Research GEMS Guidelines Commercially Sponsored Clinical Trials – CALHN Ethics Preparing Project Registration, HREA & 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 require CALHN HREC to be the Reviewing HREC Committee for a study. Please note: All Phase 1 studies are exempt from the National Mutual Acceptance scheme within South Australia. Therefore, all Phase 1 studies that are being conducted at a CALHN site must have CALHN HREC approval.

Scope

This guideline will help to achieve the following:

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

Definitions & Acronyms

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

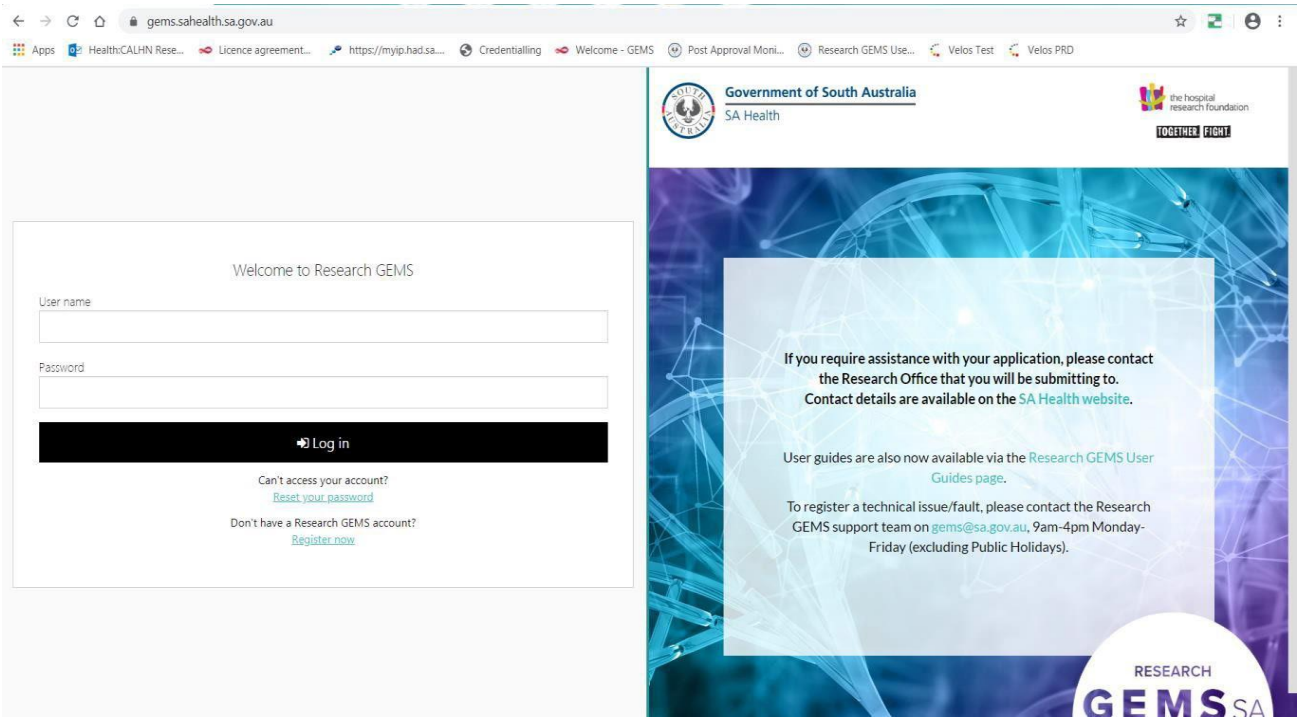
Quick Links

Procedures

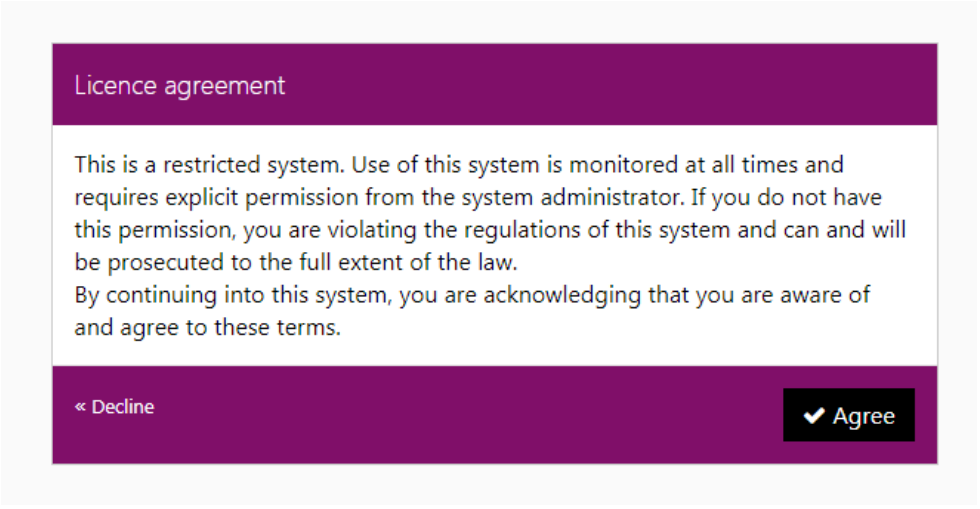
Registering a Project

1. Go to the GEMS Website located here <https://gems.sahealth.sa.gov.au/>

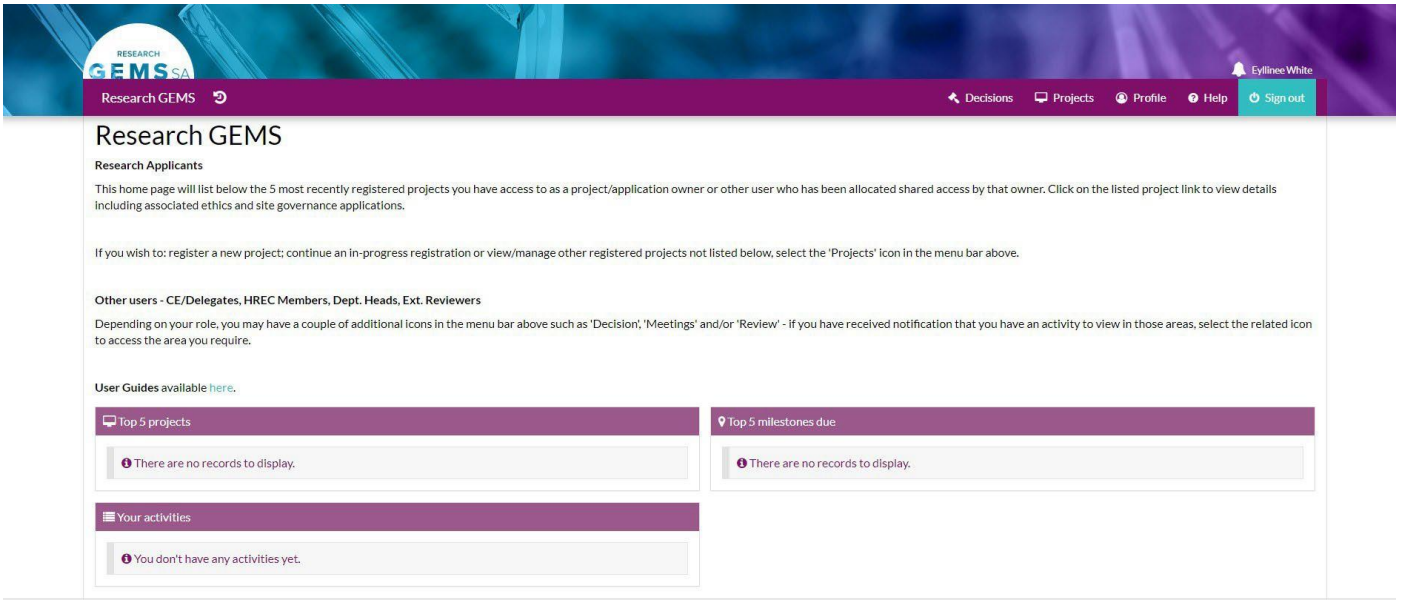
2. Login/Register Account



   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

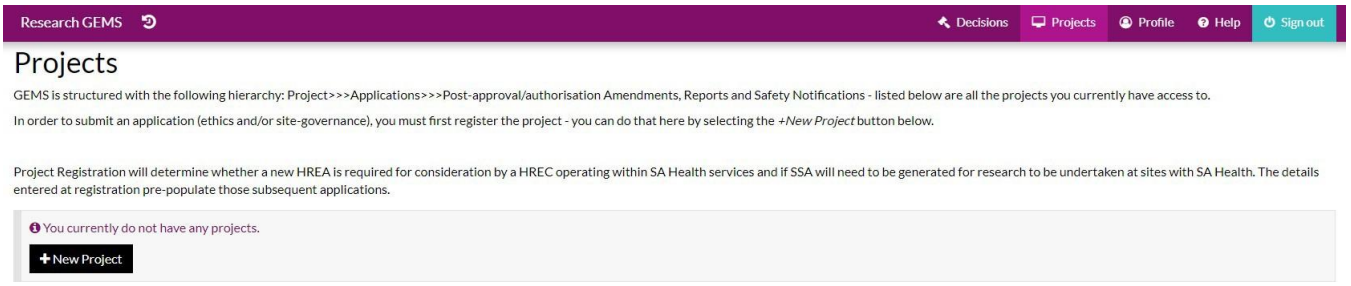


3. Registering your Project
    a. You will now have been directed to the External Portal Homepage for Researchers / Research Personnel.

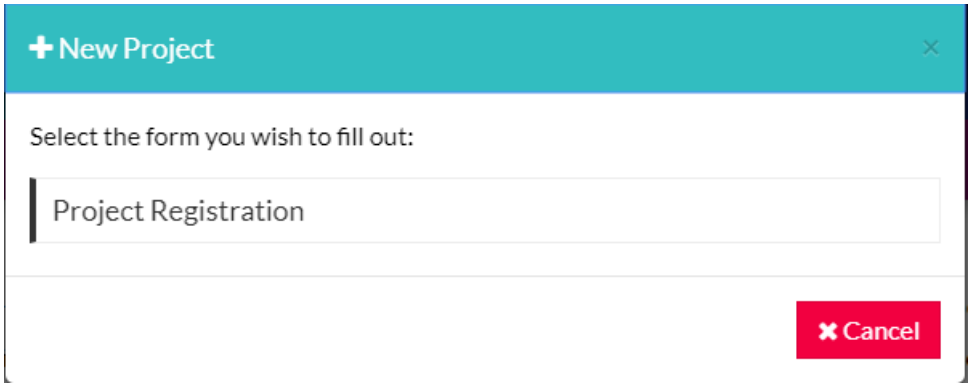


    b. To register a project, navigate to the ‘Projects’ tab on the right hand corner

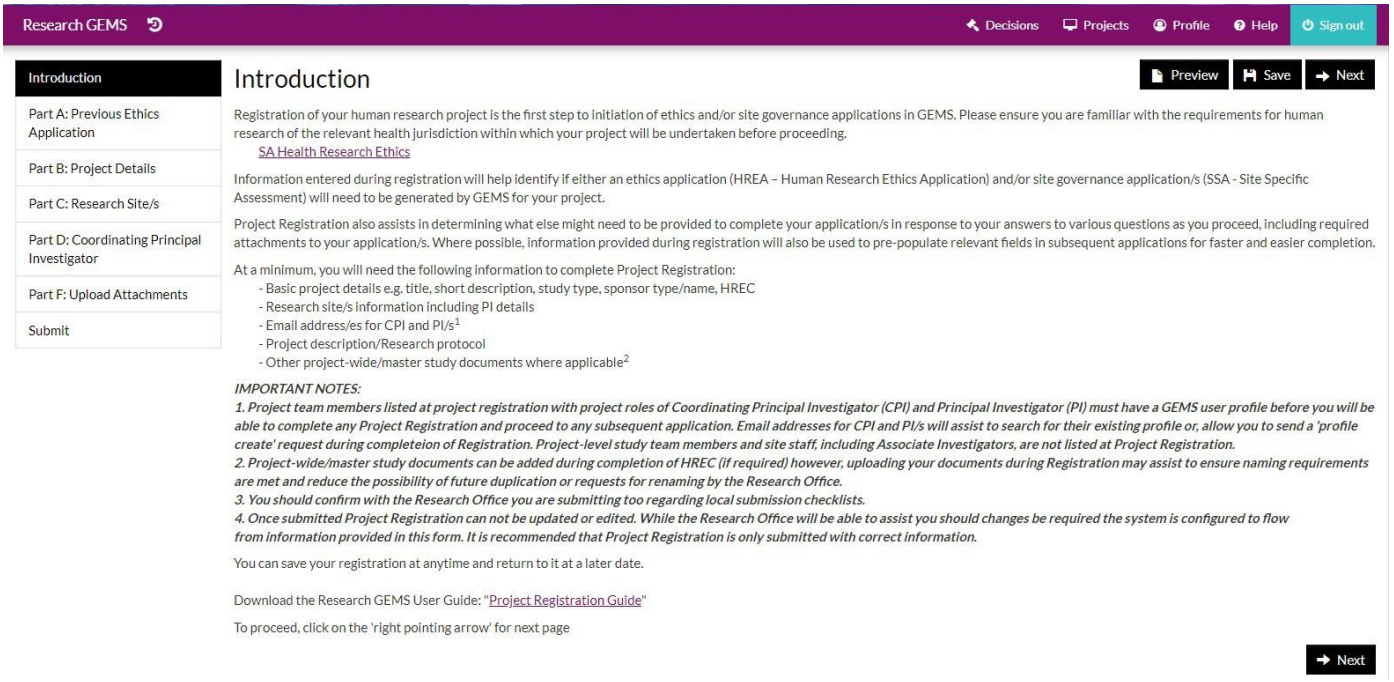
    c. Click ‘New Project’



d. Select ‘Project Registration’

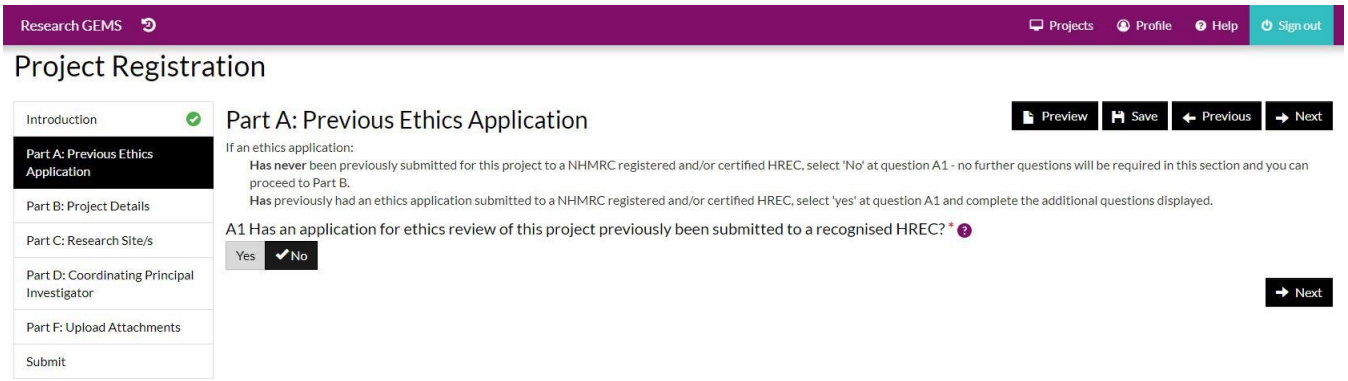


e. This will then navigate you to the ‘New Project Registration’ Page on the ‘Introduction’ tab. Read this information, then click next.



f. This will navigate through Tabs A-F.

g. Part A: Previous Ethics Application



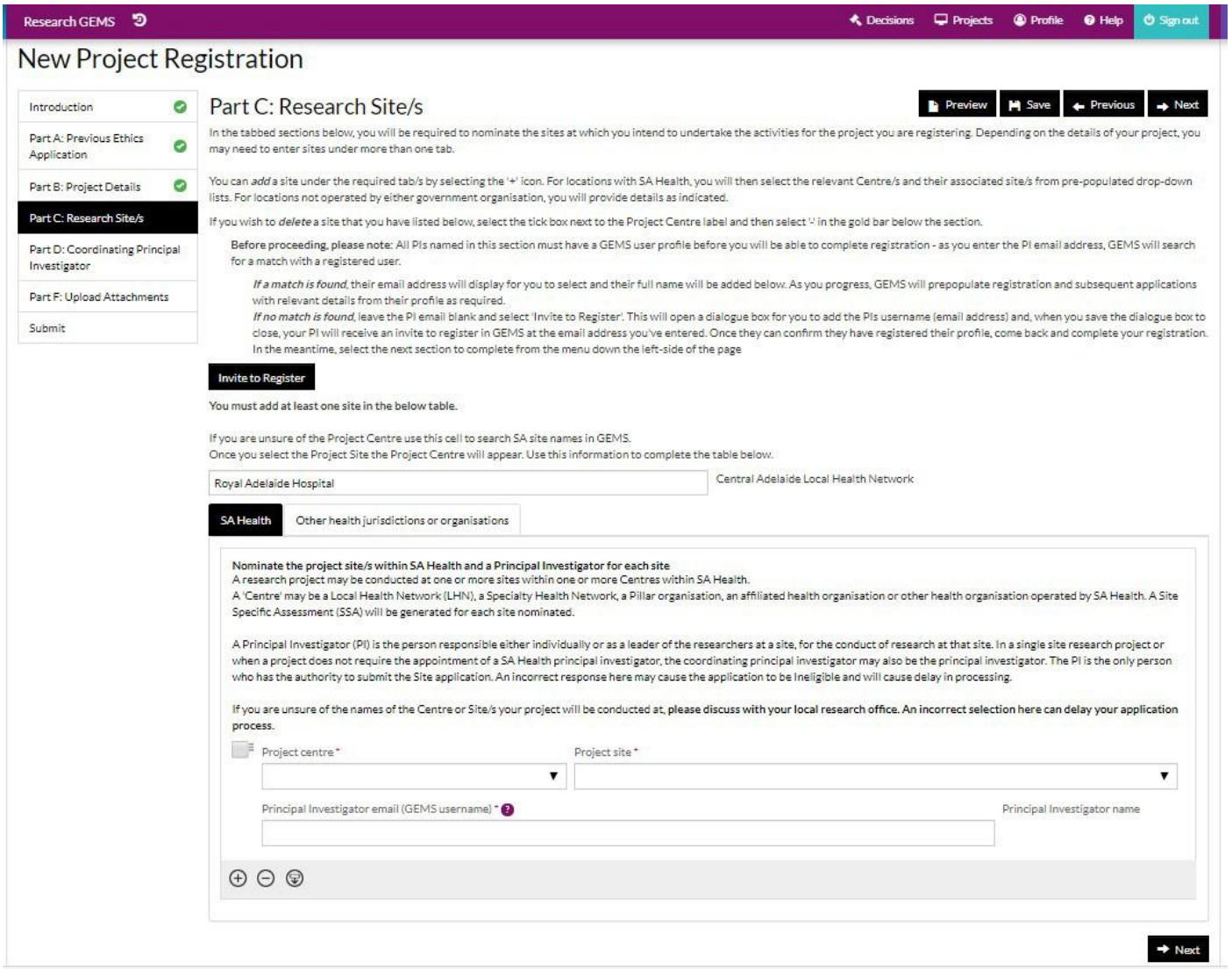
i. For Internal (CALHN) ethics > Select ‘No’

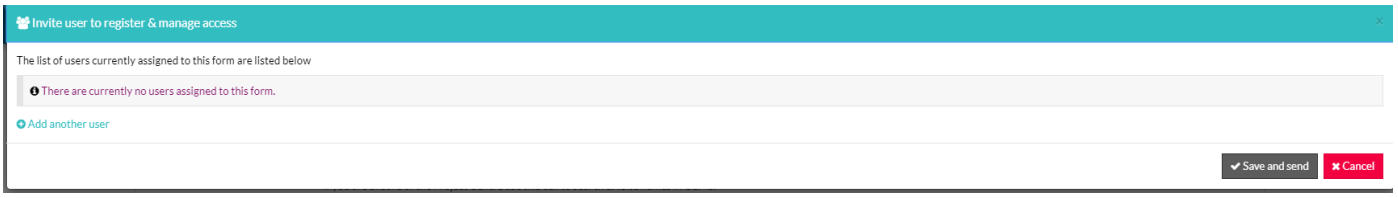
h. Part B: Project Details

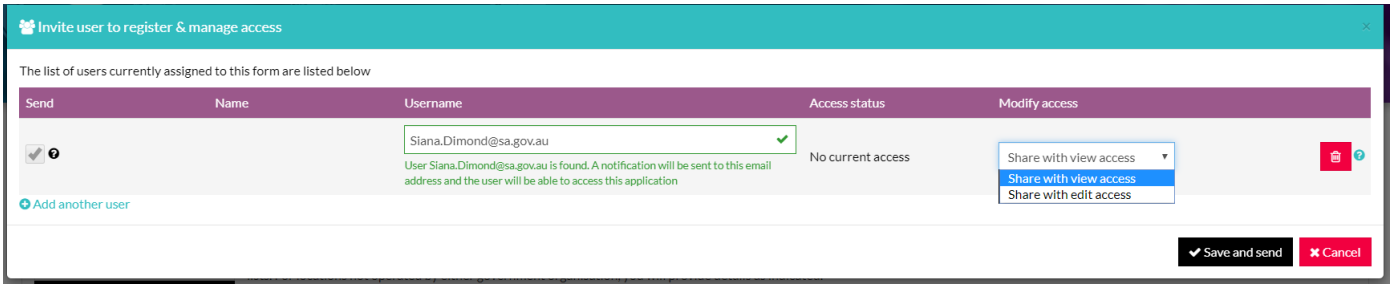
i. Fill in details related to your project
ii. Enter your Short Title or Protocol first – how you want to view it later on
iii. > click next

i. Part C: Research Site(s)

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

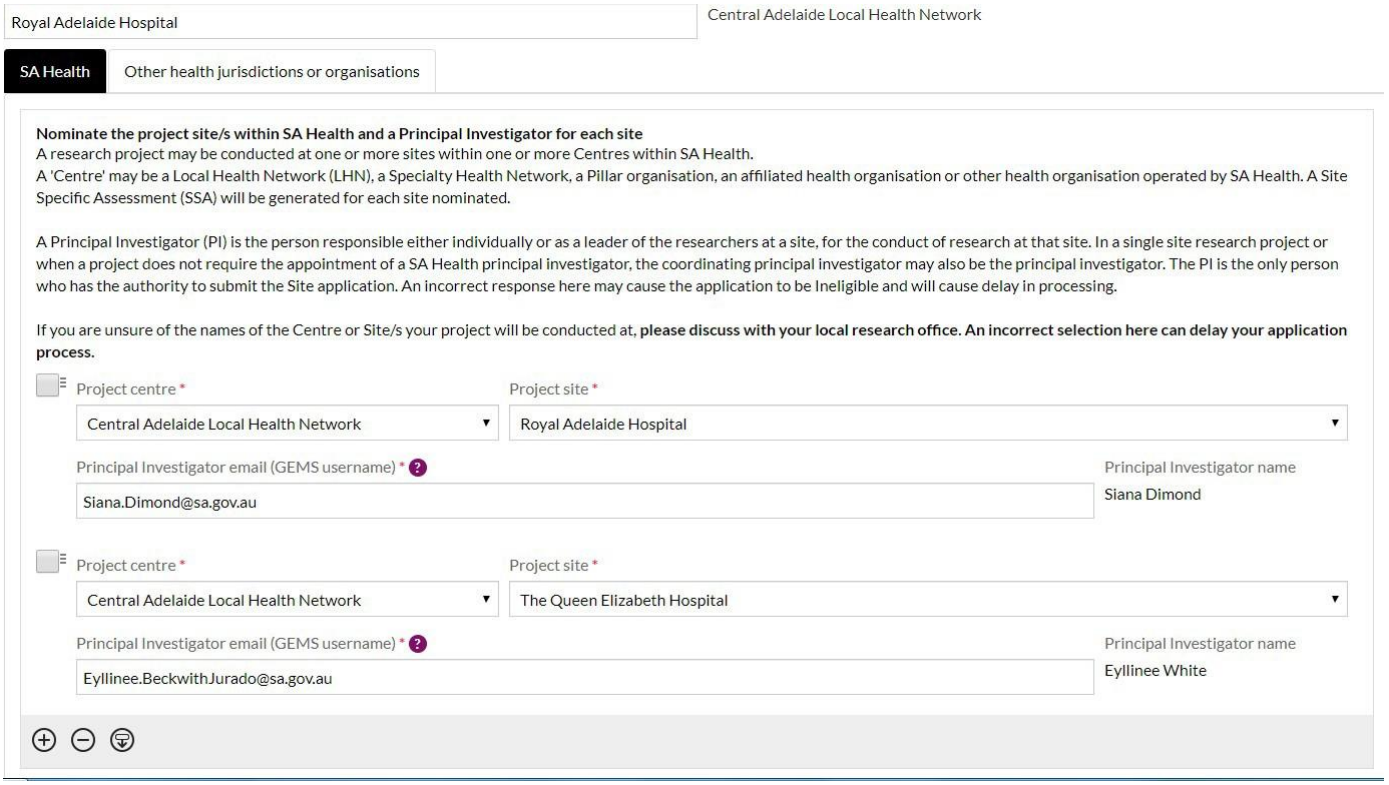






viii. Select the site you will be conducting the research at, when you begin to type the site should appear in the drop down selector box. This will then pre-fill the local health network next to the site name,

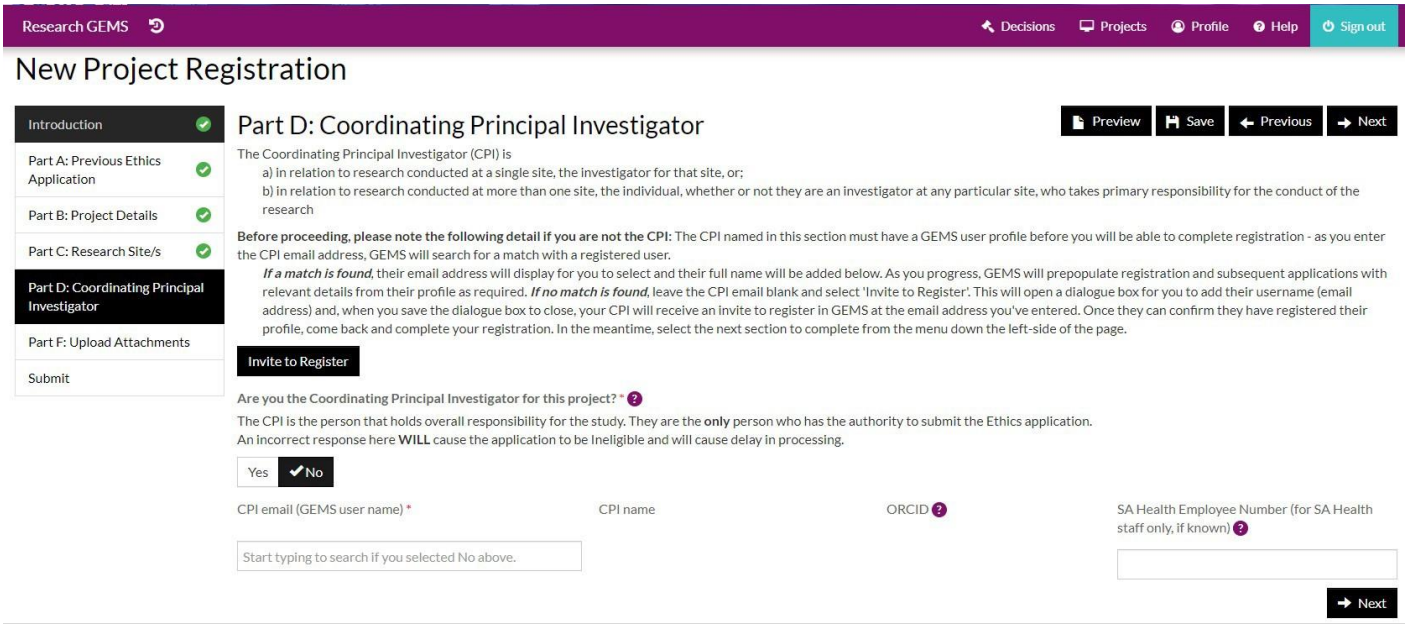
ix. Then fill in the ‘Nominate the project site/s within SA Health and a PI for each site’ section



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



k. Part F – Upload Attachments

i. Where CALHN is the Reviewing HREC please upload the:
   - Protocol

ii. All other supporting documentation should be uploaded against the HREA.

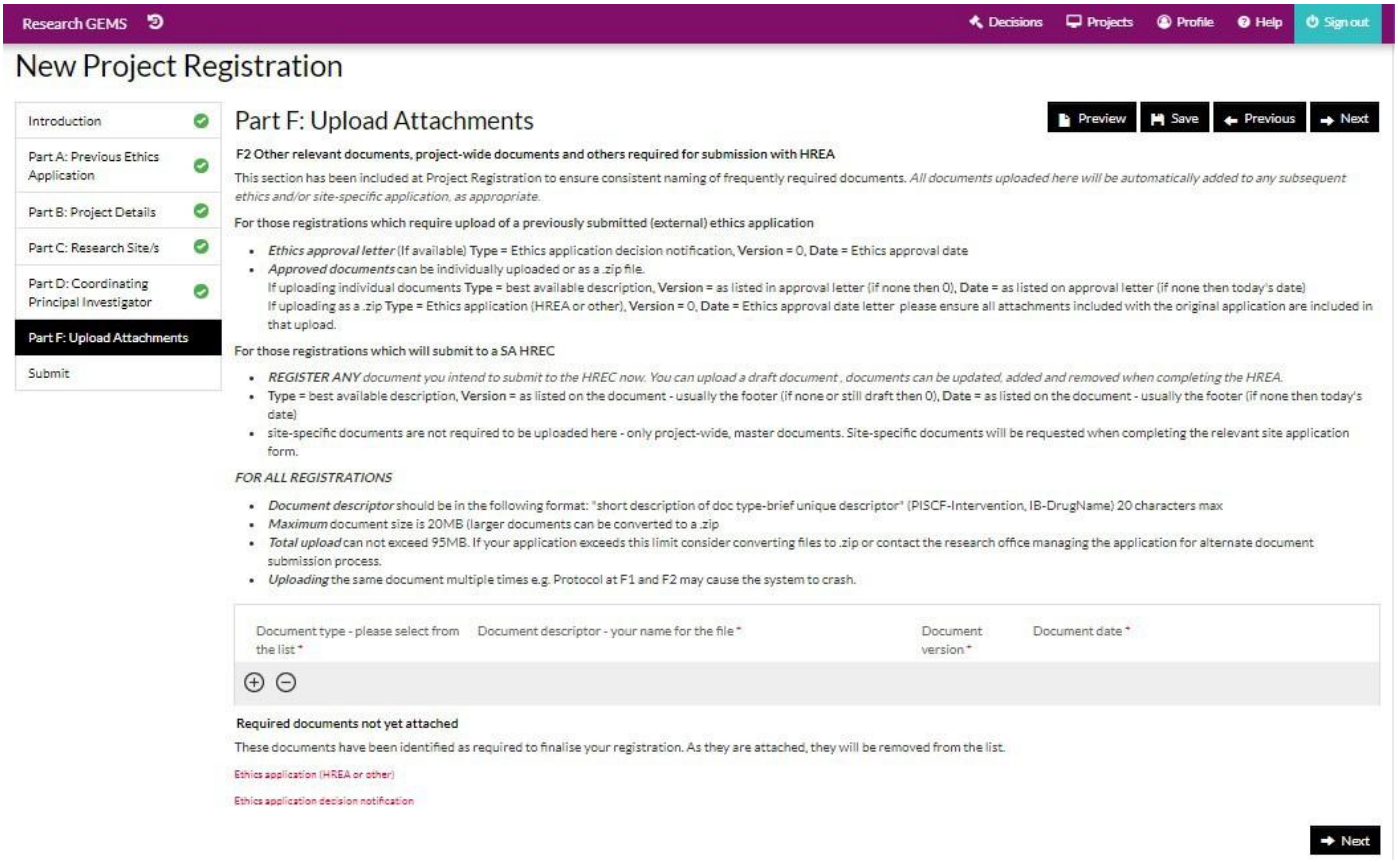
iii. To upload documents, select the "+" button in the bottom left-hand corner

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

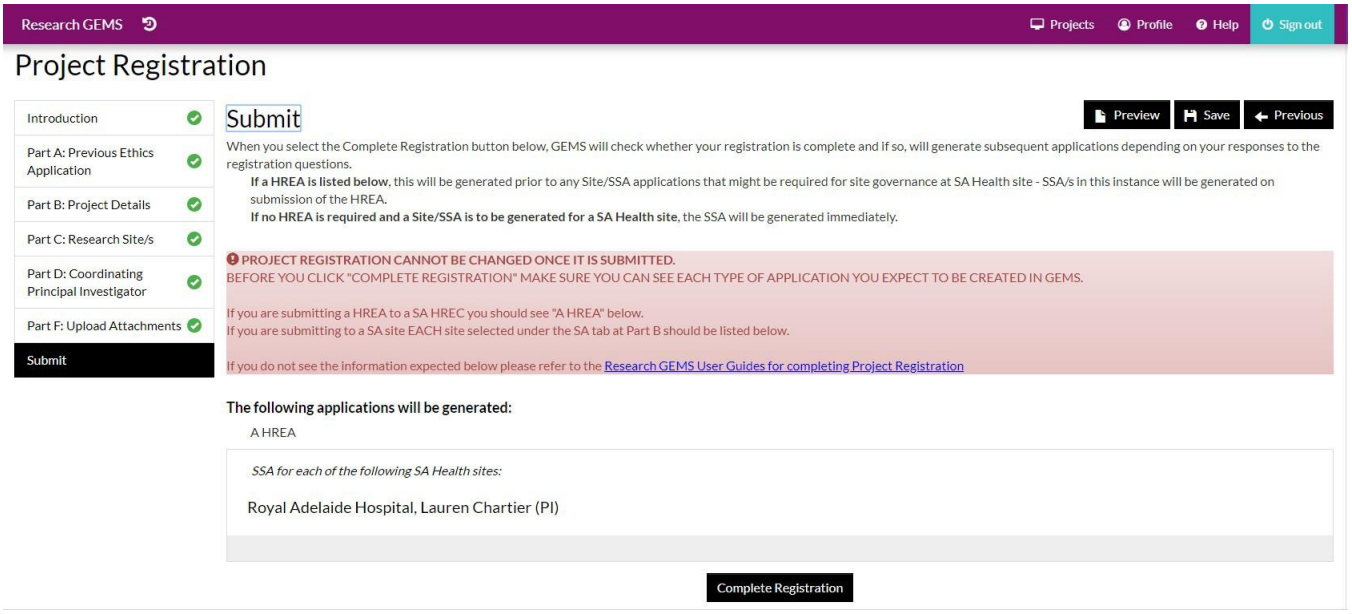
vi. Fill in, 'Version Number' (please put N/A if there is none) and then the date of the document (please do not enter a random date as this will follow through your application)

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

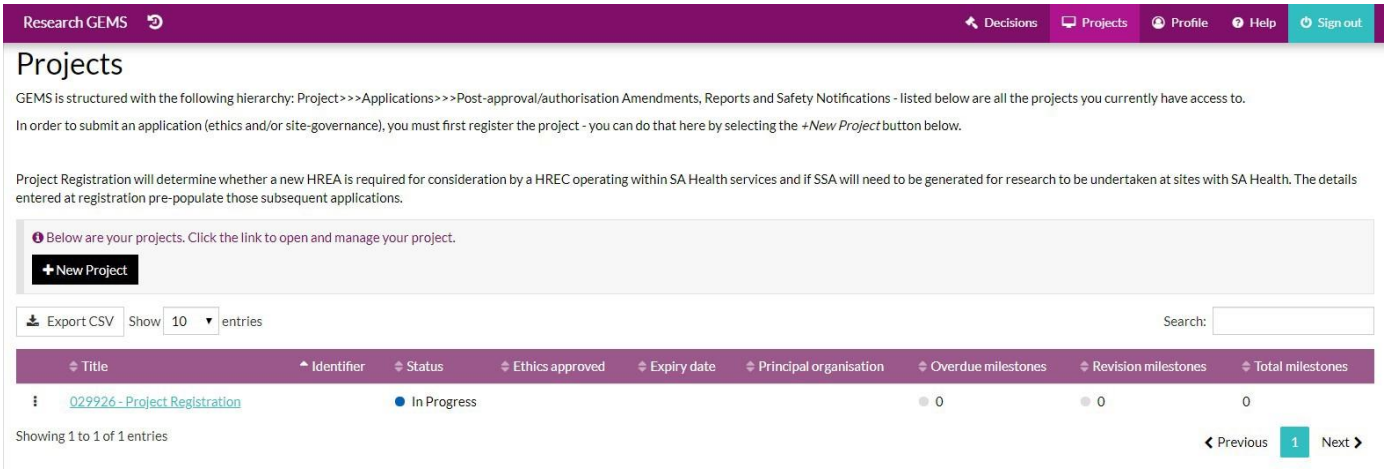


viii. Then upload the document by selecting "Select upload new" > Choose the file > Select the file > Open > Start Upload
ix. Then click the (+) button to add upload additional documents via the same method
x. Click 'Next' once all the documents have been uploaded

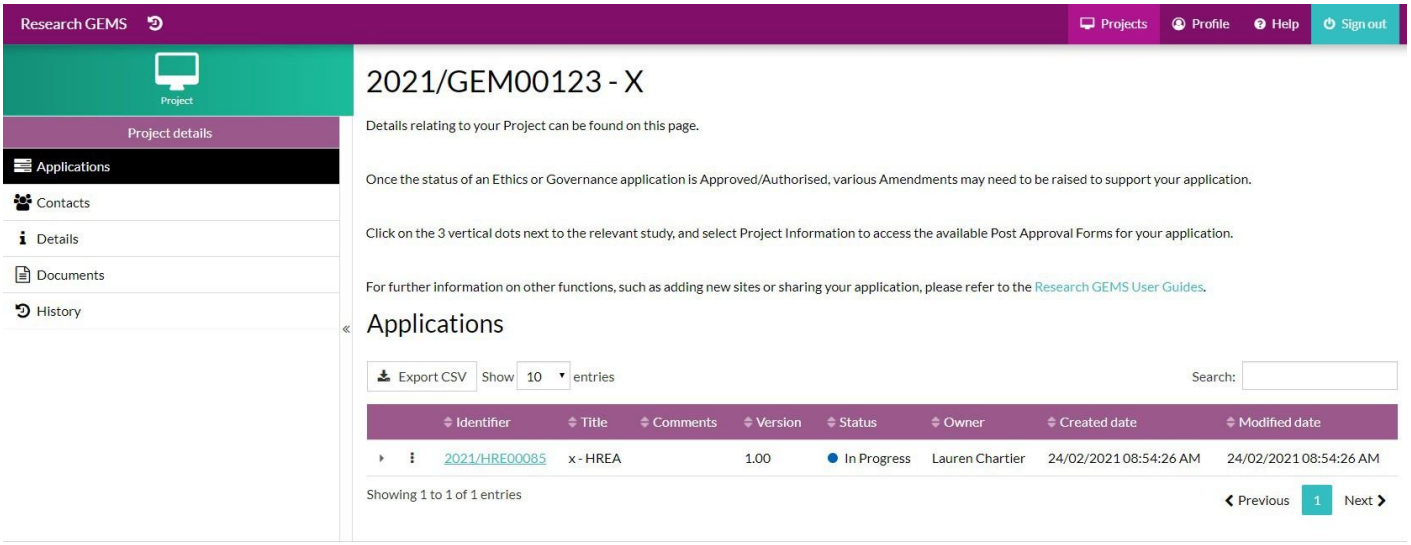
I. Submit



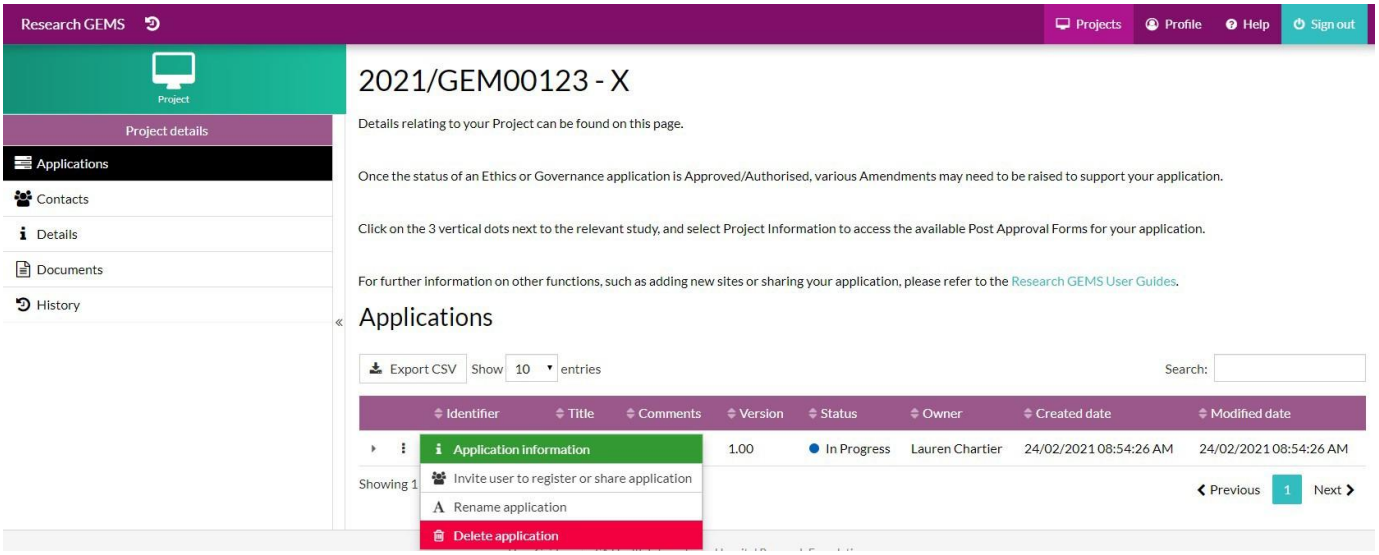
i. Please double check your project registration is correct before you submit it, as you **can't** make edits to it once it has been submitted
ii. As CALHN is the Reviewing HREC – check that 'A HREA' is listed as well as an SSA to ensure you have completed the registration correctly.
iii. When satisfied the registration information entered is correct, click 'Complete Registration'
iv. 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'



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



- **Note** - you can share this application with other study personnel by clicking the three dots on the left-hand side next to the application title and selecting 'Invite user to register or share application'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History
2021/GEM00123 - X
Details relating to your Project can be found on this page.
Once the status of an Ethics or Governance application is Approved/Authorised, various Amendments may need to be raised to support your application.
Click on the 3 vertical dots next to the relevant study, and select Project Information to access the available Post Approval Forms for your application.
For further information on other functions, such as adding new sites or sharing your application, please refer to the Research GEMS User Guides.
Applications
Export CSV
Show 10 entries
Search:
Identifier
Title
Comments
Version
Status
Owner
Created date
Modified date
Application information
Invite user to register or share application
Rename application
Delete application
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In Progress
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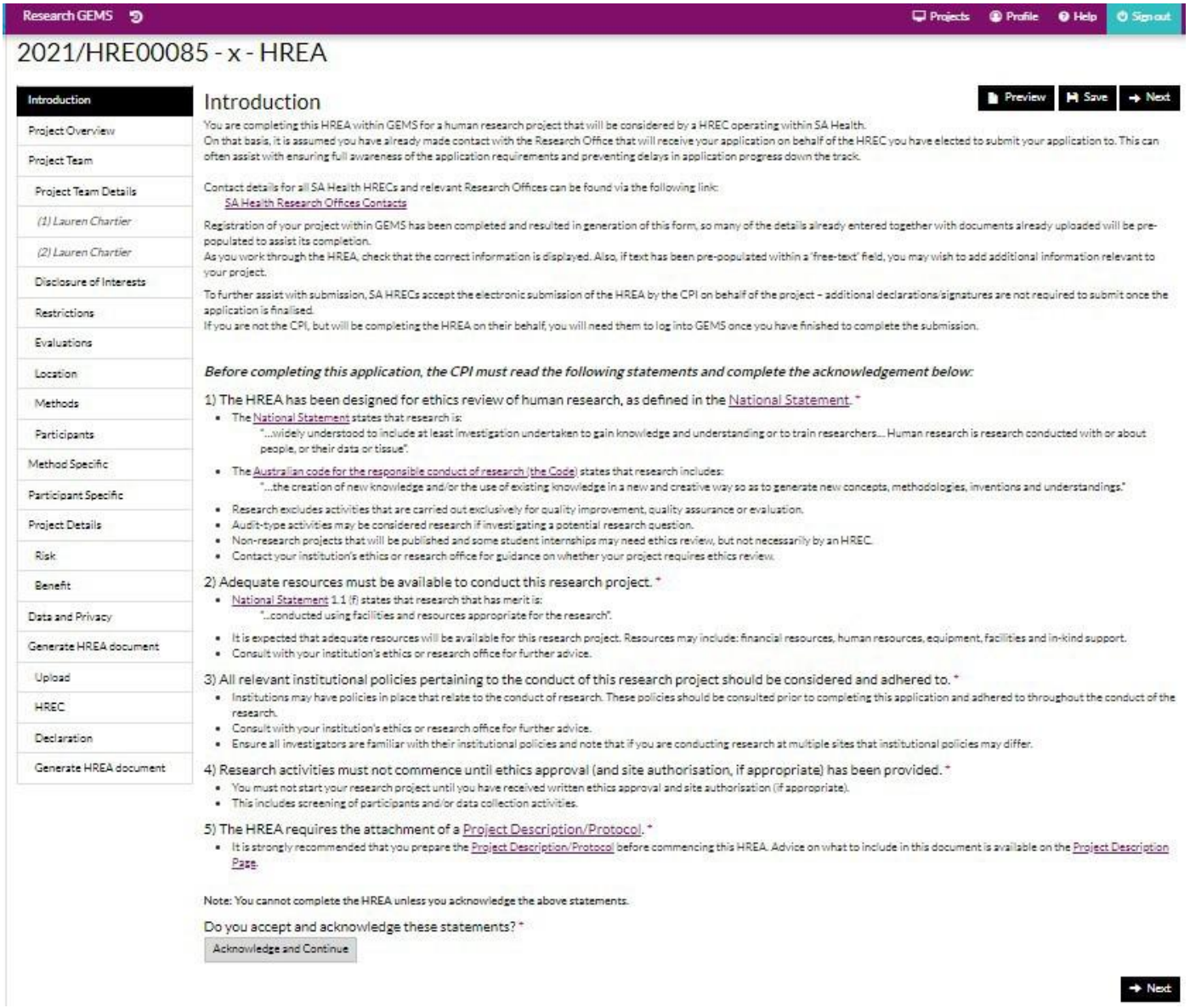
Previous
1
Next

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 HREA, however only the CPI will be able to submit the HREA



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

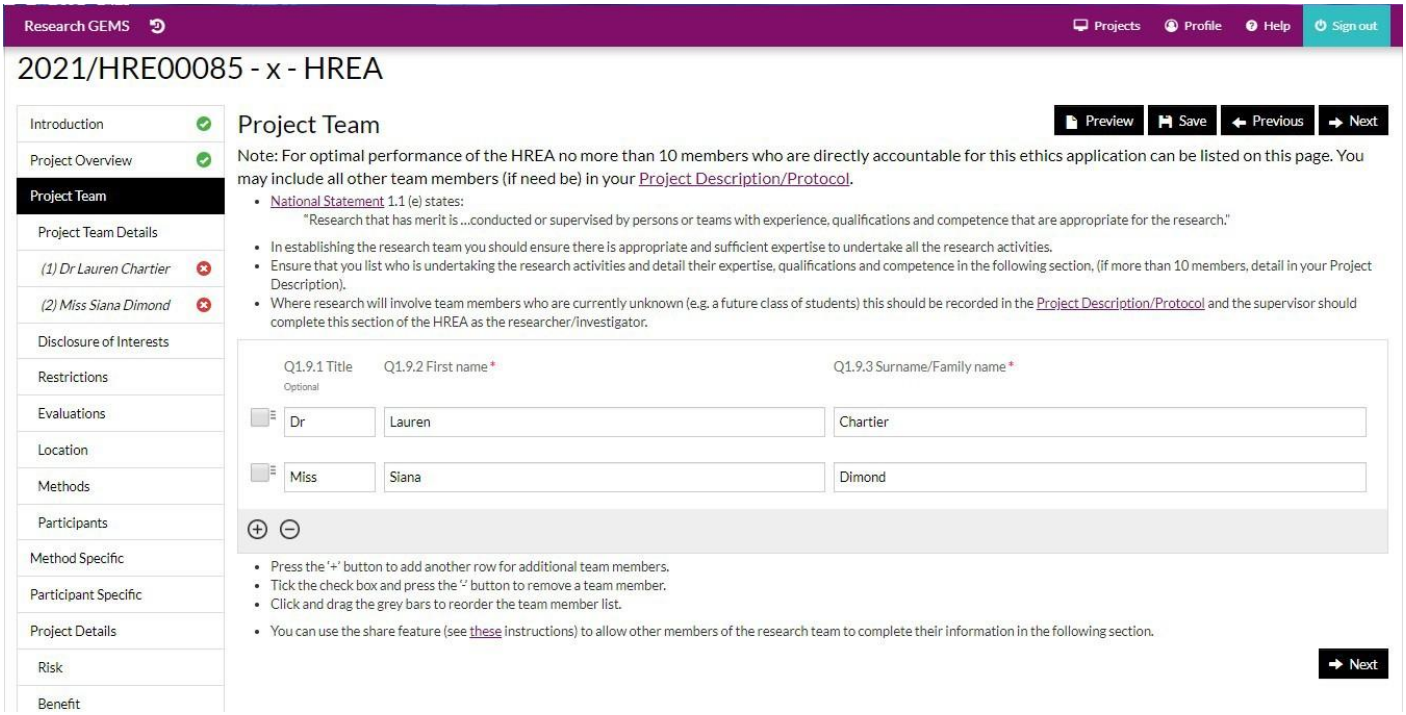
1. Project Overview

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

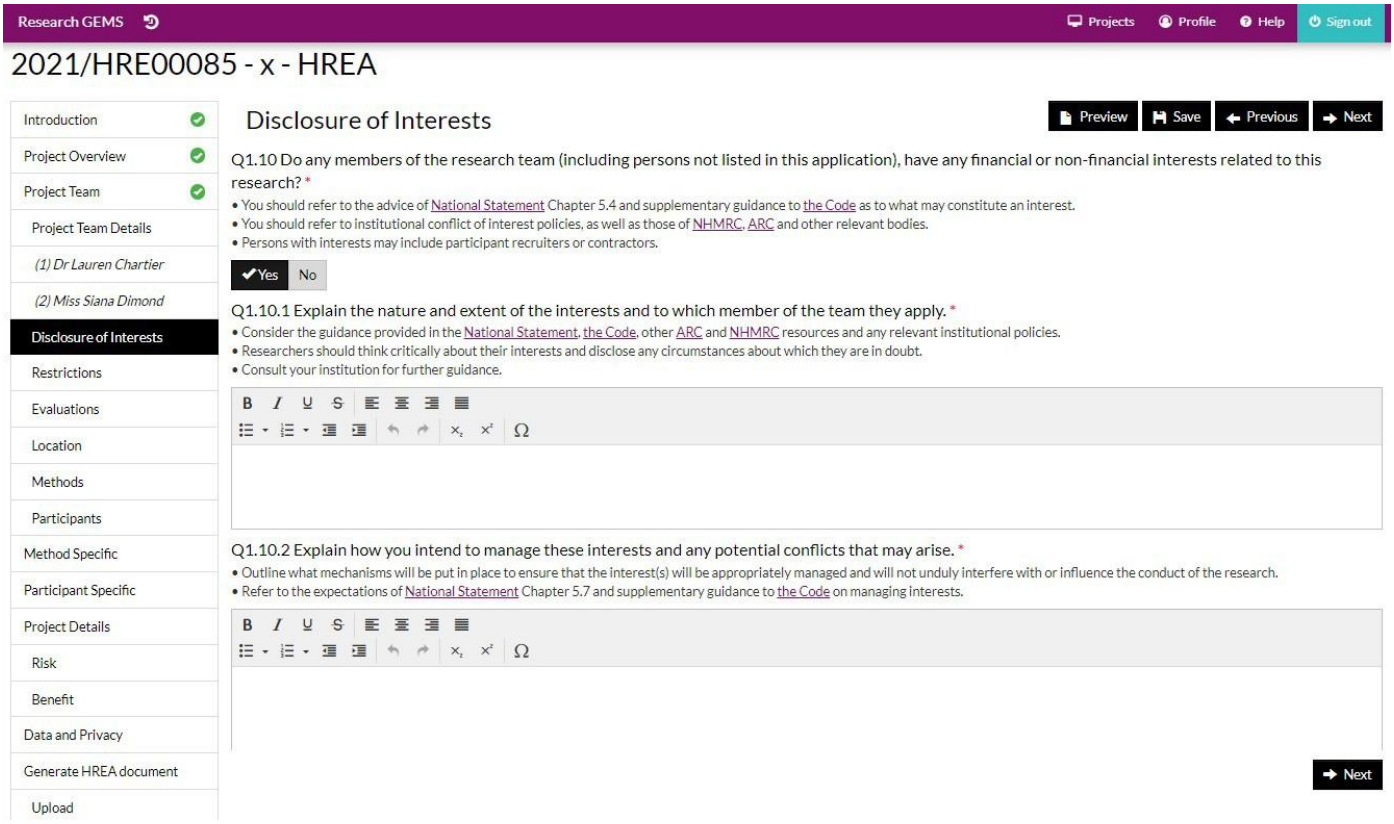
2. Project Team

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

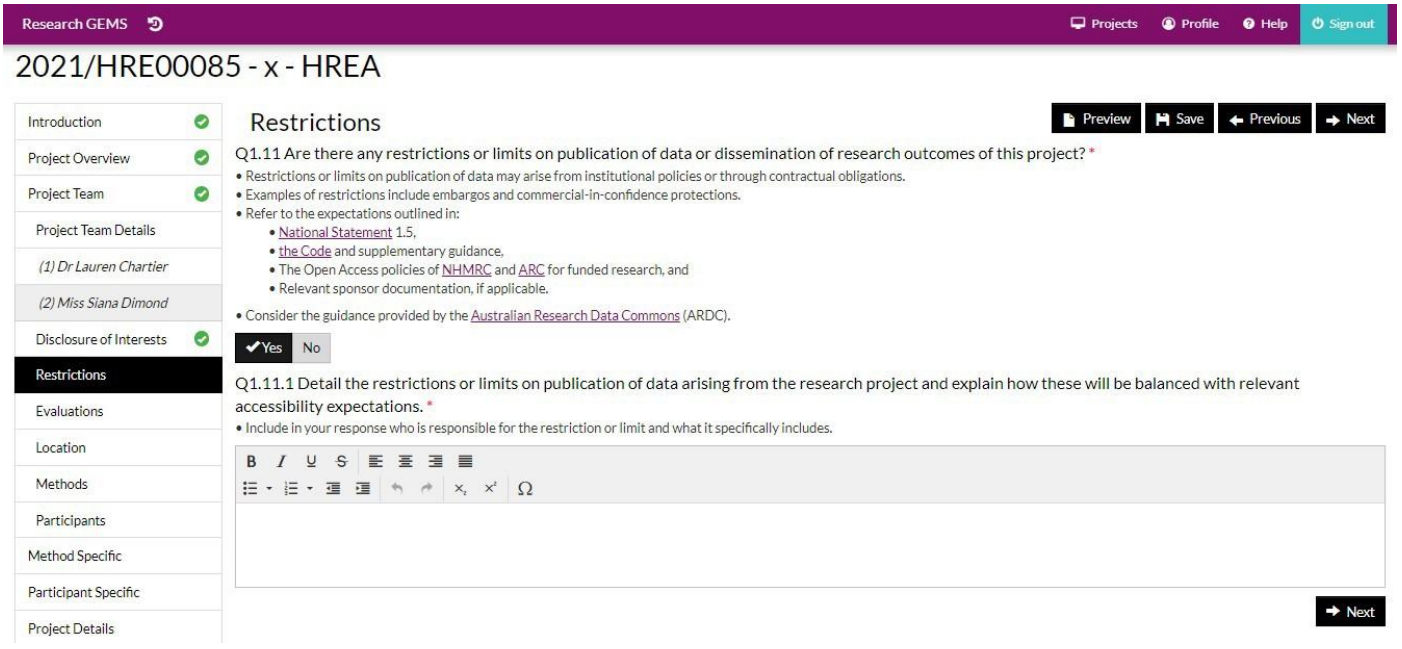
i. Select ‘No’ if there are no conflicts of interest to disclose
ii. Selecting ‘Yes’ will prompt some additional questions related to the disclosure



4. Restrictions

i. 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



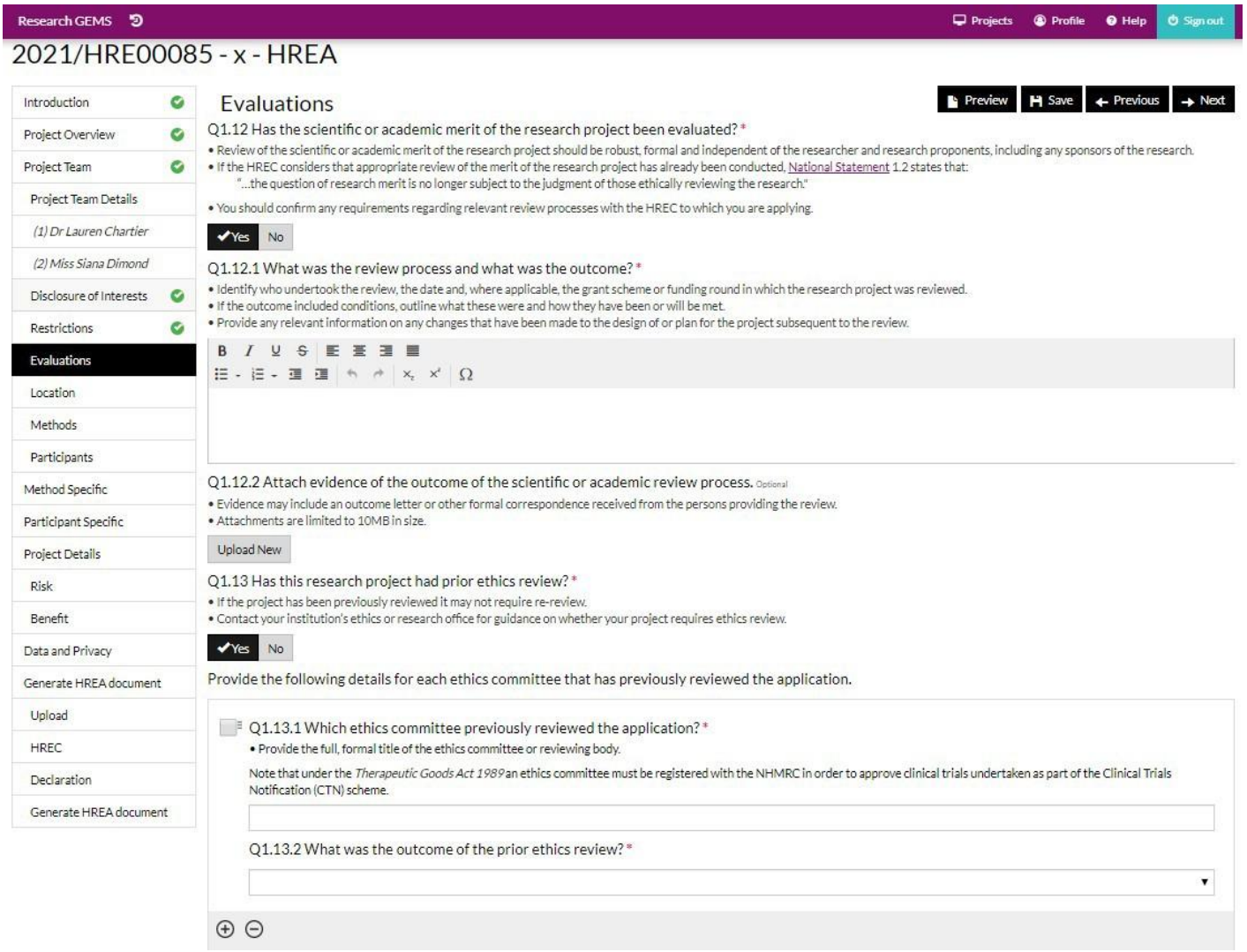
5. Evaluations

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

ii. Q1.12 - selecting 'Yes' will prompt some additional questions related to the evaluations. You can also upload evidence or the outcome of this scientific evaluation, however, this is optional

iii. Q1.13 – select 'Yes' if the project has had previous ethics review by another committee, for example the Aboriginal Human Research Ethics Committee.

iv. You can add and remove previous ethics review details by selecting the '+' and '-'

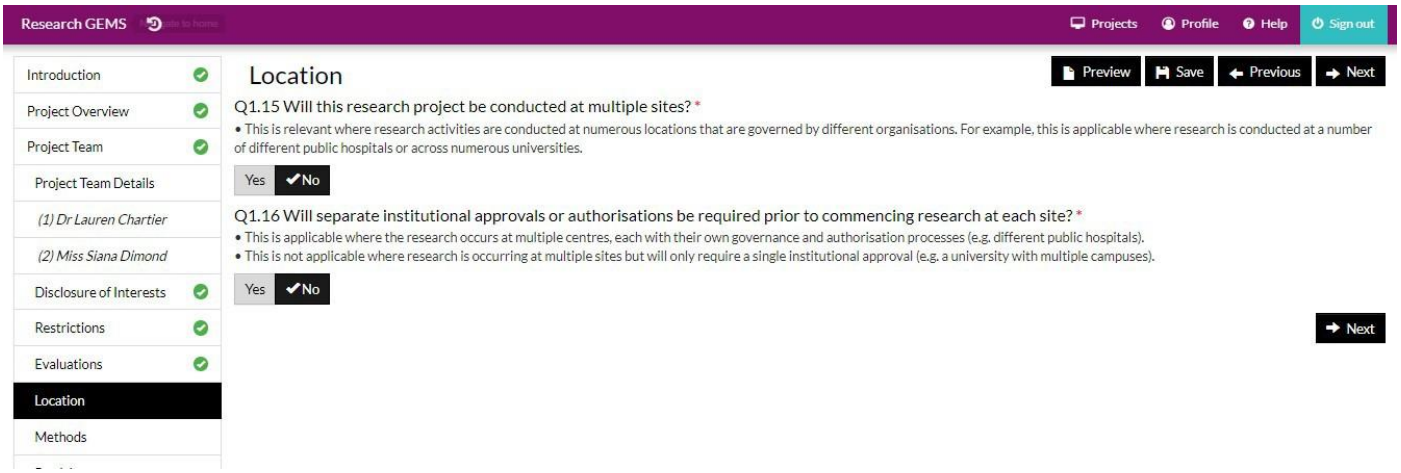


i. Q1.14 – Selecting 'Yes' will ask for details of who is conducting specialist review and when this will be sought

6. Location

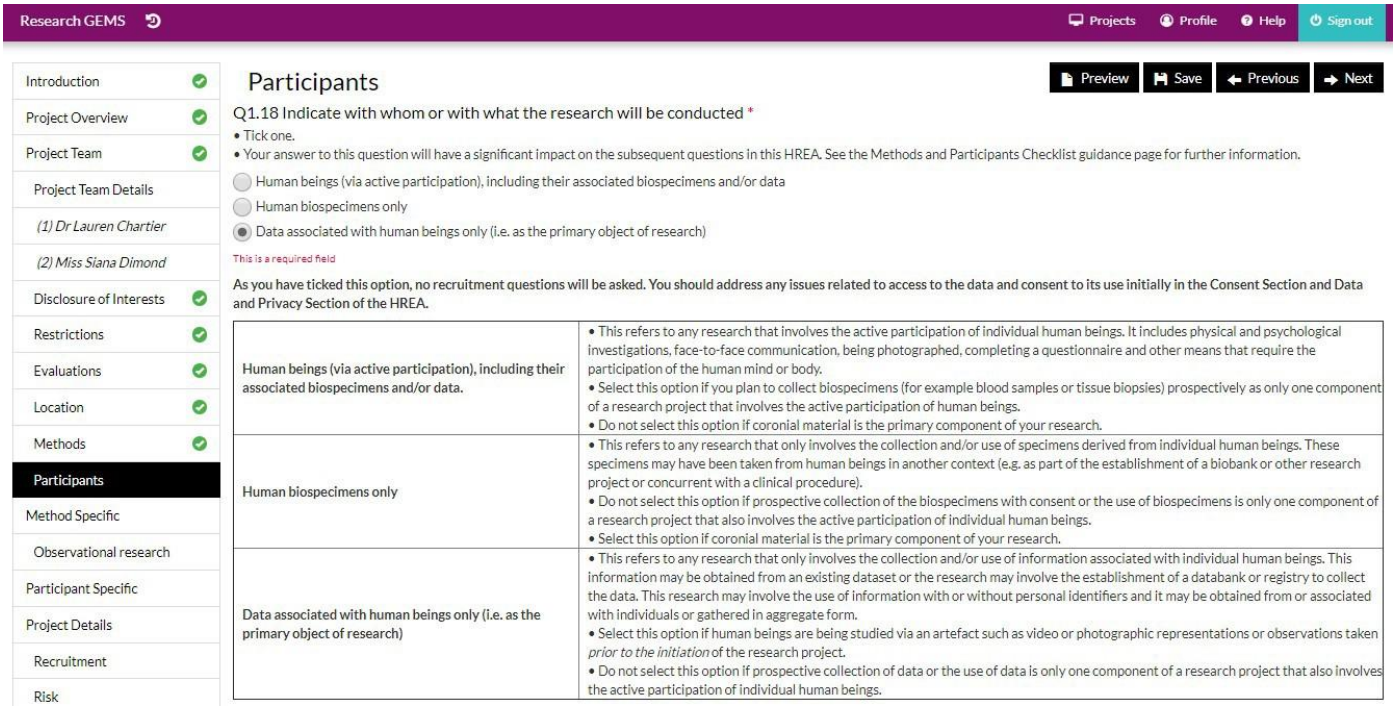
i. Q1.15 – If single-site select 'No', if multi-site select 'Yes'

ii. Q1.16 – If governance approval is required for other sites (not CALHN) select 'Yes'. If all study sites are CALHN sites, select 'No'



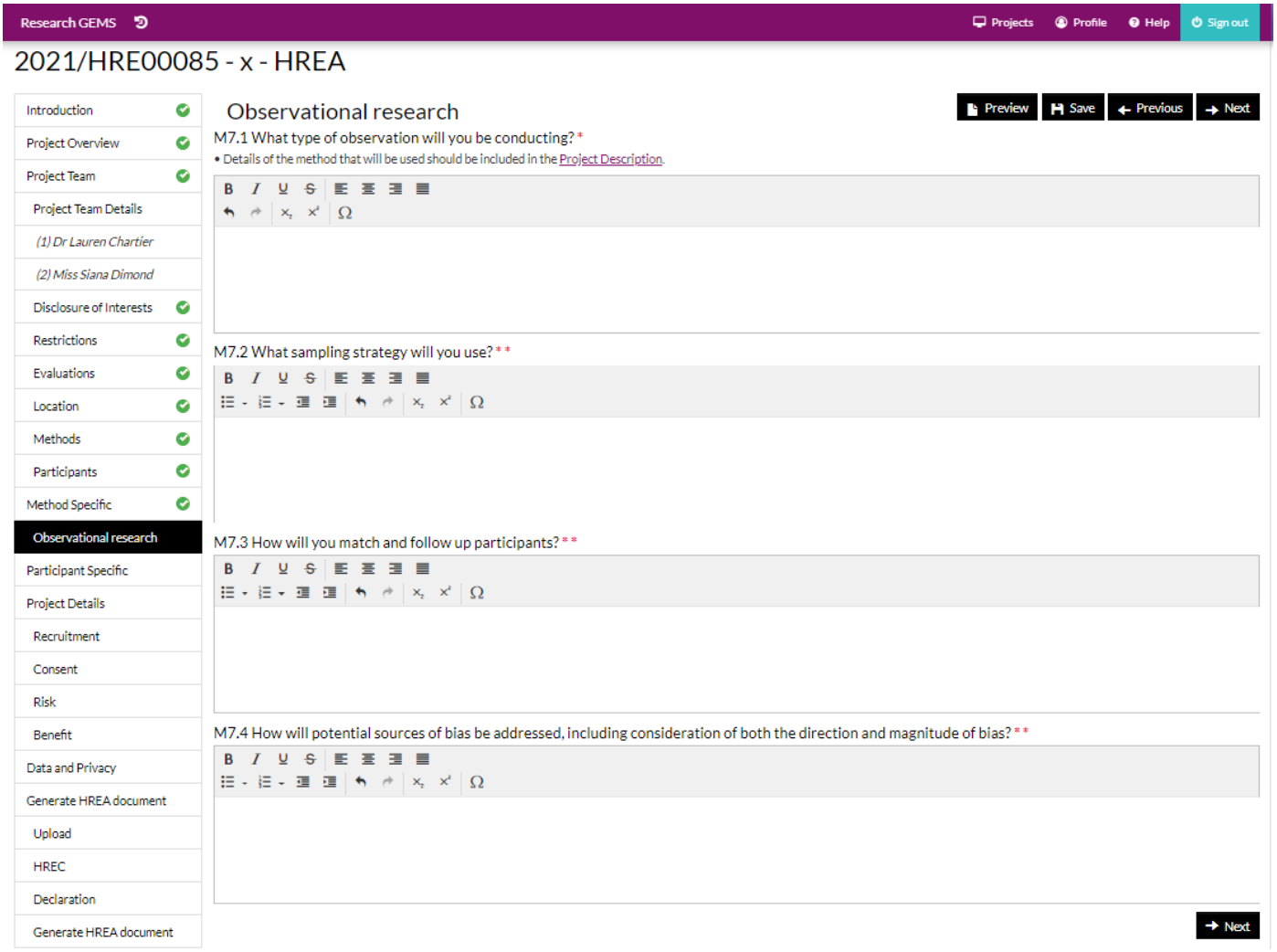
7. **Methods**
   i. Select all methods that apply to the current study as per the descriptions provided

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)

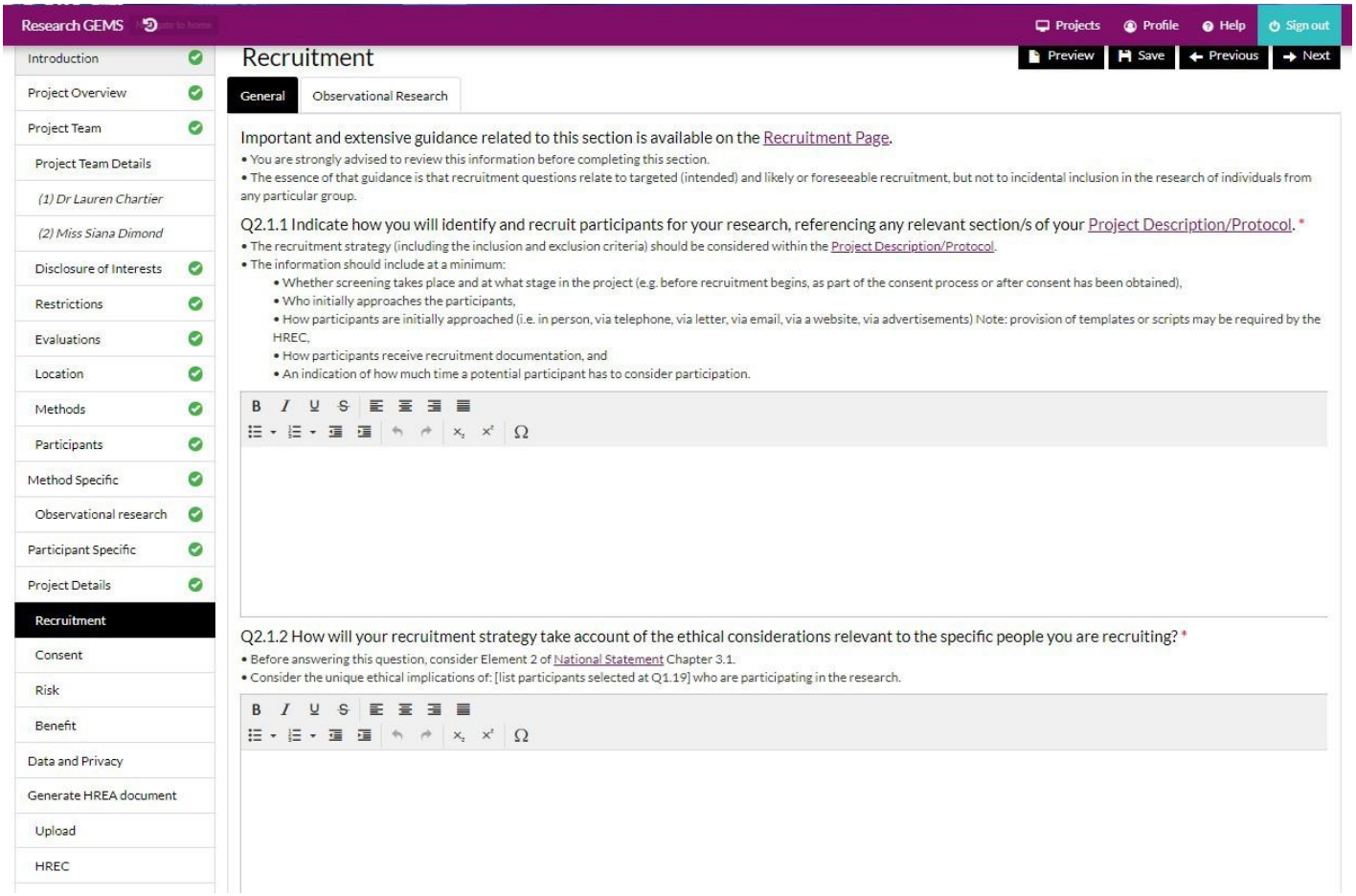


10. Participant Specific

i. 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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Project Team Details
(1) Dr Lauren Chartier
(2) Miss Siana Dimond
Disclosure of Interests
Restrictions
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Observational research
Participant Specific
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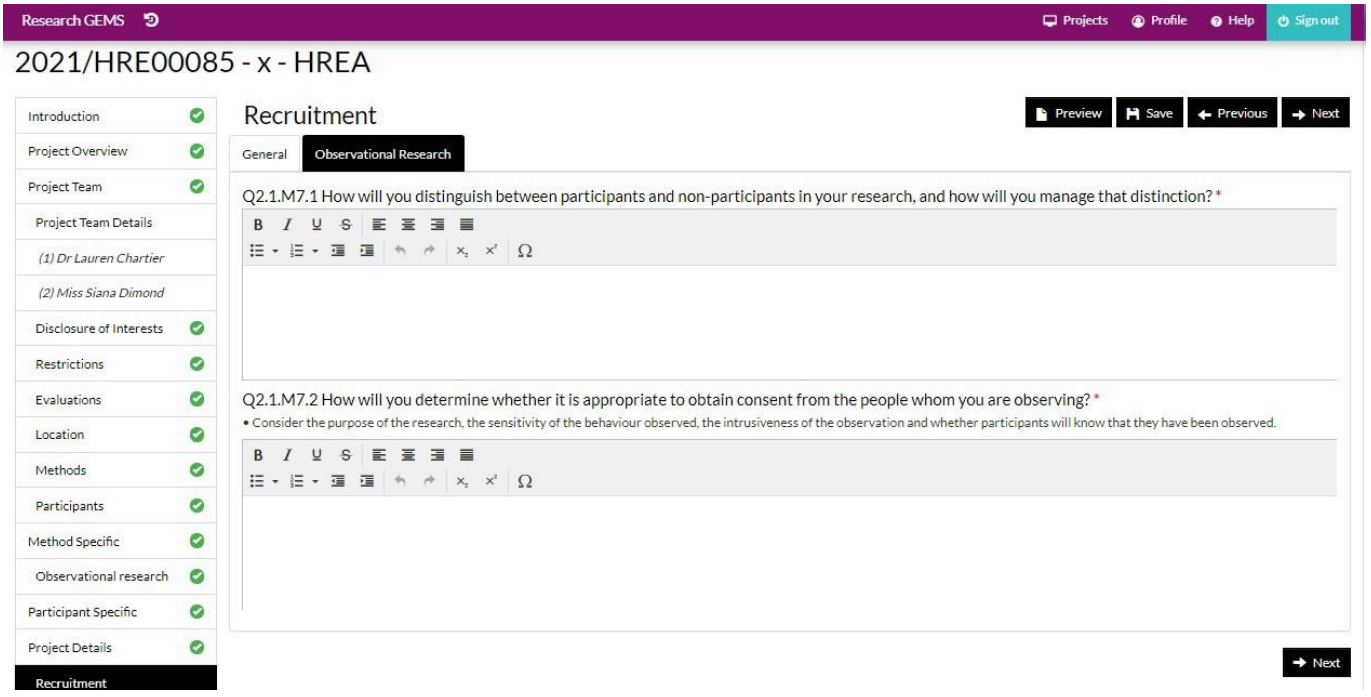
General
Observational Research
Important and extensive guidance related to this section is available on the Recruitment Page.
• You are strongly advised to review this information before completing this section.
• The essence of that guidance is that recruitment questions relate to targeted (intended) and likely or foreseeable recruitment, but not to incidental inclusion in the research of individuals from any particular group.
Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant section/s of your Project Description/Protocol. *
• The recruitment strategy (including the inclusion and exclusion criteria) should be considered within the Project Description/Protocol.
• The information should include at a minimum:
• Whether screening takes place and at what stage in the project (e.g. before recruitment begins, as part of the consent process or after consent has been obtained),
• Who initially approaches the participants,
• How participants are initially approached (i.e. in person, via telephone, via letter, via email, via a website, via advertisements) Note: provision of templates or scripts may be required by the HREC,
• How participants receive recruitment documentation, and
• An indication of how much time a potential participant has to consider participation.
Q2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting? *
• Before answering this question, consider Element 2 of National Statement Chapter 3.1.
• Consider the unique ethical implications of: [list participants selected at Q1.19] who are participating in the research.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(2) Miss Siana Dimond
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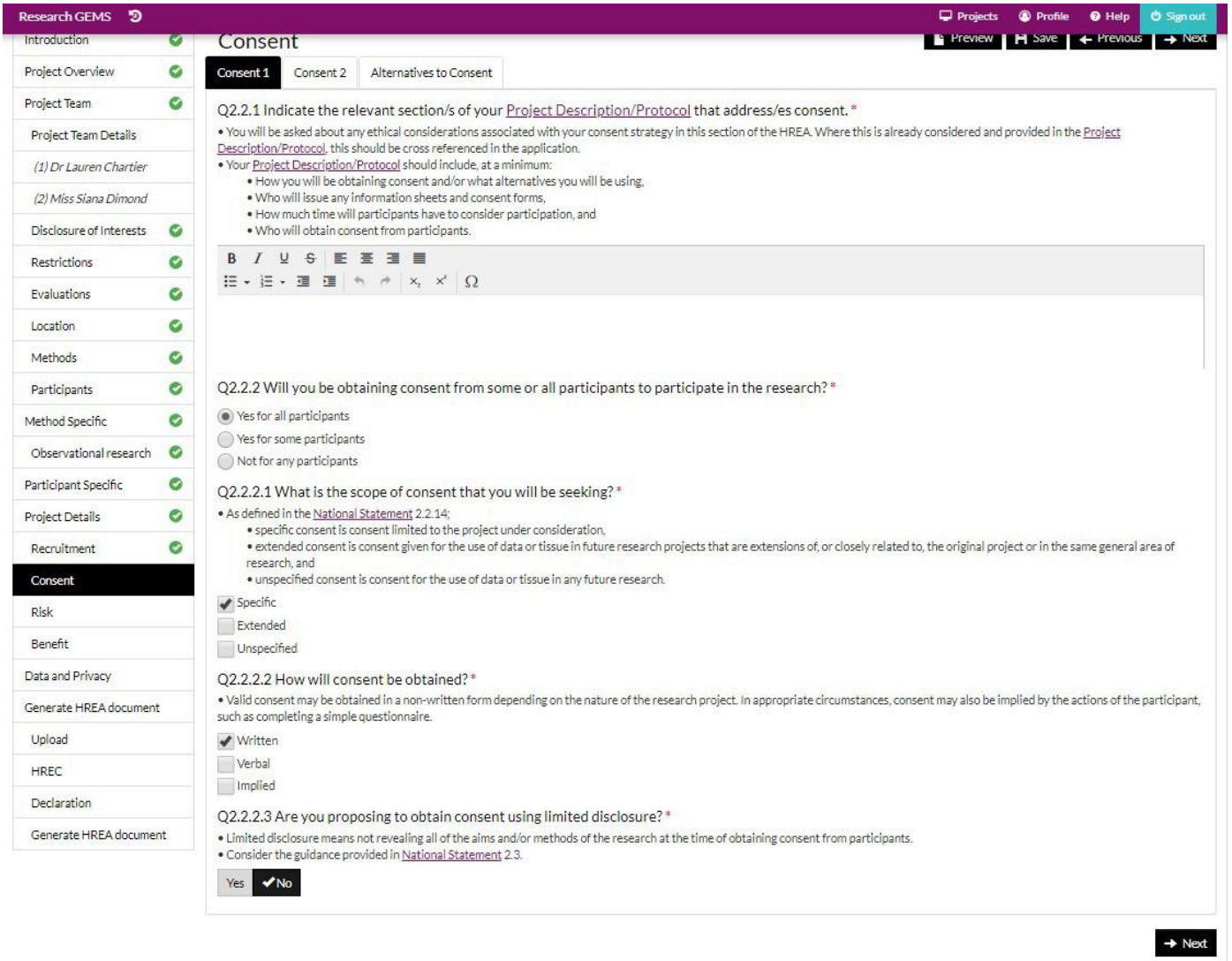
Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction? *
Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing? *
• Consider the purpose of the research, the sensitivity of the behaviour observed, the intrusiveness of the observation and whether participants will know that they have been observed.
Next

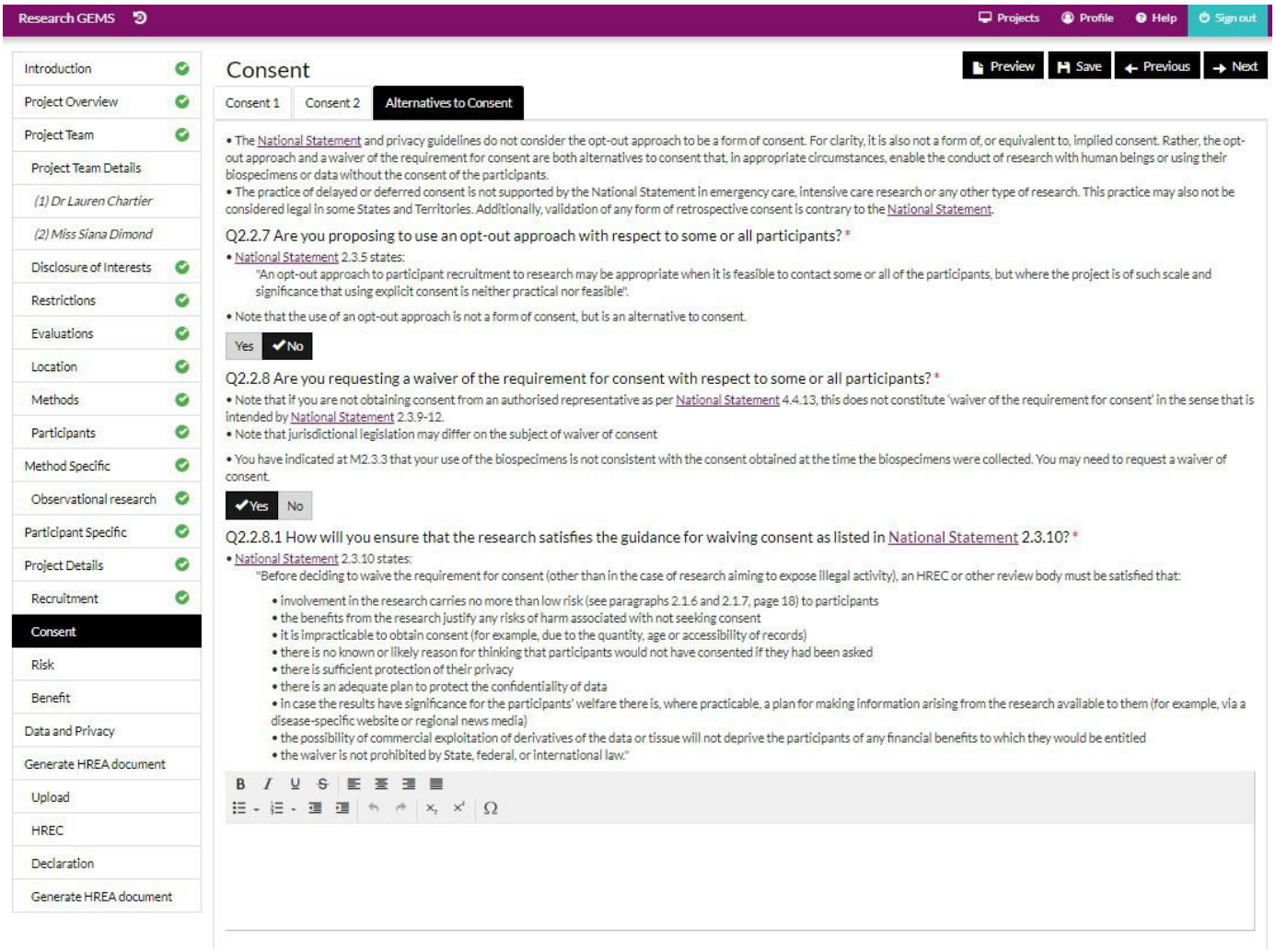
12. Consent

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'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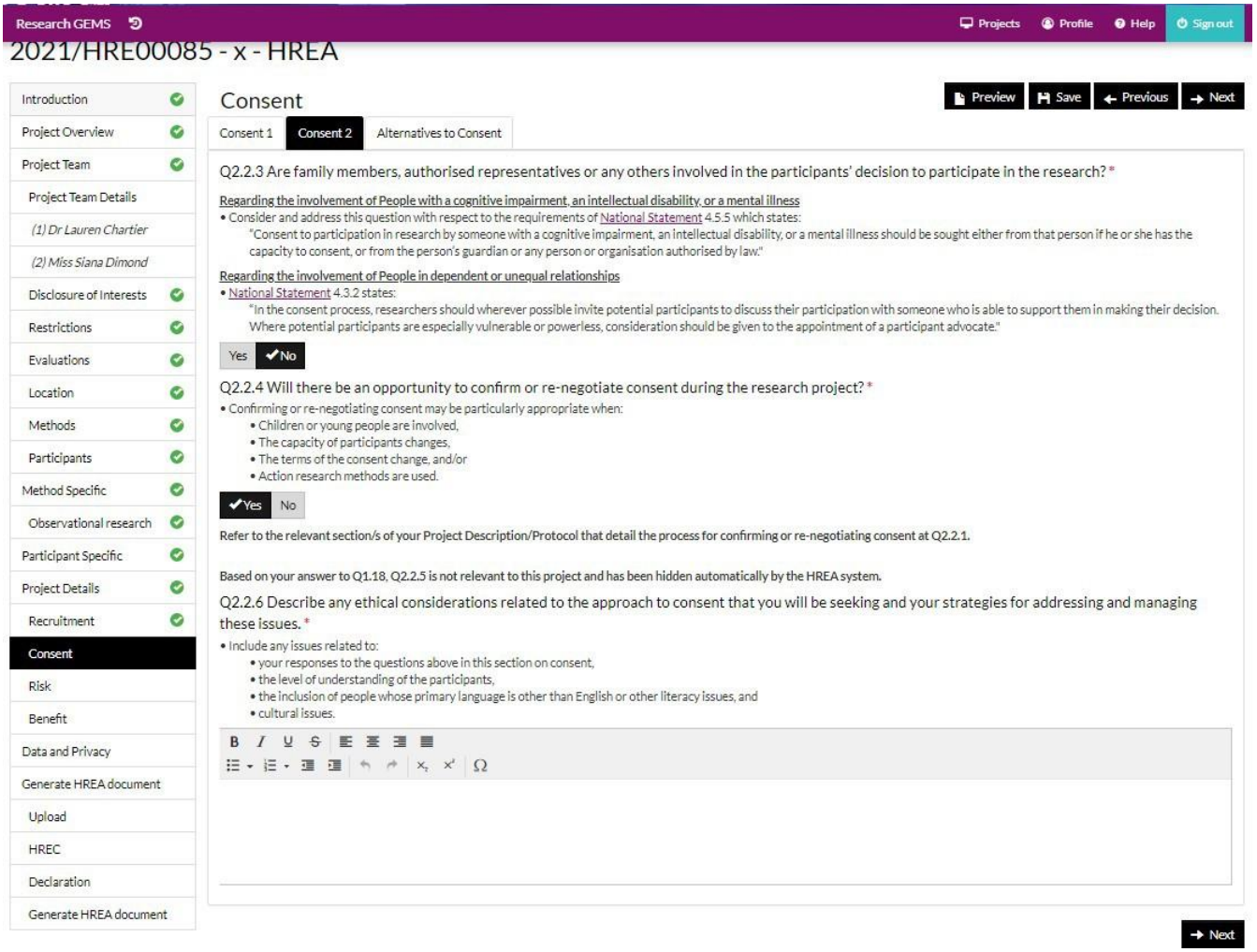
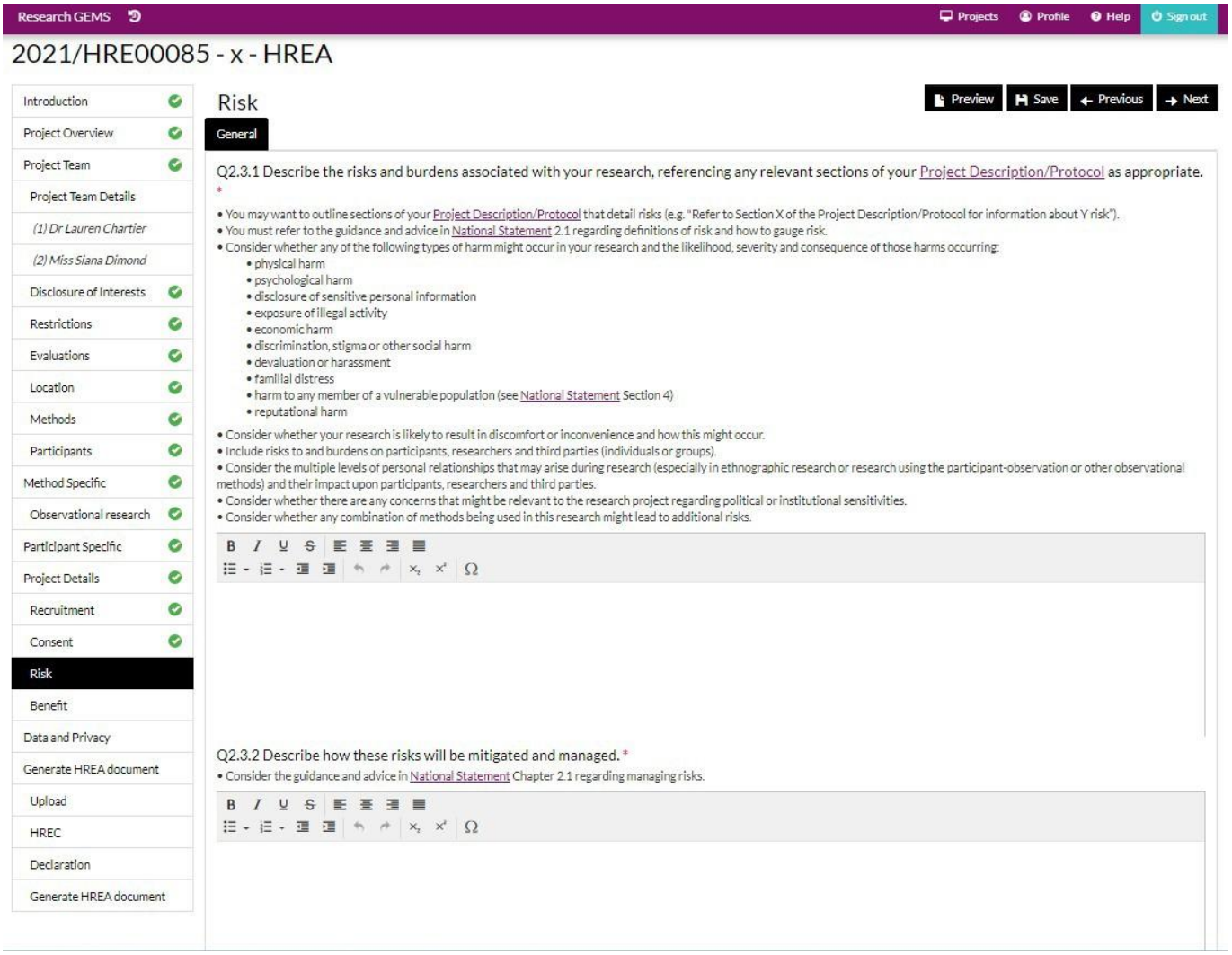
Participant Specific
Project Details
Recruitment
Consent
Risk
Benefit
Data and Privacy
Generate HREA document
Upload
HREC
Declaration
Generate HREA document
Consent
Preview
Save
Previous
Next
Consent 1
Consent 2
Alternatives to Consent
• The National Statement and privacy guidelines do not consider the opt-out approach to be a form of consent. For clarity, it is also not a form of, or equivalent to, implied consent. Rather, the opt-out approach and a waiver of the requirement for consent are both alternatives to consent that, in appropriate circumstances, enable the conduct of research with human beings or using their biospecimens or data without the consent of the participants.
• The practice of delayed or deferred consent is not supported by the National Statement in emergency care, intensive care research or any other type of research. This practice may also not be considered legal in some States and Territories. Additionally, validation of any form of retrospective consent is contrary to the National Statement.
Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all participants? *
• National Statement 2.3.5 states:
"An opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible".
• Note that the use of an opt-out approach is not a form of consent, but is an alternative to consent.
Yes
No
Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants? *
• Note that if you are not obtaining consent from an authorised representative as per National Statement 4.4.13, this does not constitute 'waiver of the requirement for consent' in the sense that is intended by National Statement 2.3.9-12.
• Note that jurisdictional legislation may differ on the subject of waiver of consent
• You have indicated at M2.3.3 that your use of the biospecimens is not consistent with the consent obtained at the time the biospecimens were collected. You may need to request a waiver of consent.
Yes
No
Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in National Statement 2.3.10? *
• National Statement 2.3.10 states:
"Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:
• involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
• the benefits from the research justify any risks of harm associated with not seeking consent
• it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
• there is no known or likely reason for thinking that participants would not have consented if they had been asked
• there is sufficient protection of their privacy
• there is an adequate plan to protect the confidentiality of data
• in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
• the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
• the waiver is not prohibited by State, federal, or international law."


Research GEMS
Projects
Profile
Help
Sign out
2021/HRE00085 - x - HREA
Introduction
Project Overview
Project Team
Project Team Details
(1) Dr Lauren Chartier
(2) Miss Siana Dimond
Disclosure of Interests
Restrictions
Evaluations
Location
Methods
Participants
Method Specific
Observational research
Participant Specific
Project Details
Recruitment
Consent
Risk
Benefit
Data and Privacy
Generate HREA document
Upload
HREC
Declaration
Generate HREA document
Consent
Preview
Save
Previous
Next
Consent 1
Consent 2
Alternatives to Consent
Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research? *
Regarding the involvement of People with a cognitive impairment, an intellectual disability, or a mental illness
• Consider and address this question with respect to the requirements of National Statement 4.5.5 which states:
"Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law."
Regarding the involvement of People in dependent or unequal relationships
• National Statement 4.3.2 states:
"In the consent process, researchers should wherever possible invite potential participants to discuss their participation with someone who is able to support them in making their decision. Where potential participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate."
Yes
No
Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project? *
• Confirming or re-negotiating consent may be particularly appropriate when:
• Children or young people are involved,
• The capacity of participants changes,
• The terms of the consent change, and/or
• Action research methods are used.
Yes
No
Refer to the relevant section/s of your Project Description/Protocol that detail the process for confirming or re-negotiating consent at Q2.2.1.
Based on your answer to Q1.18, Q2.2.5 is not relevant to this project and has been hidden automatically by the HREA system.
Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues. *
• Include any issues related to:
• your responses to the questions above in this section on consent,
• the level of understanding of the participants,
• the inclusion of people whose primary language is other than English or other literacy issues, and
• cultural issues.
Next

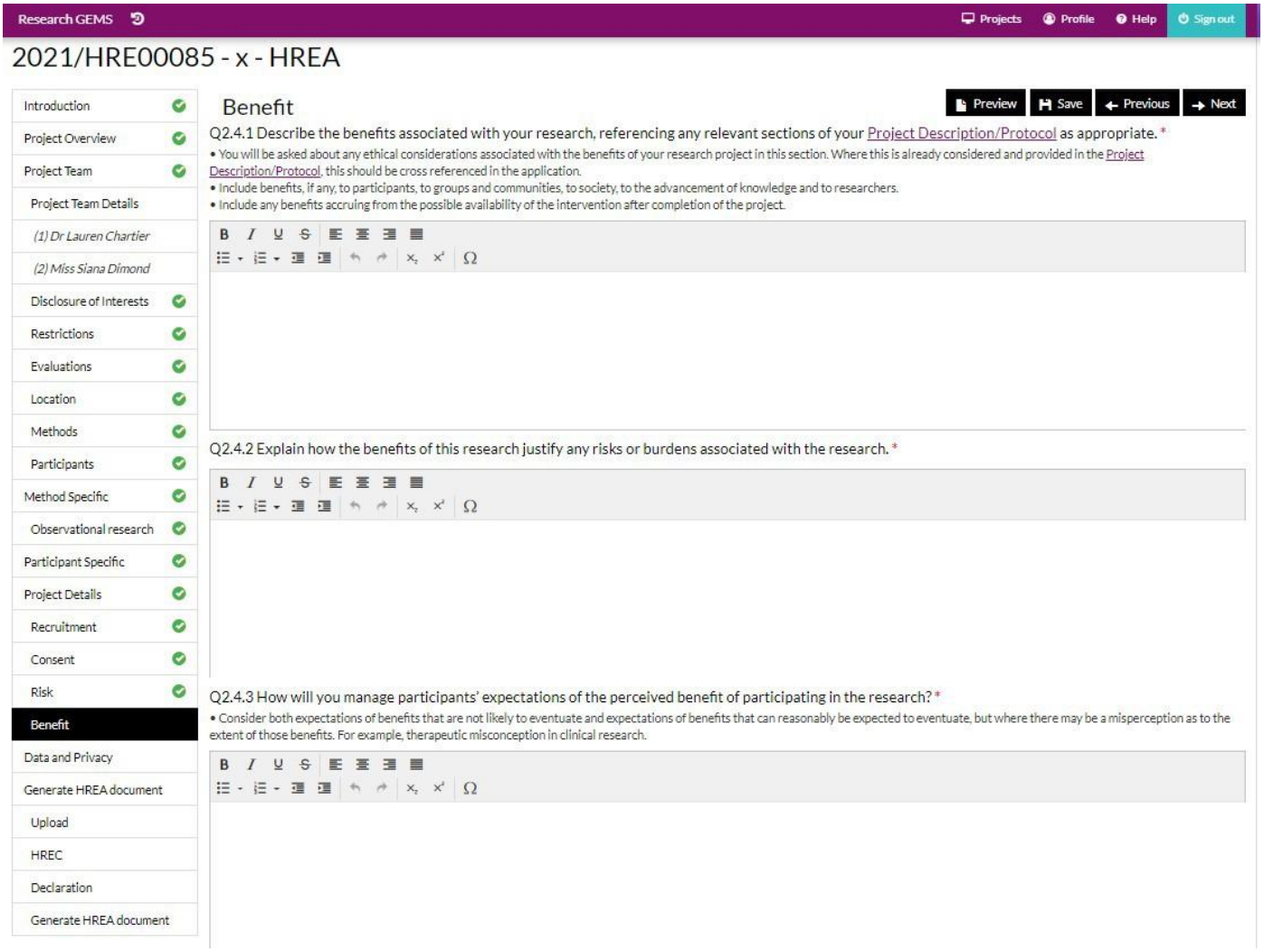
13. Risk

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

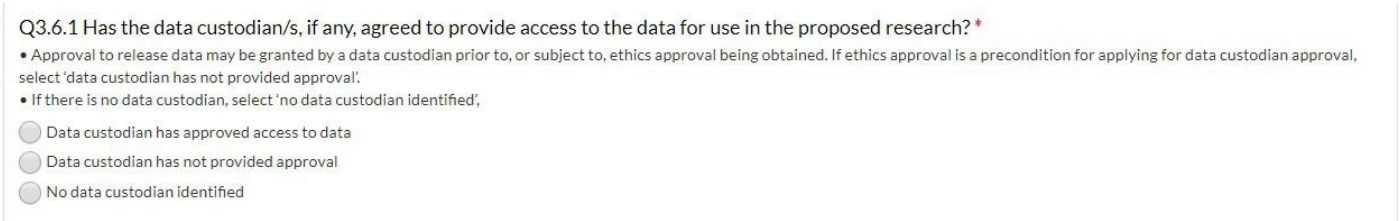


15. Data and Privacy

i. Data Characteristics - these questions are related to the type of data collected and used throughout the research project. i.e. Personal, health, identifiable, de-identifiable information

ii. Select all that apply

iii. Q3.6 – Selecting a database as a source of information will prompt Q3.6.1 relating to data custodian approval



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

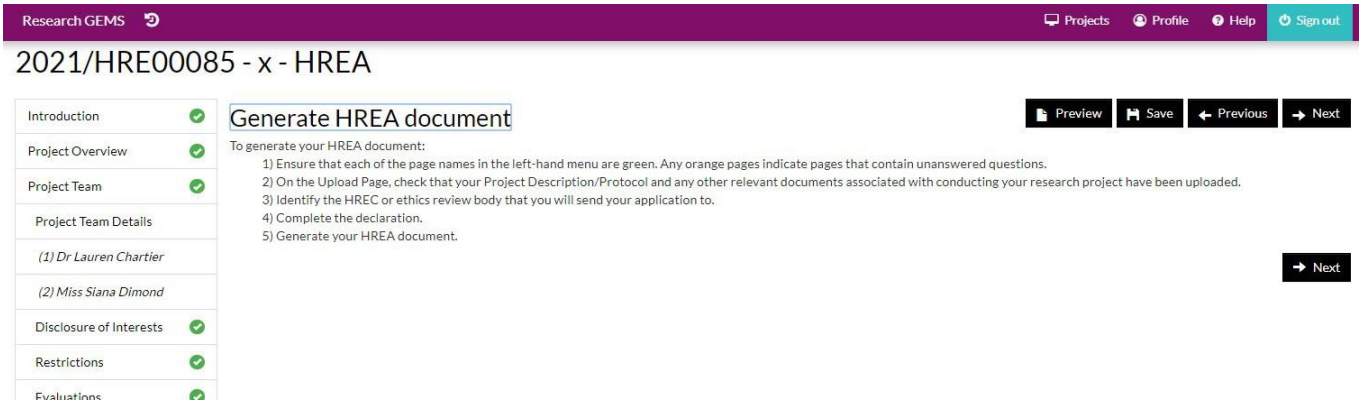
v. Refer to relevant sections of the Study Protocol

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

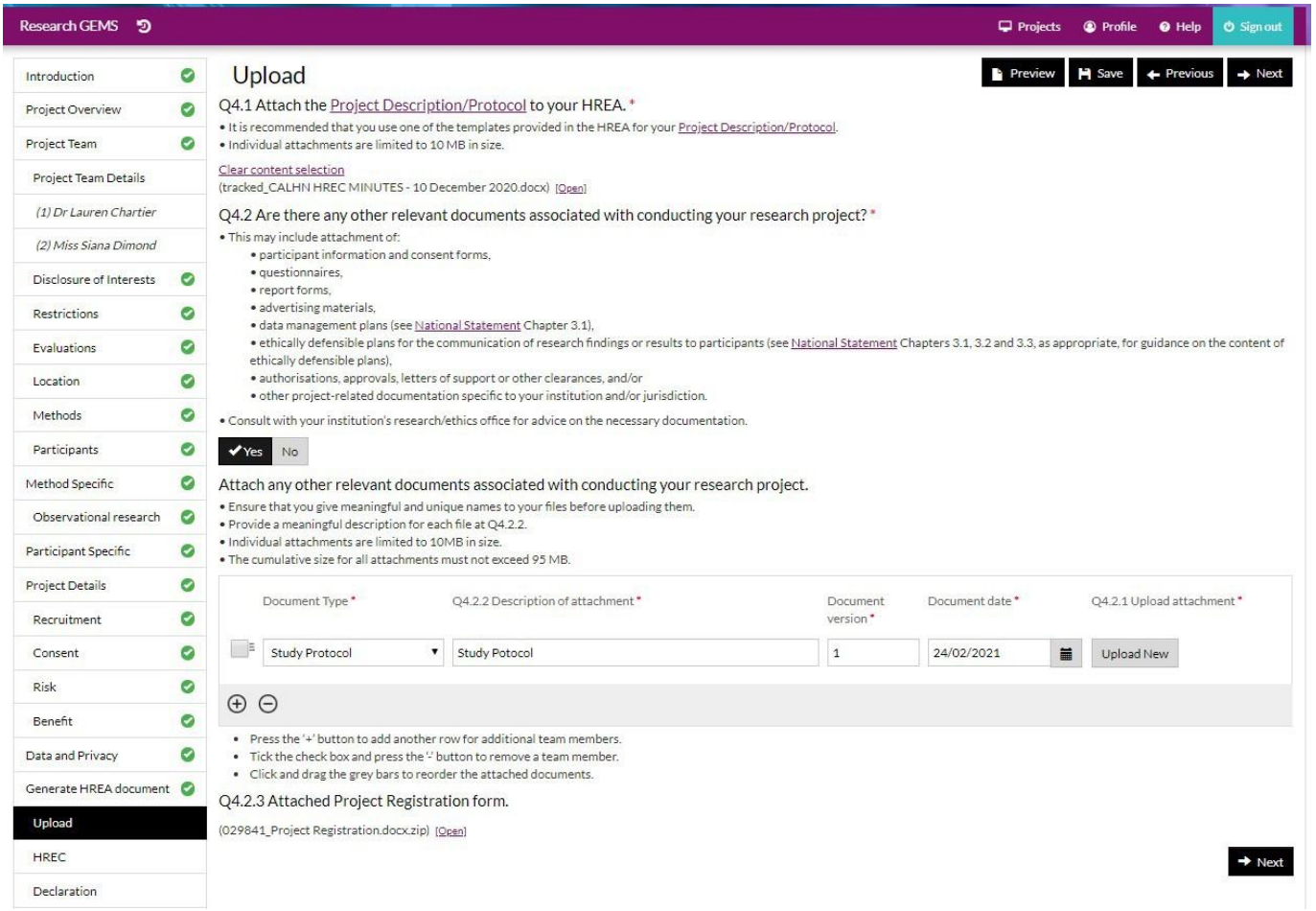
i. **<u>Attach all documents related to your application</u>** (Participant Information and Consent Form, validated questionnaires, interview guides, data collection spreadsheets etc)

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 '-'

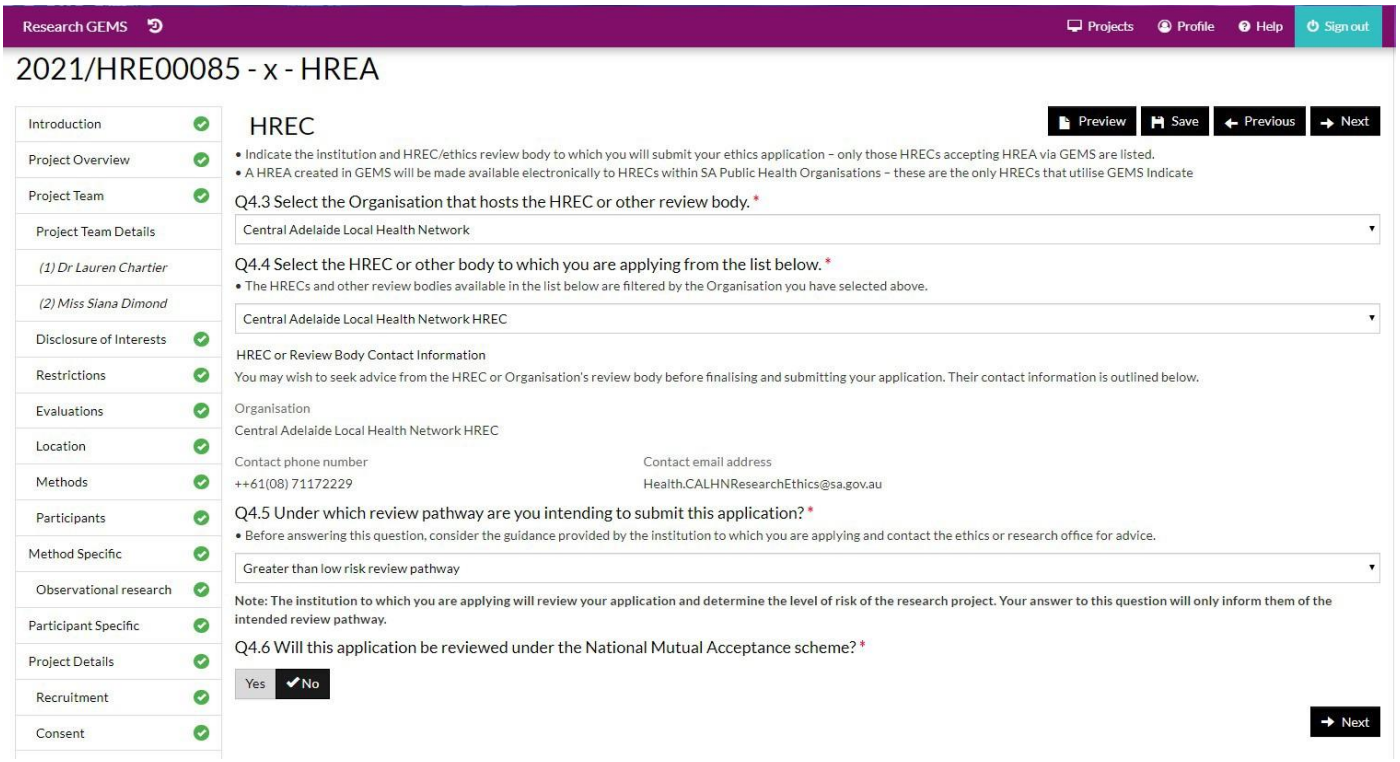
iv. The Project Registration will be automatically attached

v. <u>All study documents must be uploaded, as these will flow through to the document list on the ethics approval.</u>



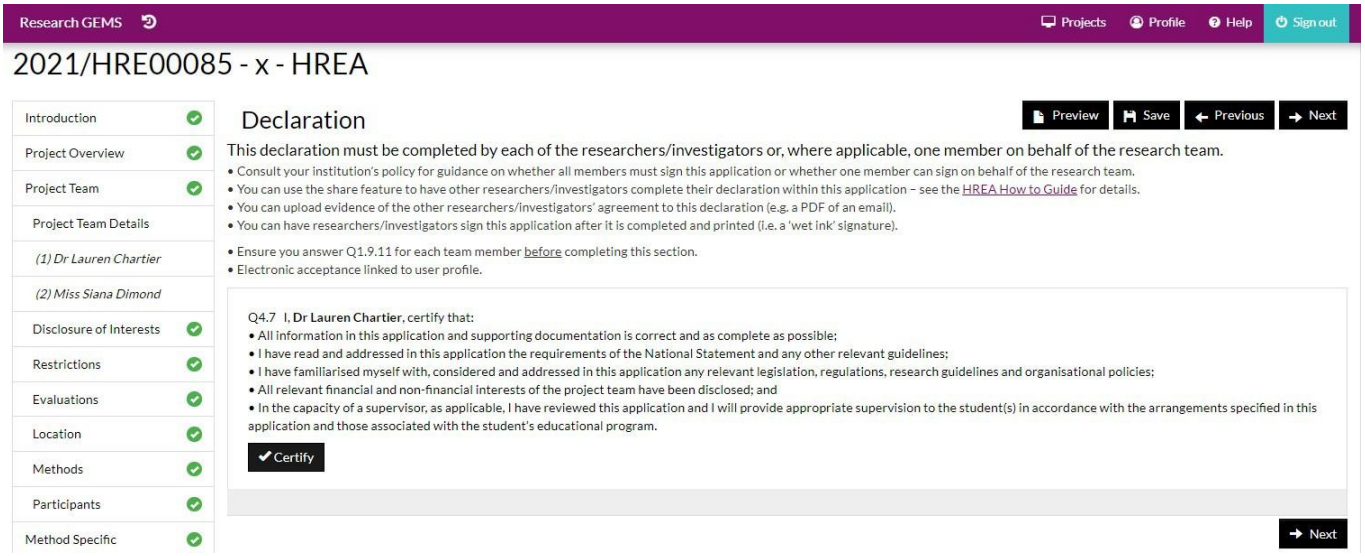
18. HREC

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

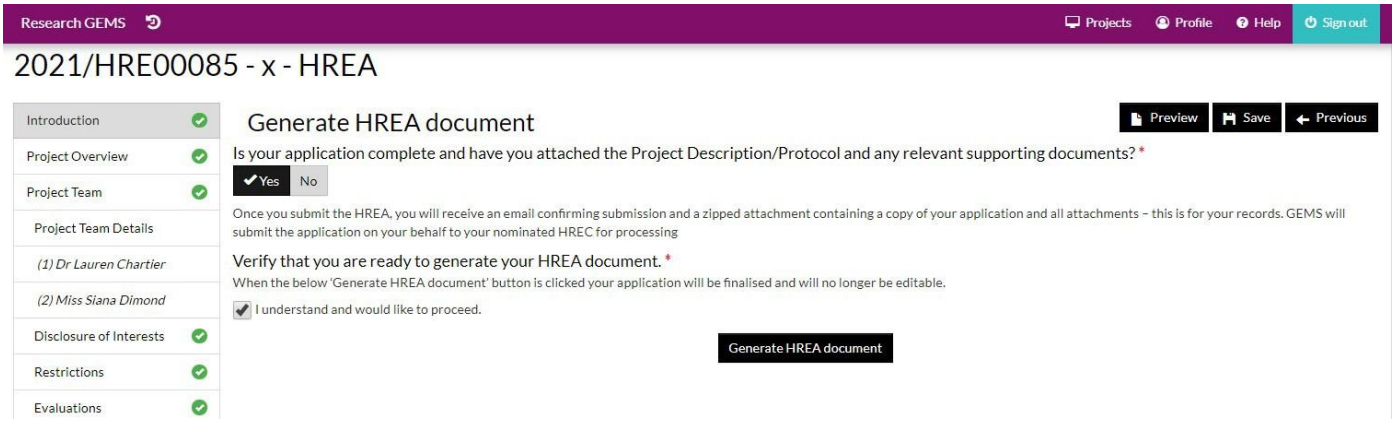
i. All study personnel will receive an email notification to complete this declaration page
ii. Select 'Certify'



20. Generate HREA document

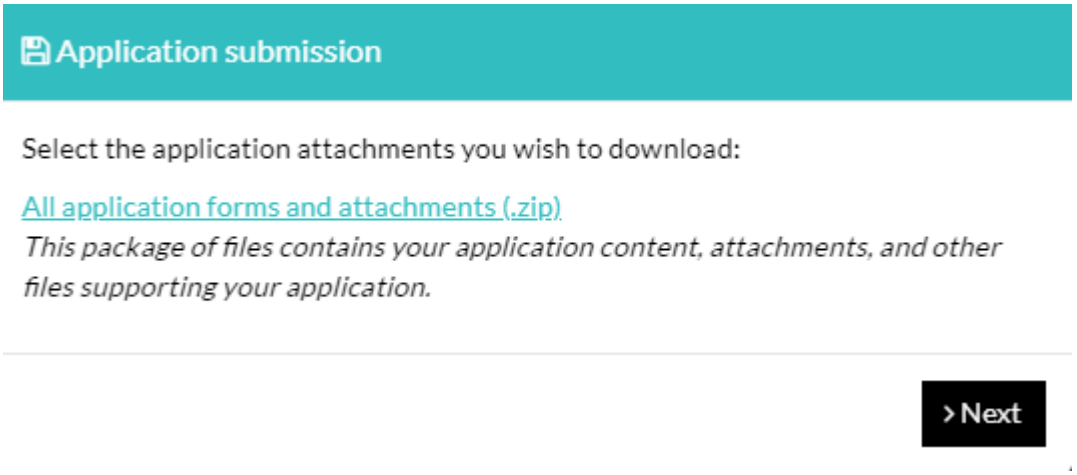
i. If all information is correct and attachments are uploaded, select 'Yes' and tick 'I understand and would like to proceed'

ii. Click 'Generate HREA document'



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

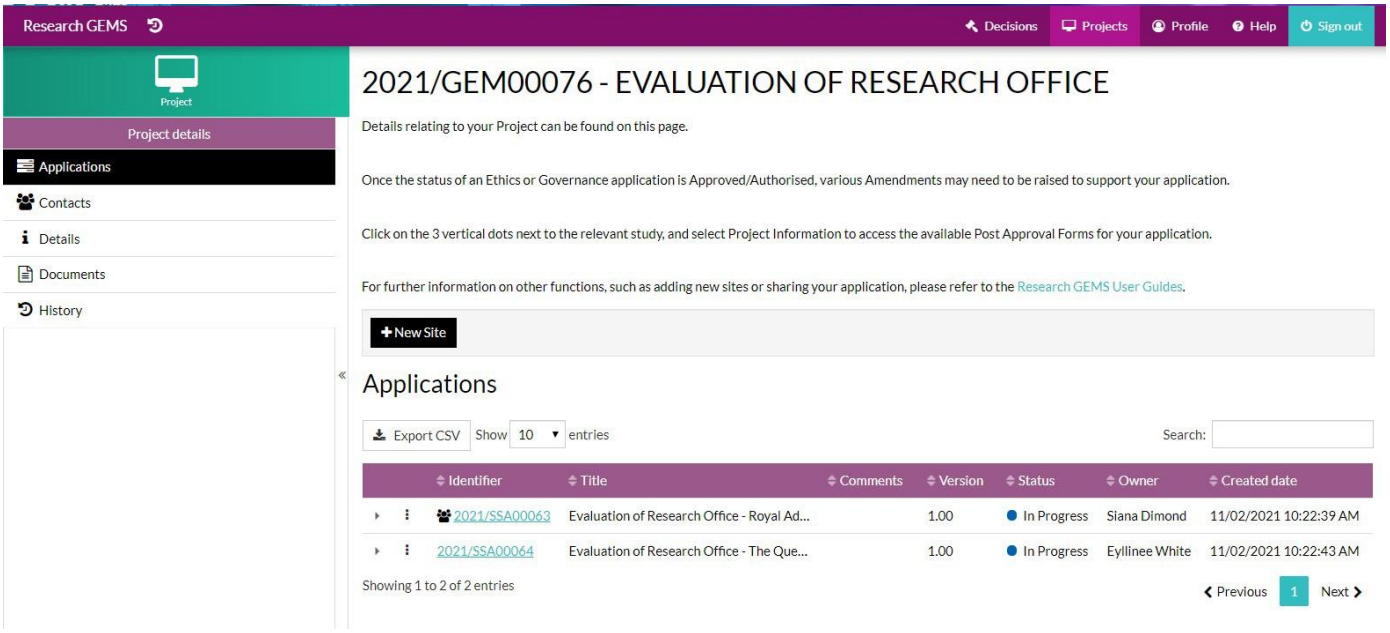


2. HRE application will now appear as 'Submitted' on the Project homepage
3. SSA's applicable to the HREA will be automatically generated and appear as 2021/SSA00XXX and 'In Progress'
4. You will receive updates on your application on GEMS through email correspondence

Site Specific Assessment

A. Once you have submitted the project registration and completed (submitted) the HREA you can proceed to creating the SSA

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

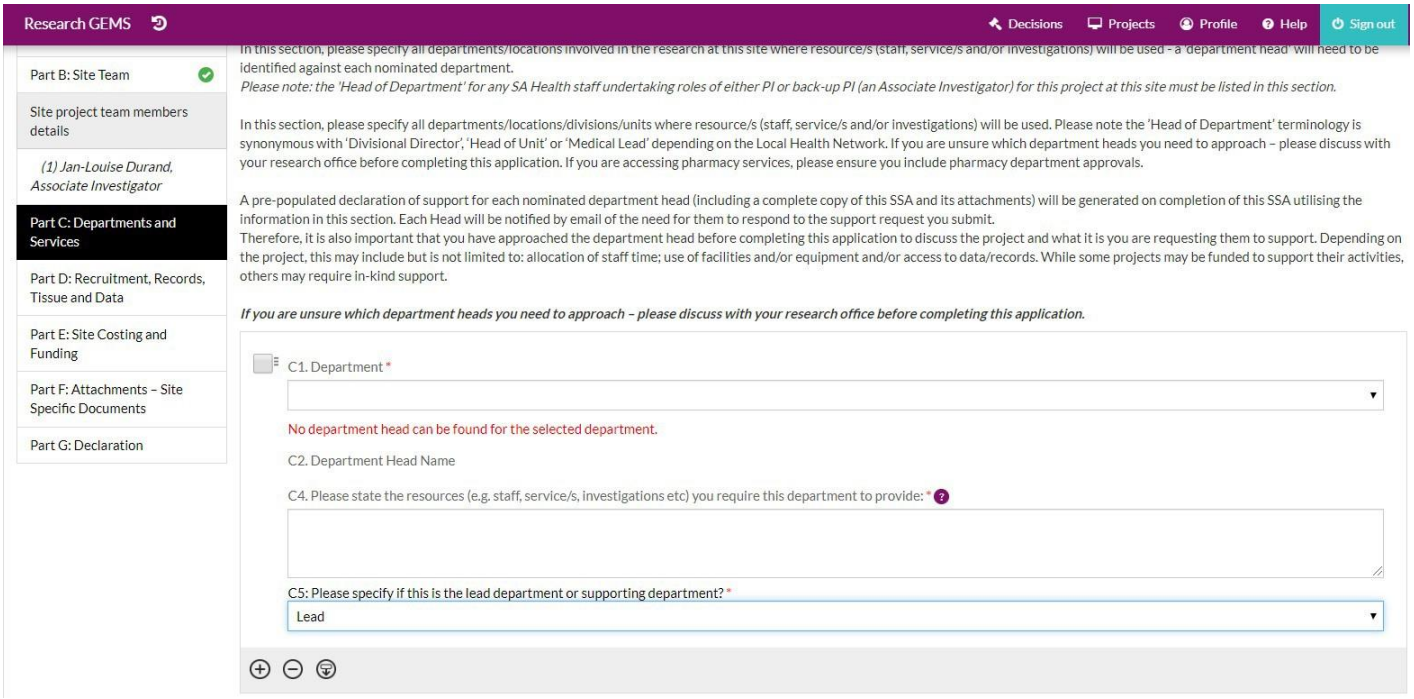
i. This is where you will add the Medical Lead, Head of Department and any Supporting Departments for declarations/approvals.

ii. You will need to add the Medical Lead first

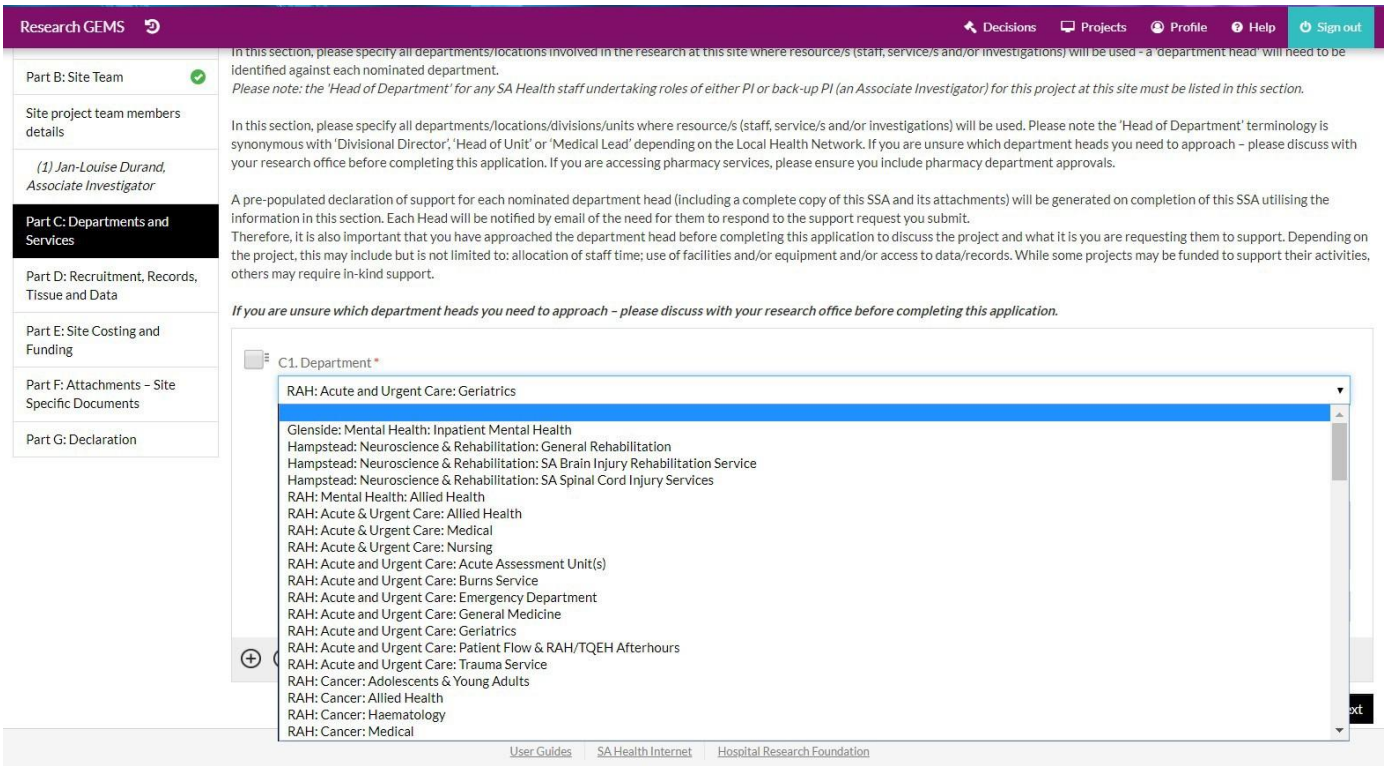
1. Select the drop down list and click on the appropriate Medical Lead for your stream. Medical Leads are named in the following naming convention:
    a. RAH: Surgery 2: Medical
    b. RAH: Surgery 2: Allied Health
    c. RAH: Surgery 2: Nursing
2. This will then pre-fill the name and email address of the Medical Lead.
3. You will then need to fill in sections C4&5
4. In section C5: select “Lead” for the Medical/Allied Health/Nursing Lead

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

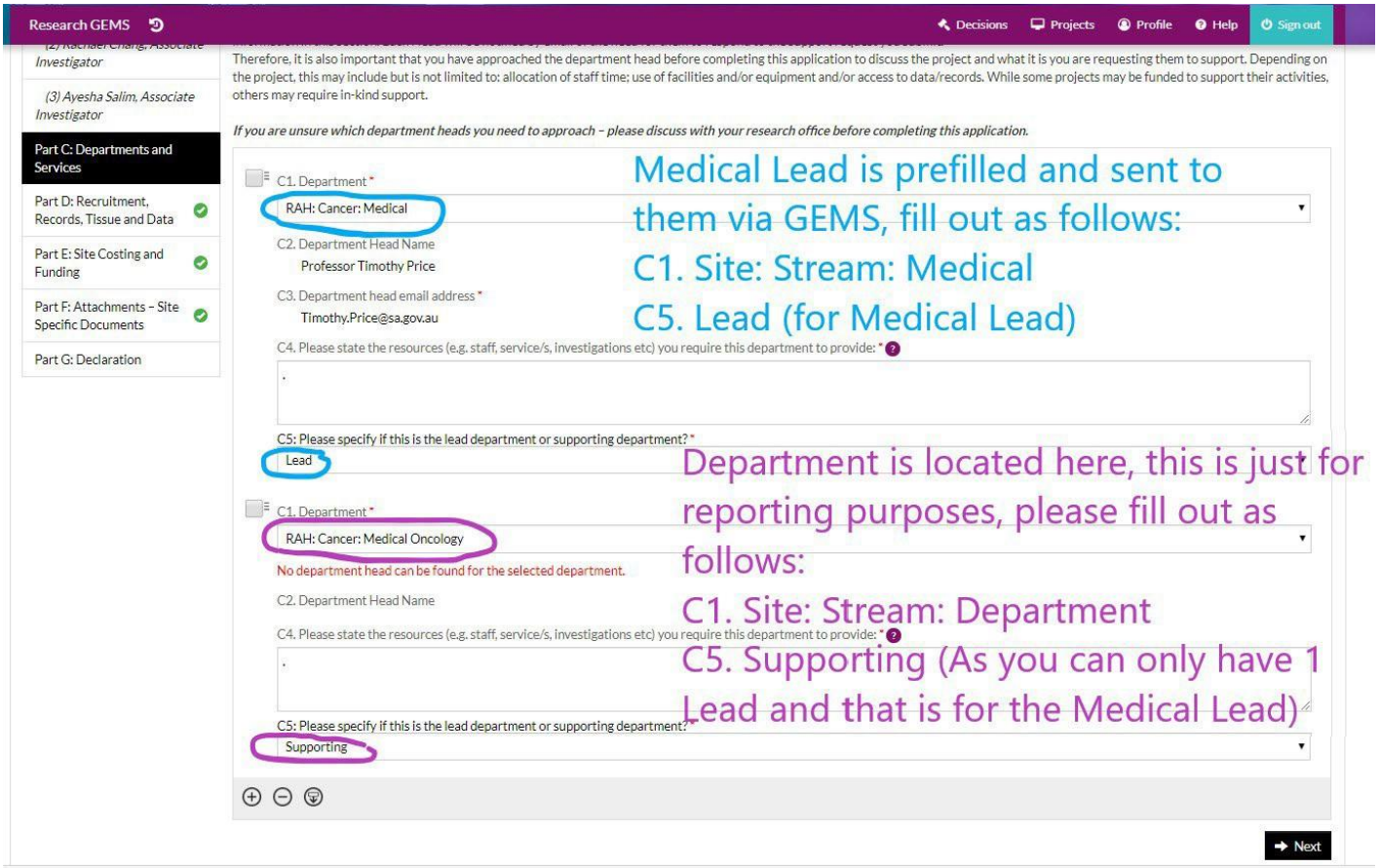
iv. Add any other Supporting Departments the same way as the Head of Department and gain their approval outside of the system.



v. Naming conventions can be seen here:

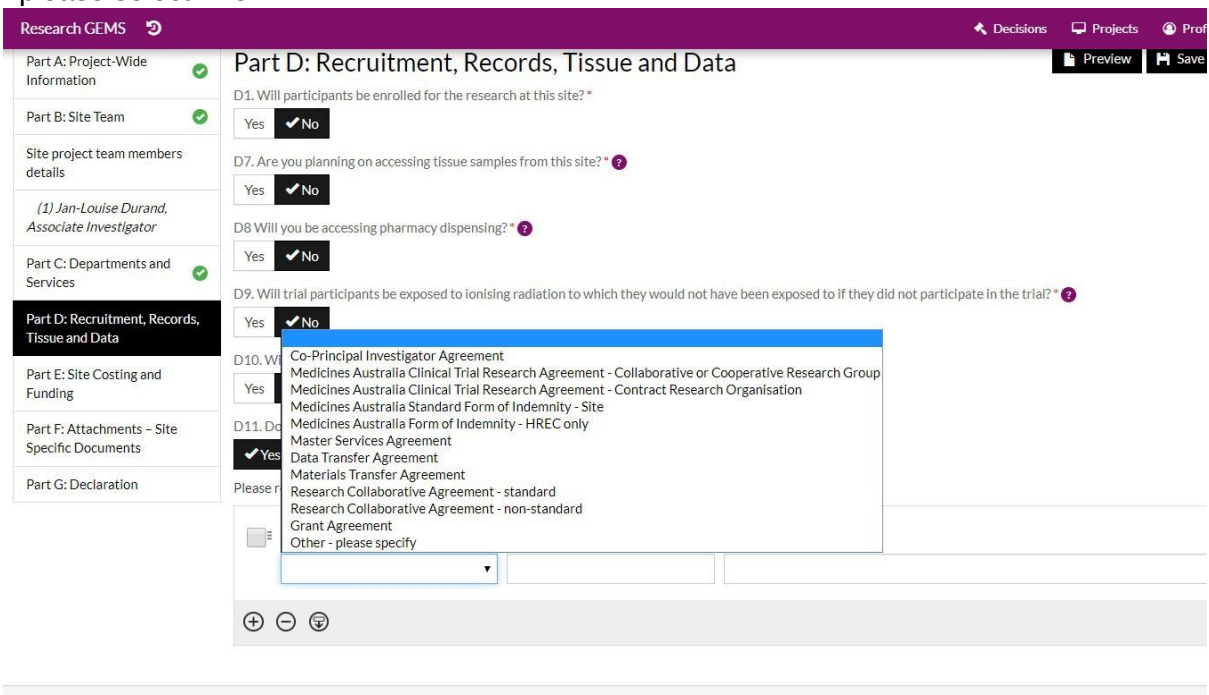


Once you have finished, it should look like this as an example:



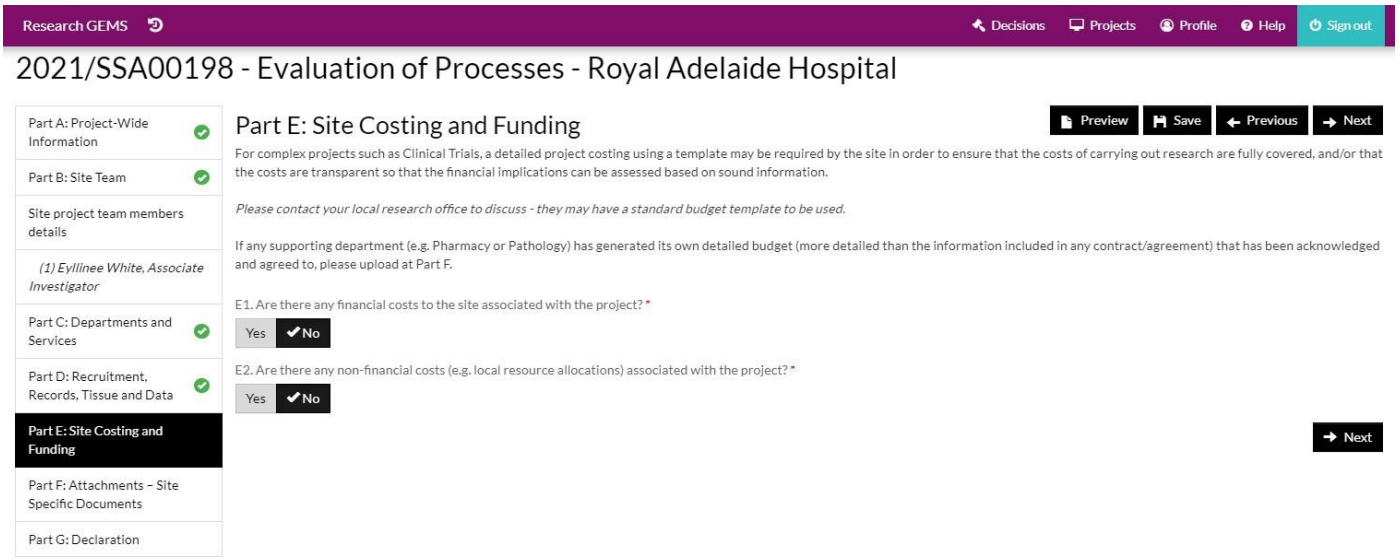
E. Part D – Recruitment, Records, Tissue & Data

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

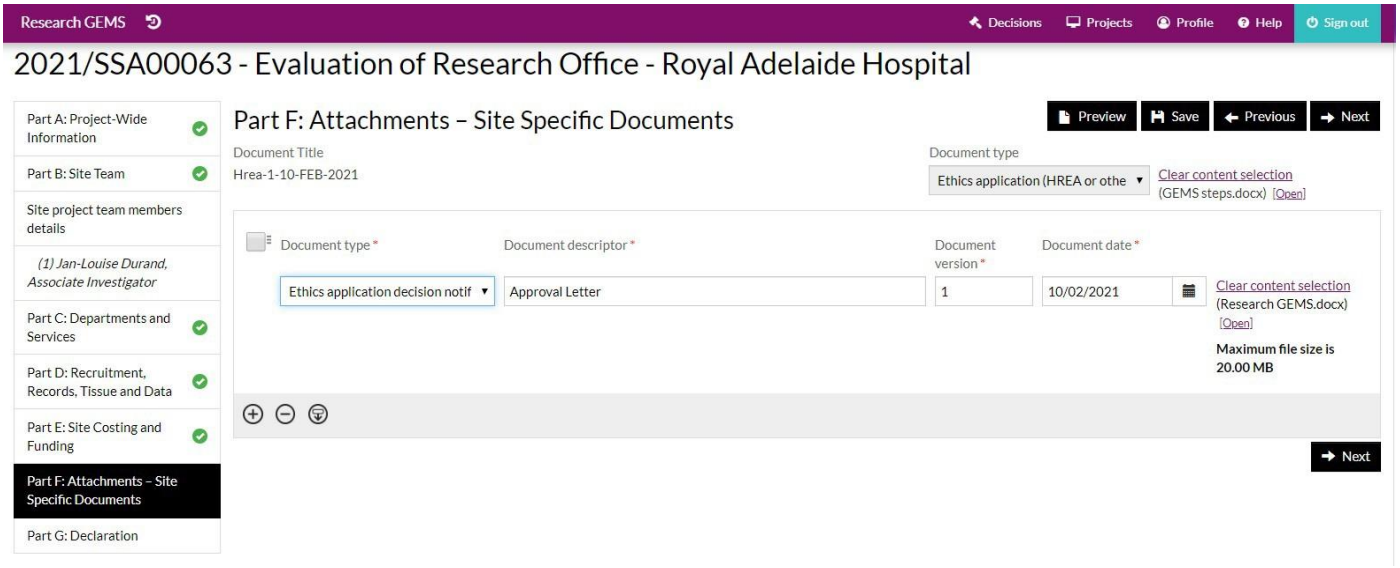
i. Click ‘No’ to both options.



G. Part F – Attachments/Site Specific Documents

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

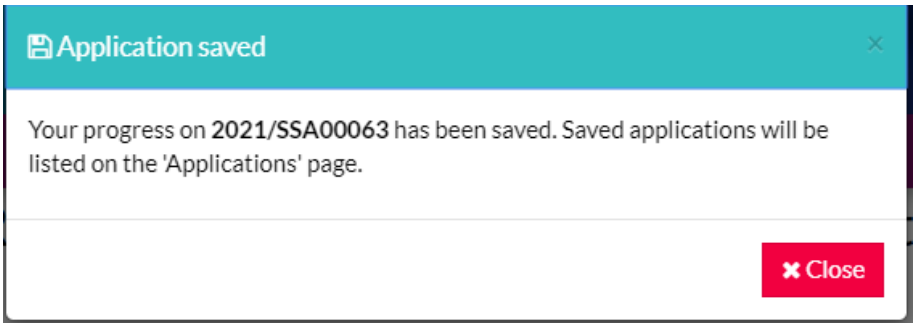
ii. Check that the documents did come across from the project registration/HREA as it should appear as below
iii. Then click 'Next'



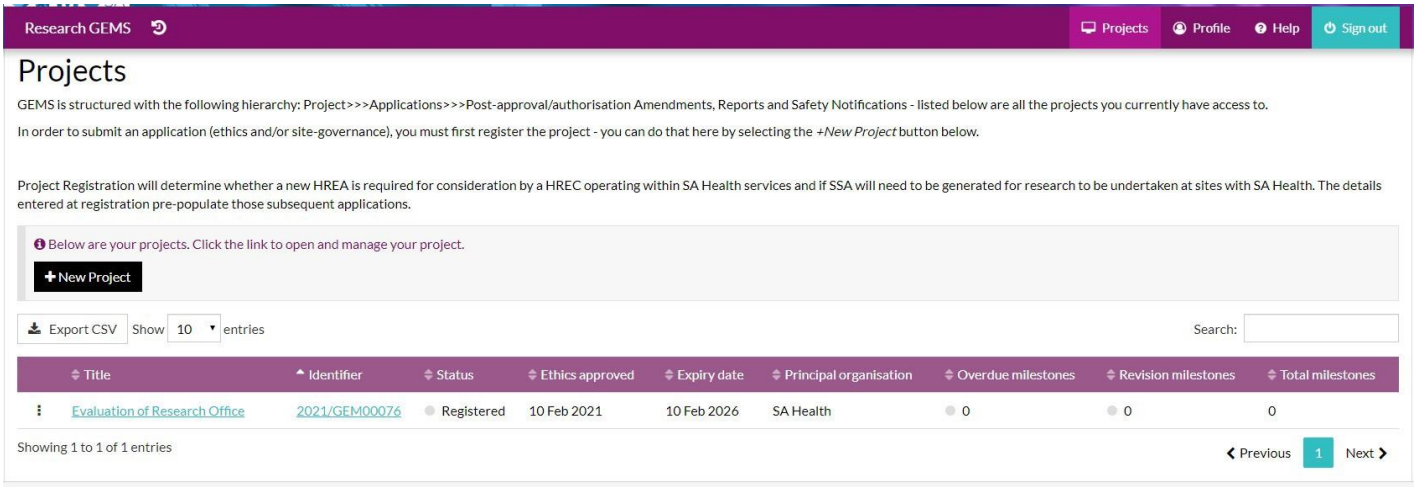
H. Part G – Declaration

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:

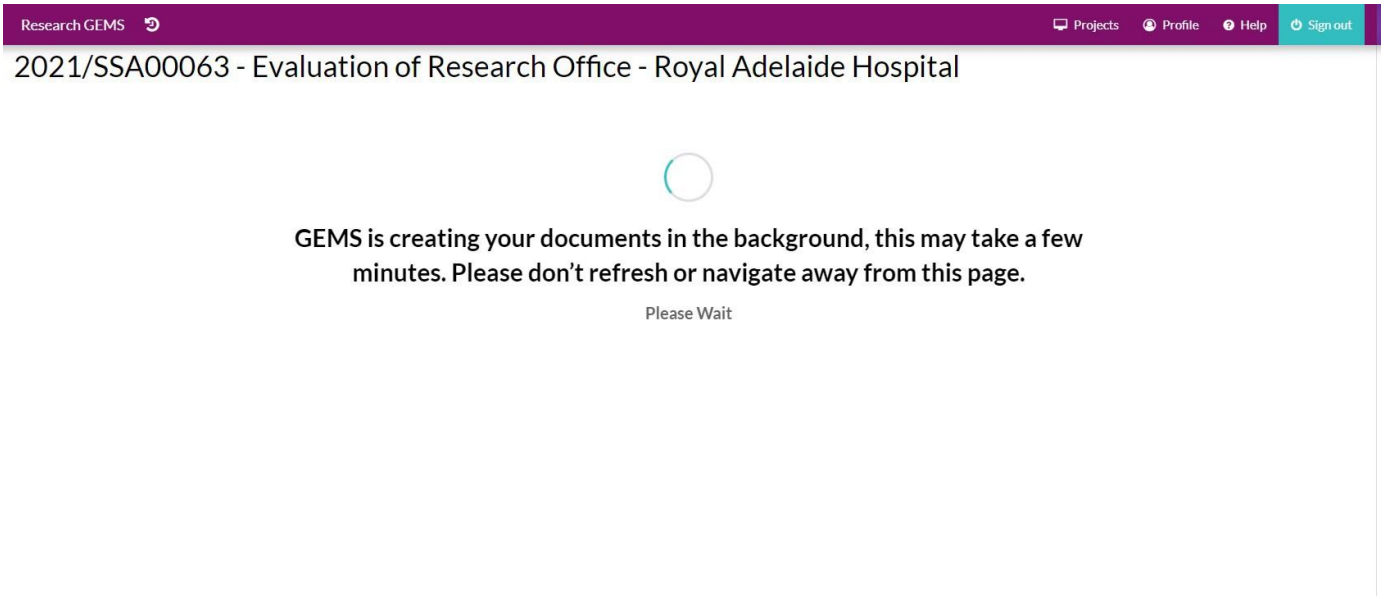


iii. The project should then appear in the PI's project list when they log in. To access the projects section, click 'Projects' on top right-hand corner

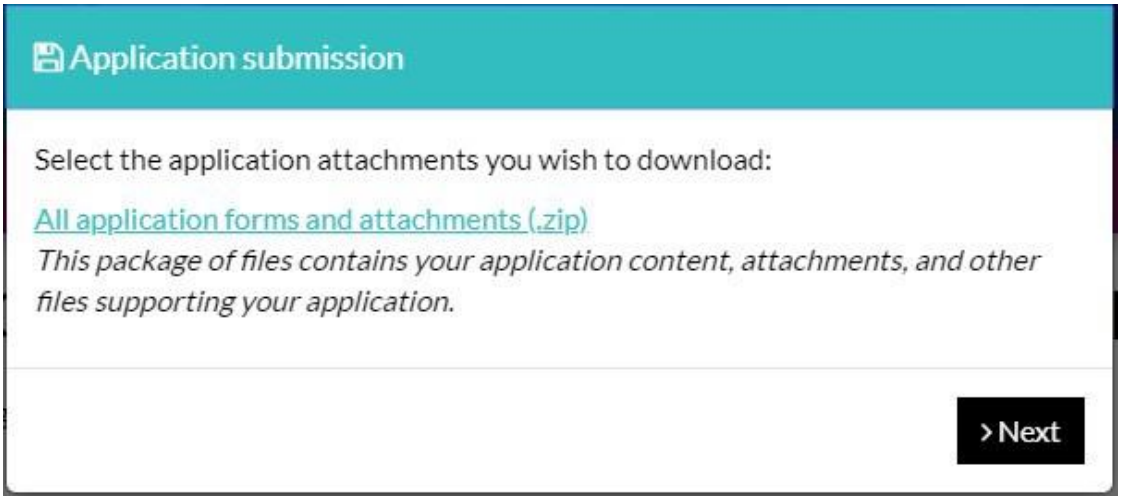


iv. Once PI has logged in, they need click on the 'Title' (Project that is applicable for the submission)
v. Then click SSA application that you are the PI for (your/their site)
vi. Click the blue Identifier title of your application – this will only let you choose your own site to submit. You will not 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'

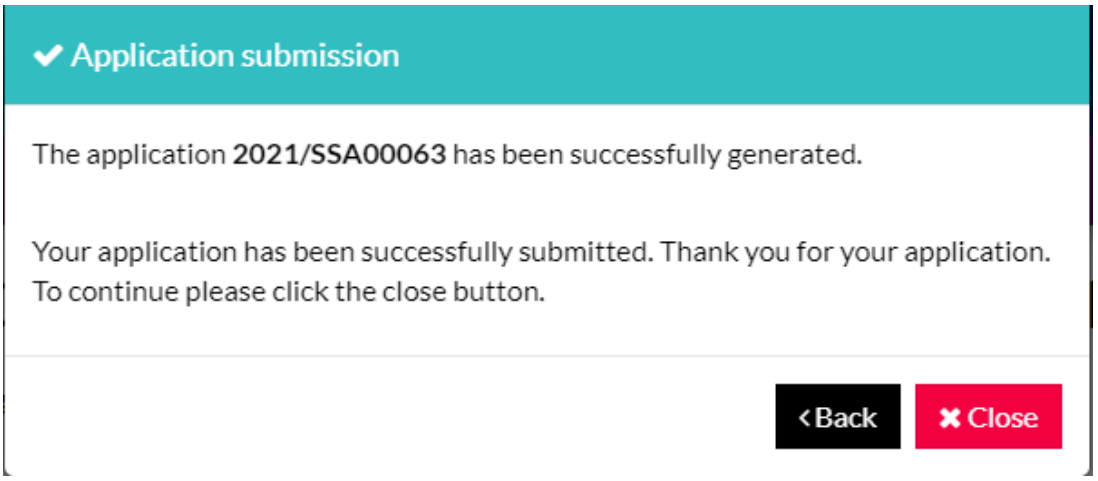
viii. This will then process



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



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



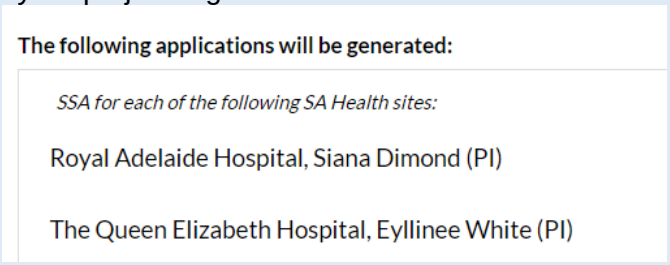
xi. The status of the project should then change from 'In Progress' to 'Submitted'

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

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	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	• 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  **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)

HREA

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

SSA
Application

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 Medical Lead, Head of Department and any Supporting Departments for declarations/approvals. • The details of the Heads of Department/Supporting Head of Departments were not migrated into the system as they are constantly being updated. Therefore you will need to provide the Head of Department with the declaration form and gain their approval via email or signature, then upload to the clinical trial share drive along with all other supporting documentation
Part D: Recruitment, Records, Tissue & Data	• Upload agreements to share drive. • Under “Agreement Location” please select “No”
Part E: Site Costing & Funding	• Select No • Select No • Do not enter any details into this section
Part F: Attachments/Site Specific Documents	• 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	• Only the PI 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).

Medical Lead approval will come via Research GEMS.

Correspondence

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

Dear CALHN Research Services,

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

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:
Resources include:

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

- **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