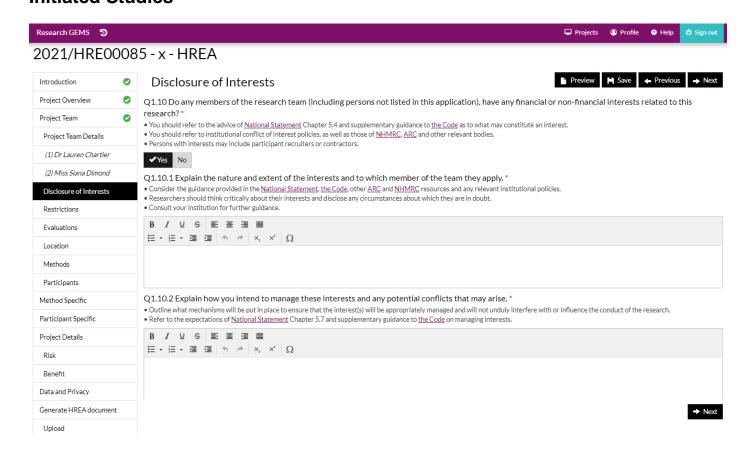
- i. This is where you will add in details about all Investigator(s) and Study Personnel
- ii. You can add more researchers to the Project Team by selecting the '+'
- iii. If you make a mistake and need to remove a Team member, select the person by clicking the large box next to their name and clicking '-'
- 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'



3. Disclosures of Interest

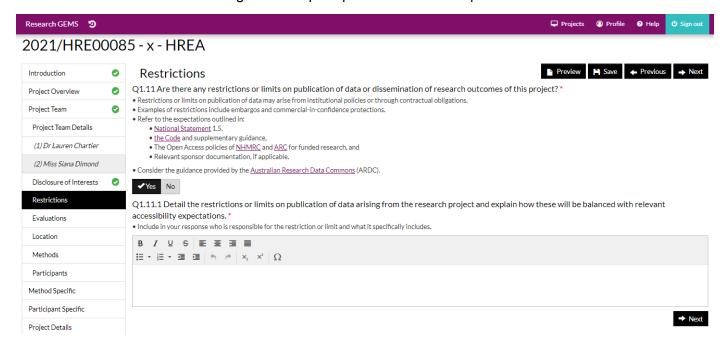
- i. Select 'No' if there are no conflicts of interest to disclose
- ii. Selecting 'Yes' will prompt some additional questions related to the disclosure





4. Restrictions

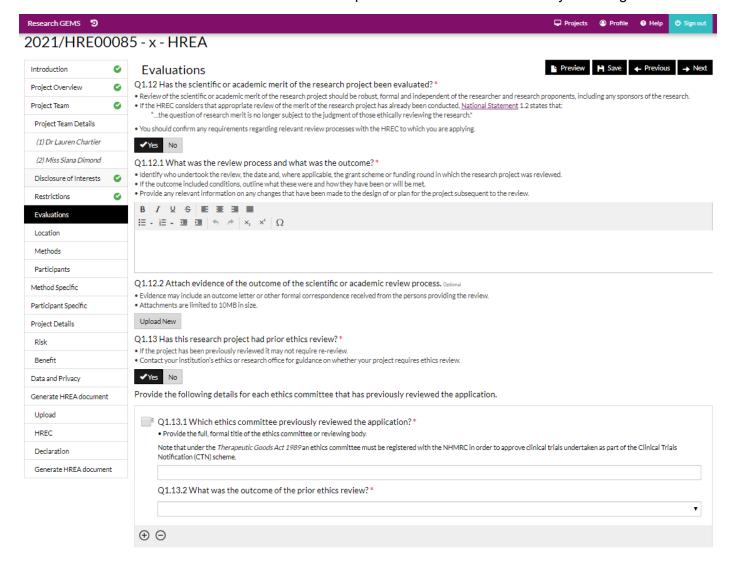
- Select 'No' if there are no restrictions on the publication/dissemination of research outcomes
- ii. Selecting 'Yes' will prompt some additional questions related to the restrictions



5. Evaluations



- Select 'No' for Q1.12, Q1.13 and Q1.14 if there are no related evaluations or previous ethics review
- 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 '-'

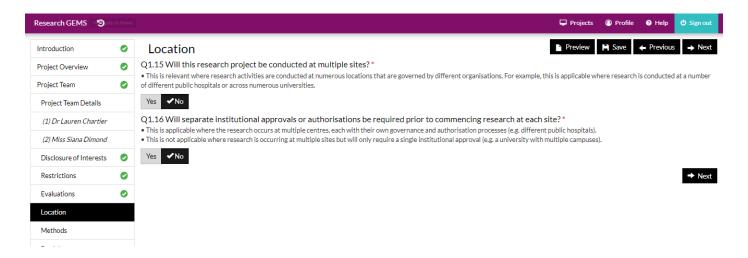


 i. Q1.14 – Selecting 'Yes' will ask for details of who is conducting specialist review and when this will be sought

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'



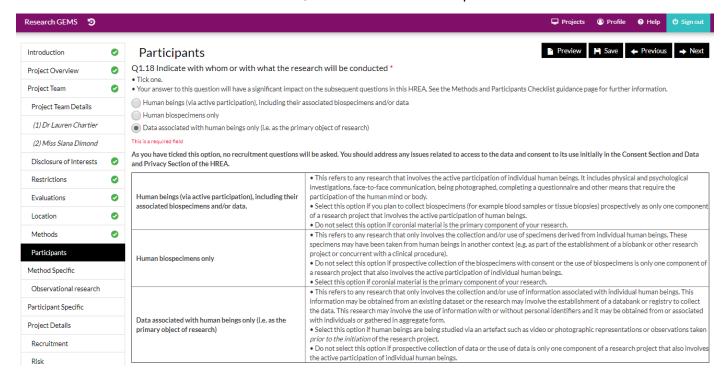


7. Methods

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

8. Participants

- i. 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.
- ii. If unsure of what to select, refer to the information provided in the table below Q1.18

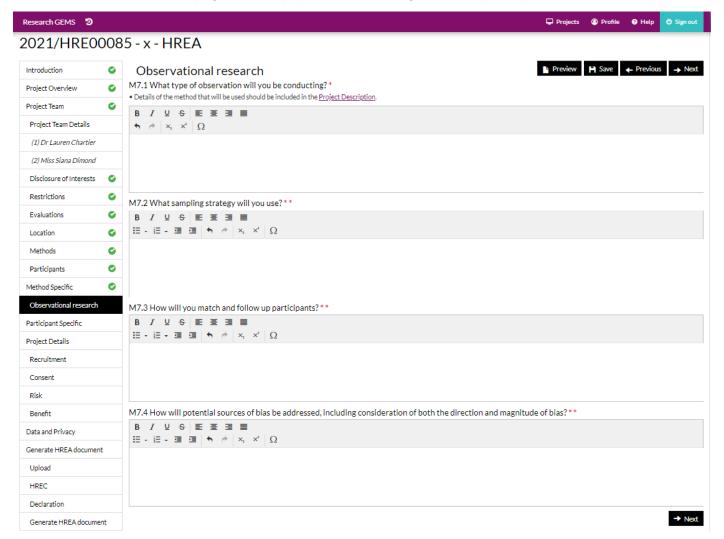


- iii. Q1.18.1 If all data collected is retrospective, select 'No'
- iv. Q1.19 Select any of the categories of participants involved if required. This section can be left blank if none of the specified participant populations are involved

9. Method Specific



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



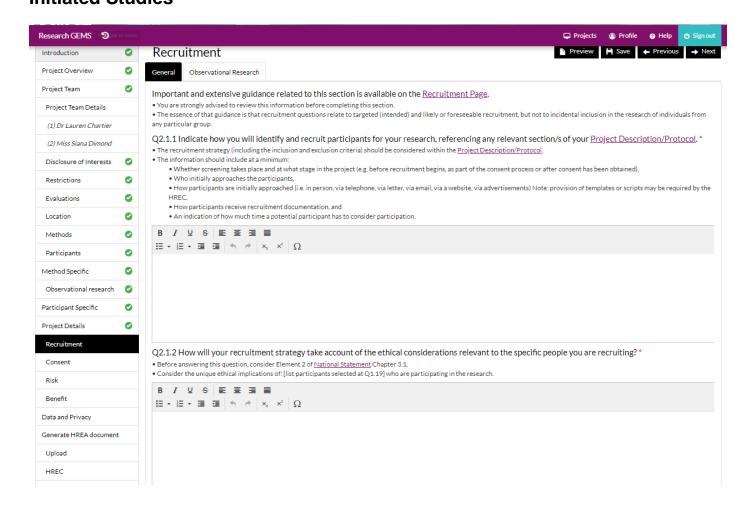
10. Participant Specific

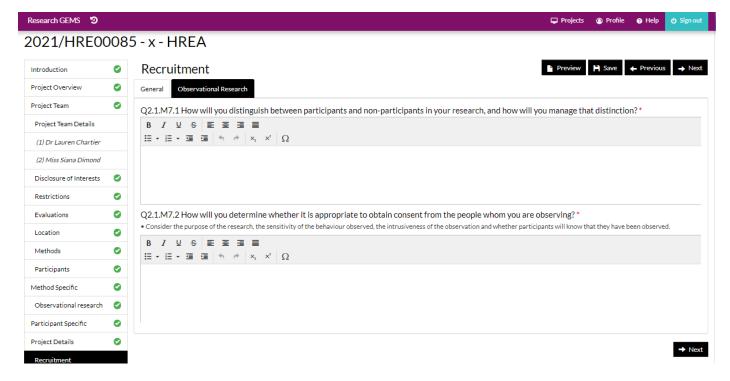
 The next pages will be populated according to the response provided in Q1.18 (Participants)

11. Recruitment

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



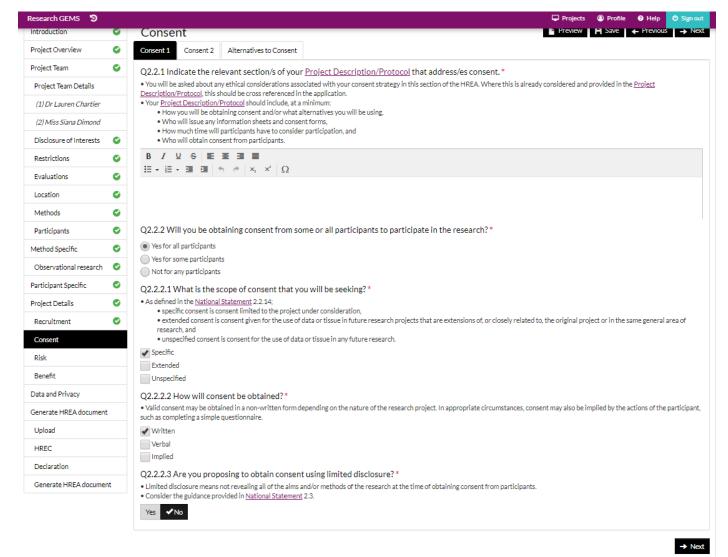






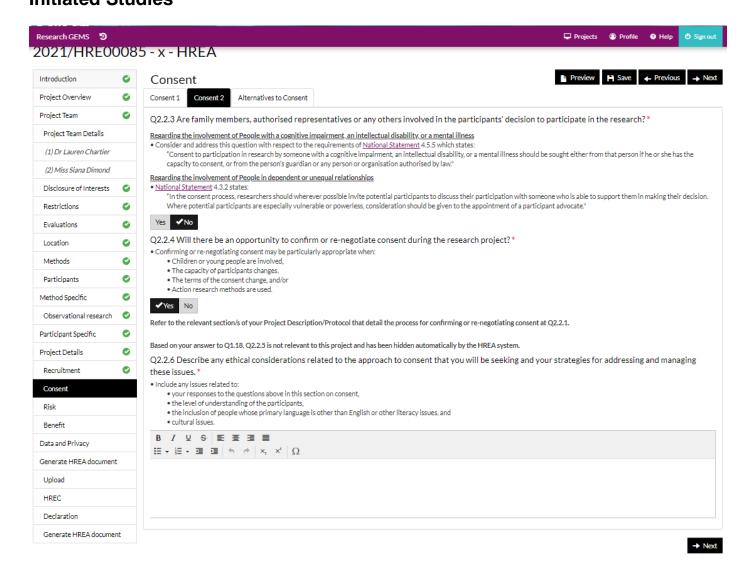
12. Consent

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

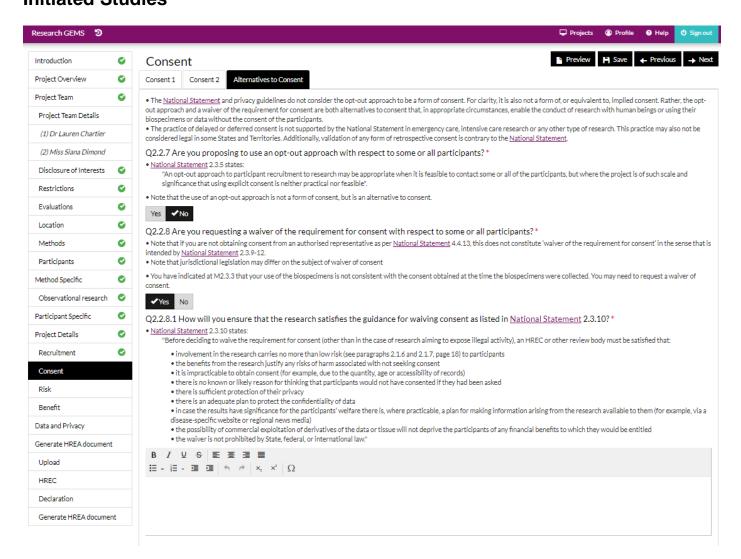


- ii. Select all tabs on the top of the page to complete this section (Consent 2, Alternatives to Consent)
- iii. If you are applying for a Waiver of Consent this will asked in the 'Alternatives to Consent Tab'





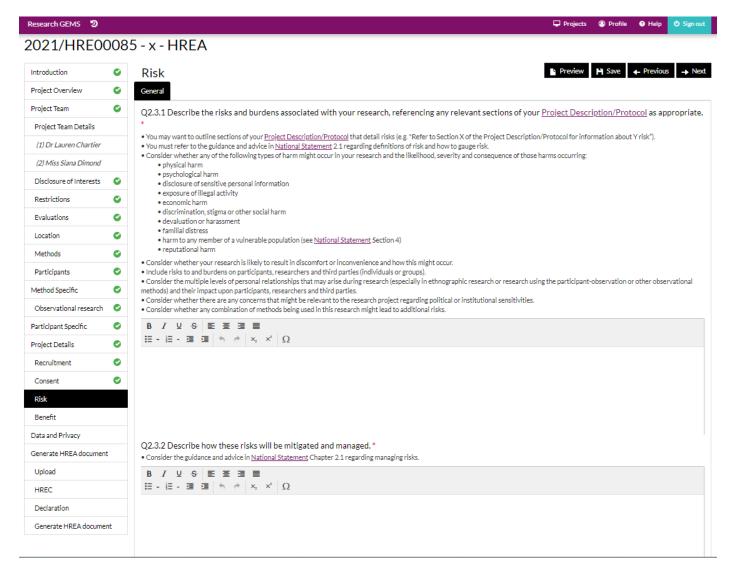




13. Risk

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

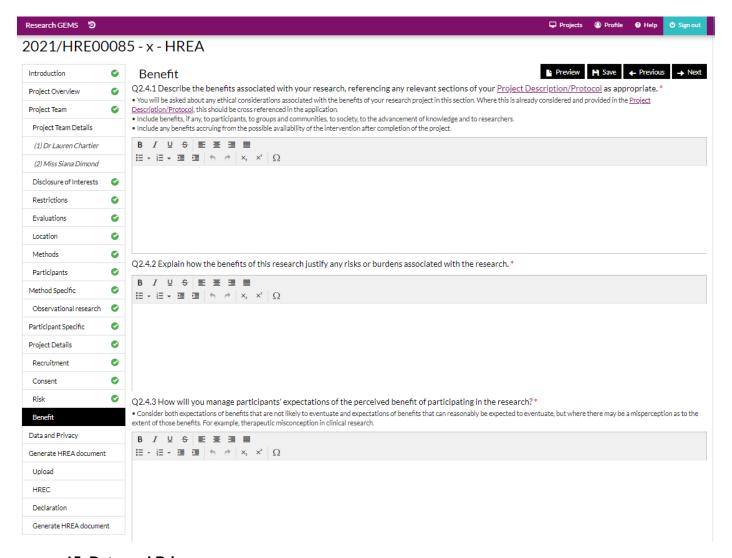




14. Benefit

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





15. Data and Privacy

- 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

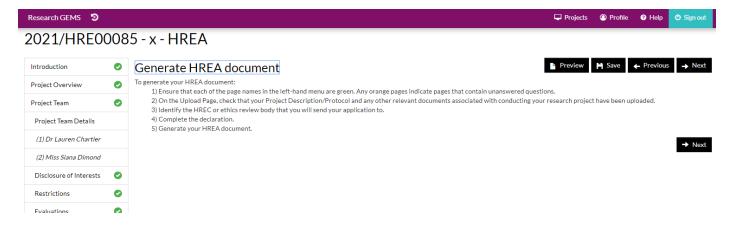
No data custodian identified

- iv. Activities with Data provide information on any sharing of data to third parties and privacy/confidentiality considerations
- v. Refer to relevant sections of the Study Protocol



16. Generate HREA document

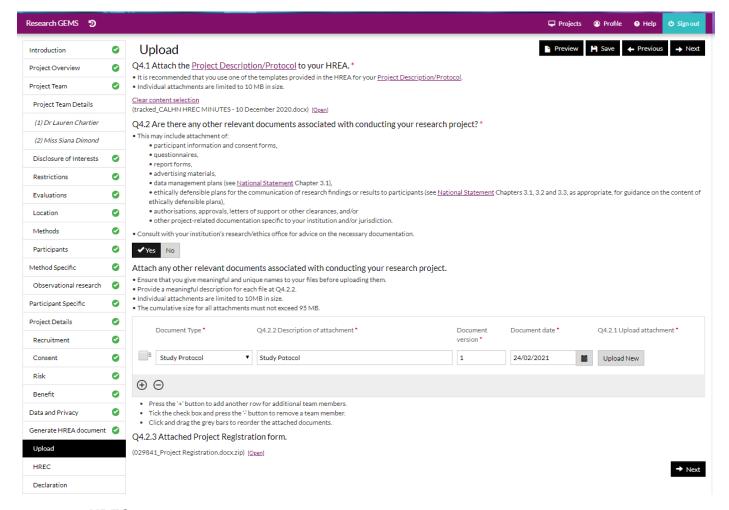
- i. The HREA document can only be generated if all sections on the left-hand side have green ticks next to it
- ii. A red cross indicates that there is a blank field, or something is not completed in that section
- iii. Select 'Next'



17. Upload

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

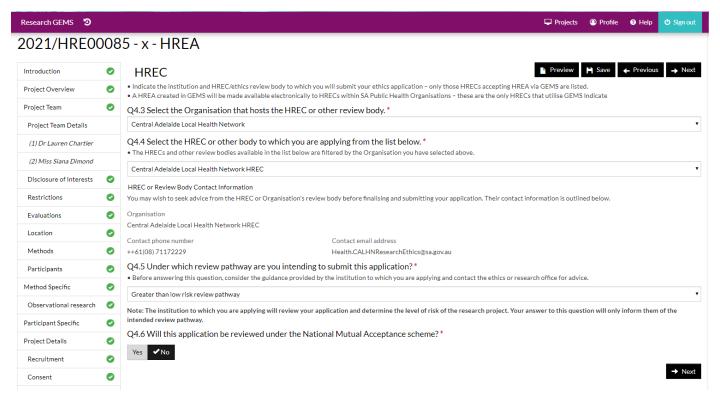




18. HREC

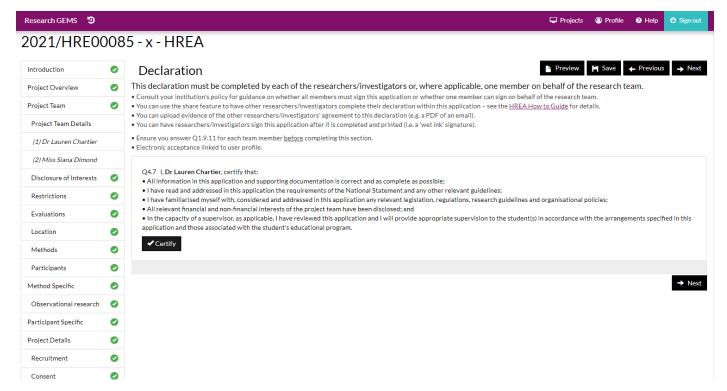
- i. Q4.3 and Q4.4 Select Central Adelaide Local Health Network from the dropdown
- ii. HREC contact details will be automatically populated
- iii. Q4.5 Select 'Greater than low risk review pathway' for full HREC submissions





19. Declaration

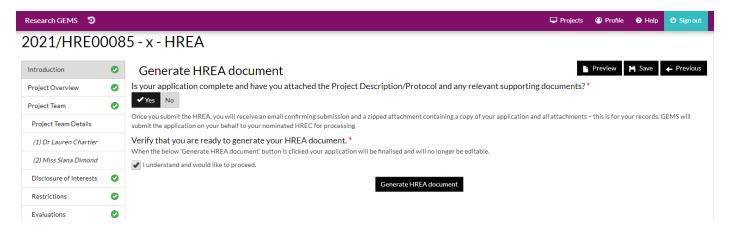
- i. All study personnel will receive an email notification to complete this declaration page
- ii. Select 'Certify'





20. Generate HREA document

- 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'



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



Select the application attachments you wish to download:

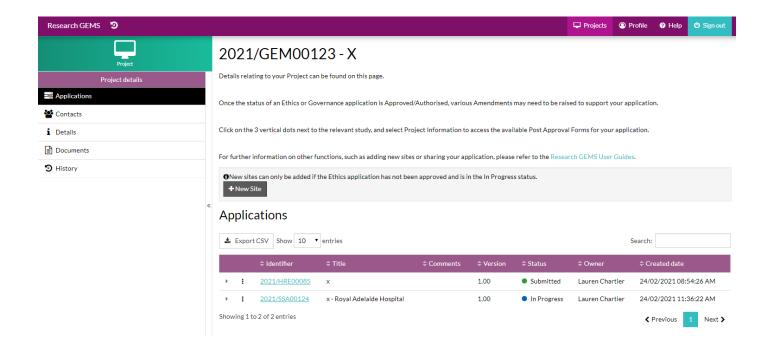
All application forms and attachments (.zip)

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



- 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
- 5. For information and guidelines on how to complete an SSA, please refer to <u>Guideline:</u> Submitting an SSA for Investigator Initiated Studies.







Hints / Tips / Key Points

Project Registration

- To Jose Hospitalion	
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	 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 an SSA application for each SA Health site added
Part B: Project Details	Ensure everything is entered precisely. <u>After submission you will not be able to edit your project registration.</u>
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.

and will delay your application

If you do not assign the correct the CPI, this will have a flow on effect

Only the CPI will be able to submit the HREA generated



Part F: Upload Attachments	 Upload the protocol. Please note: GEMS will not allow the project to be submitted if the documents have not been uploaded 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

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.

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: <u>Health.CALHNResearchEthics@sa.gov.au</u> or <u>Health.CALHNResearchGovernance@sa.gov.au</u>