Research GEMS Guidelines – Study Personnel
Preparing Project Registration and HREA for Investigator Initiated Studies

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

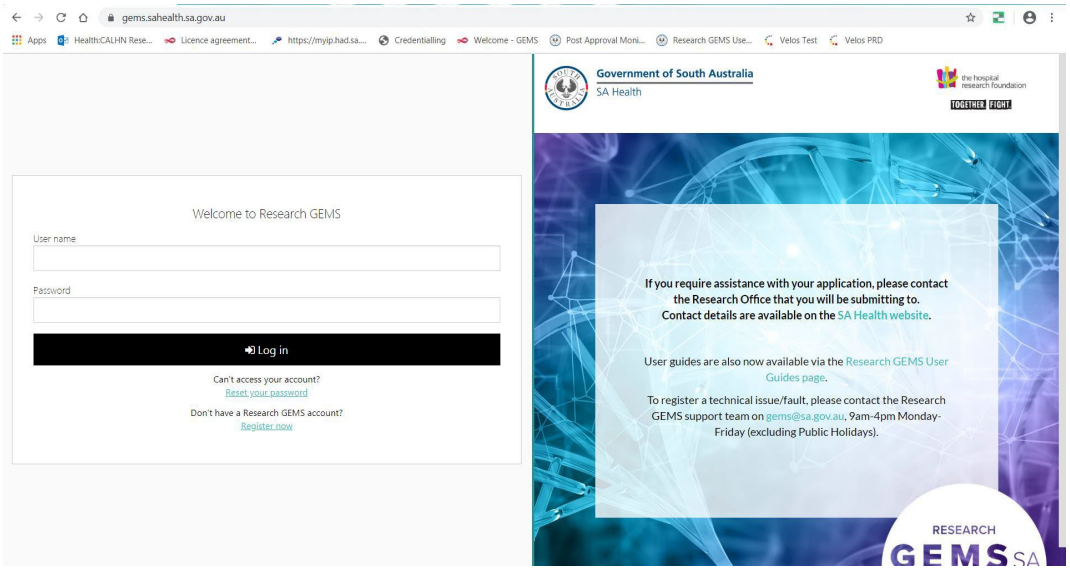
- GEMS – Governance and Ethics Management System
- HREA – Human Research Ethics Application
- SSA – Site Specific Assessment or 'Site' Application
- Project – Study
- CPI – Coordinating Principal Investigator
- PI – Principal Investigator

Procedures

Registering a Project

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

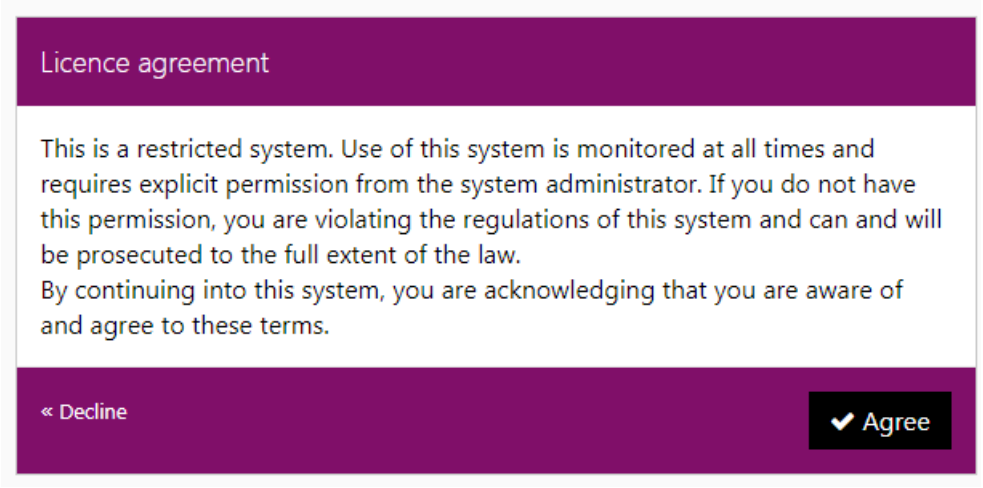
2. Login/Register Account



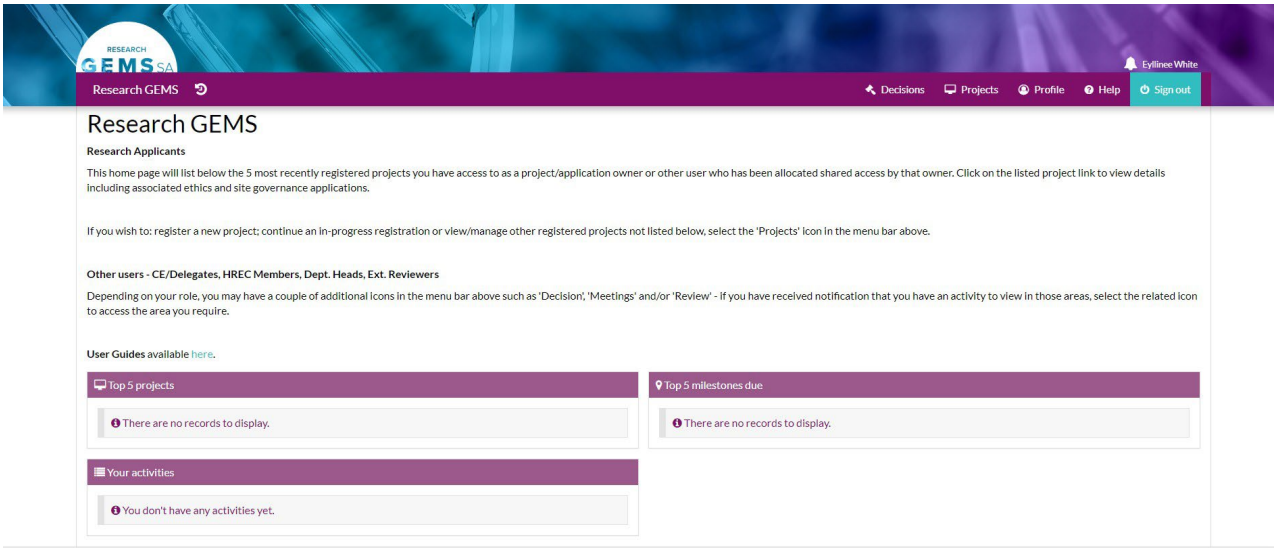
a. If your account is set up, login with your username and password
    i. If you have received an email but have not yet logged in before, click ‘Reset your password’ and enter the email address the original email went to

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)

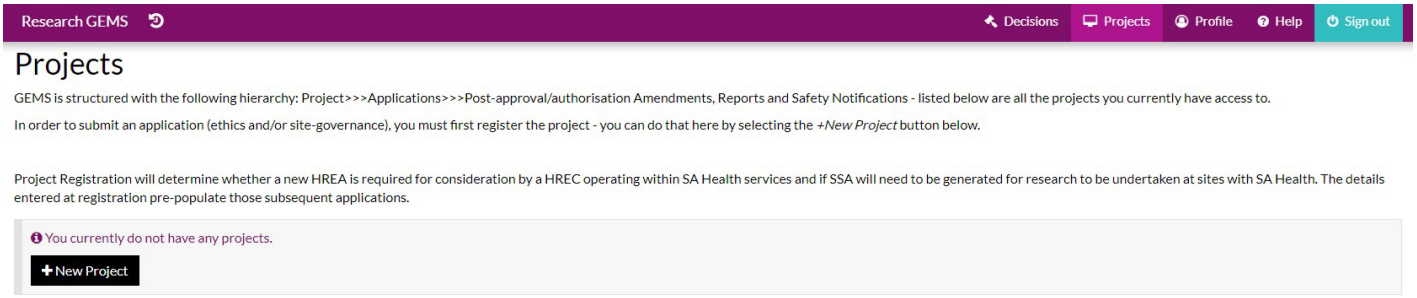
c. Once you have successfully logged in, click ‘Agree’ to License Agreement Statement



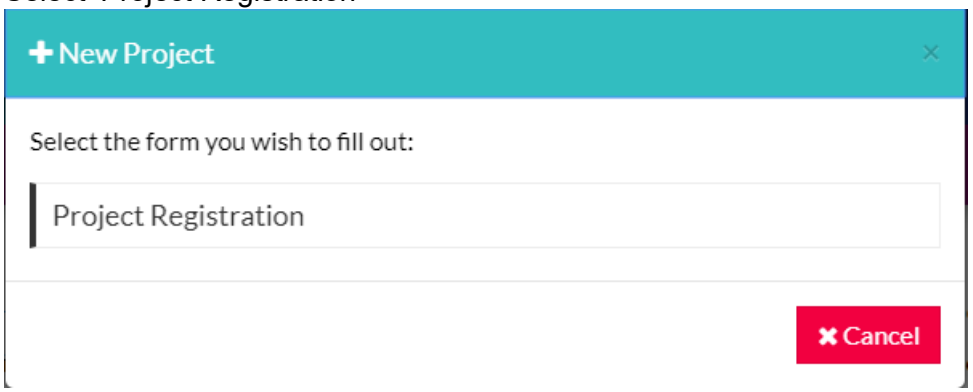
3. Registering your Project
    a. You will now have been directed to the External Portal Homepage for Researchers / Research Personnel.



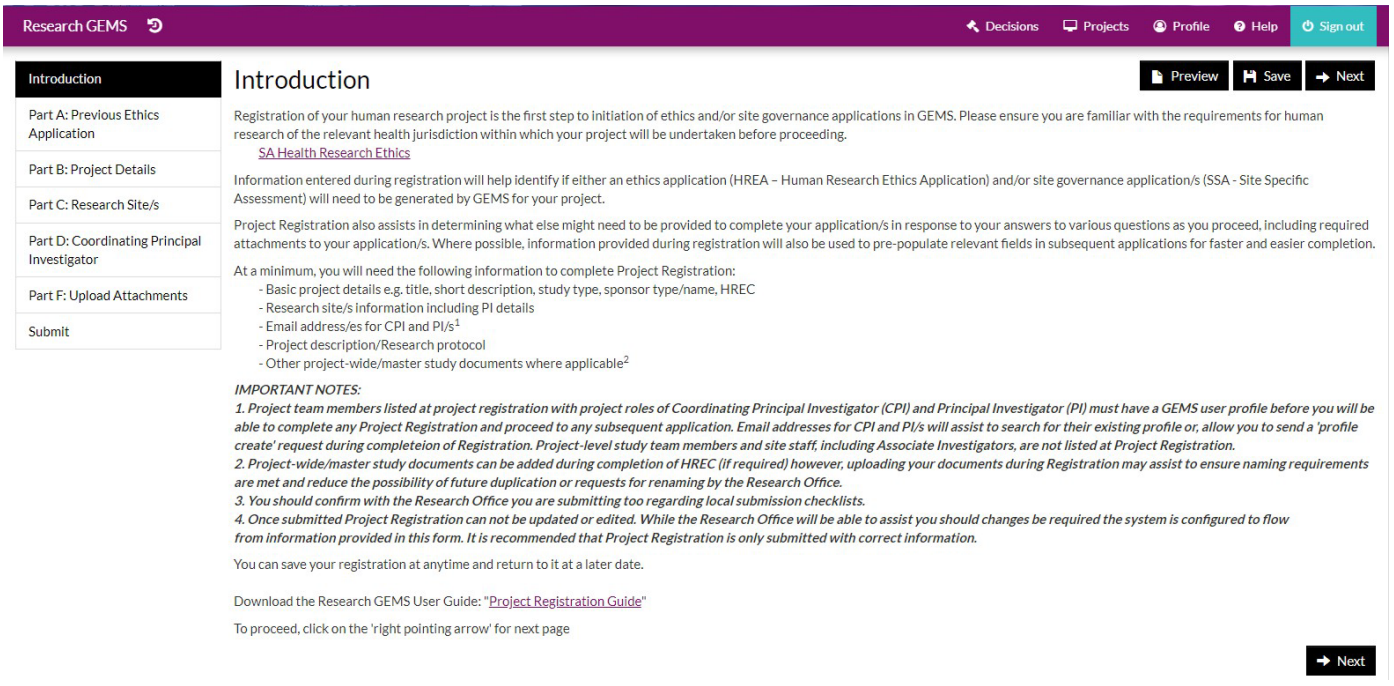
b. To register a project, navigate to the ‘Projects’ tab on the right hand corner
c. Click ‘New Project’



d. Select 'Project Registration'

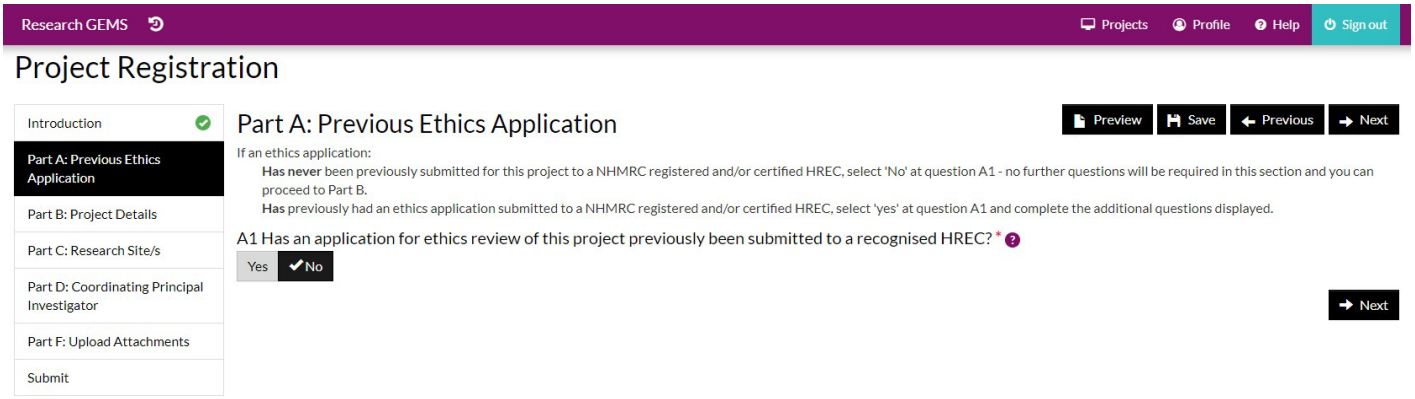


e. This will then navigate you to the 'New Project Registration' Page on the 'Introduction' tab. Read this information, then click next.

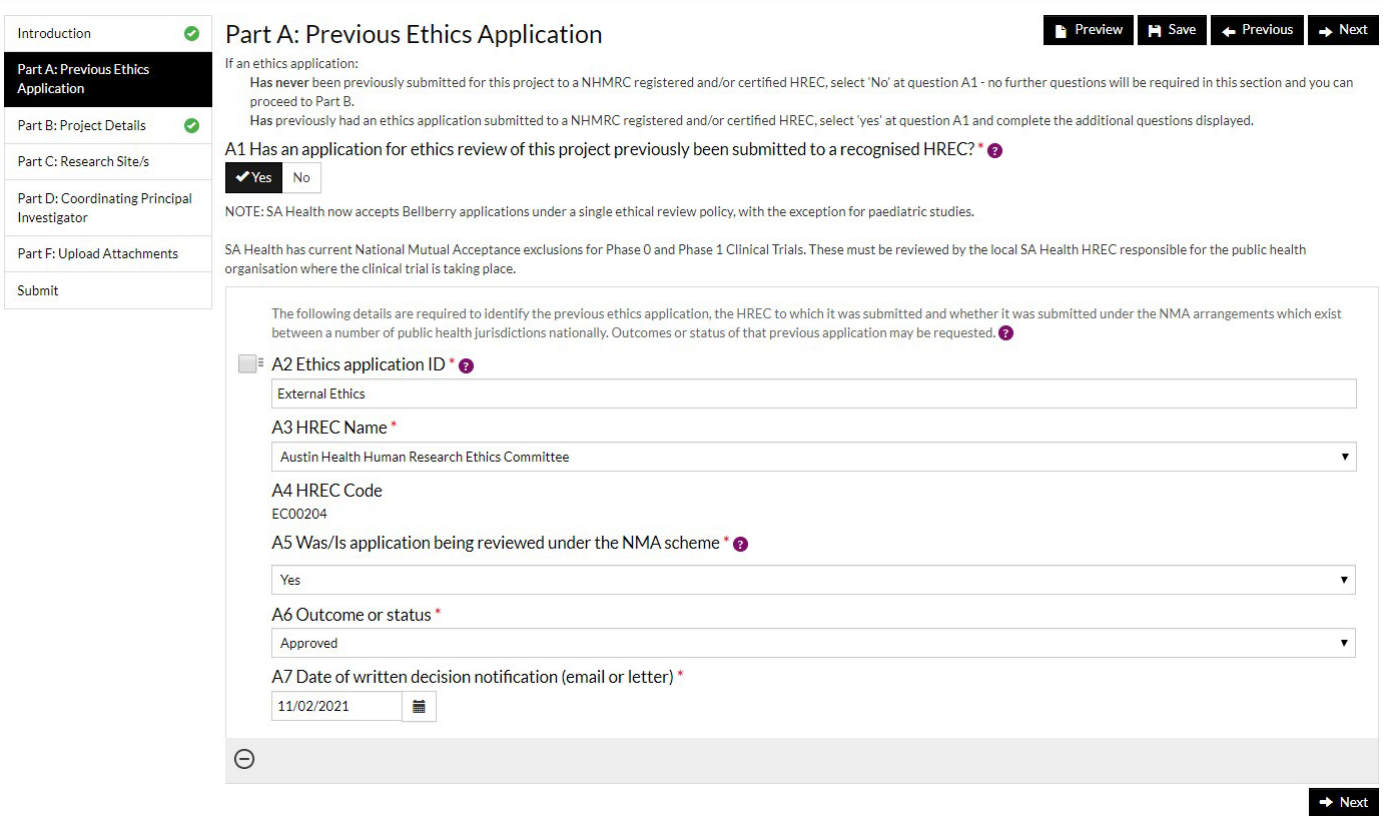


f. This will navigate through Tabs A-F.

g. Part A: Previous Ethics Application



i. 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'

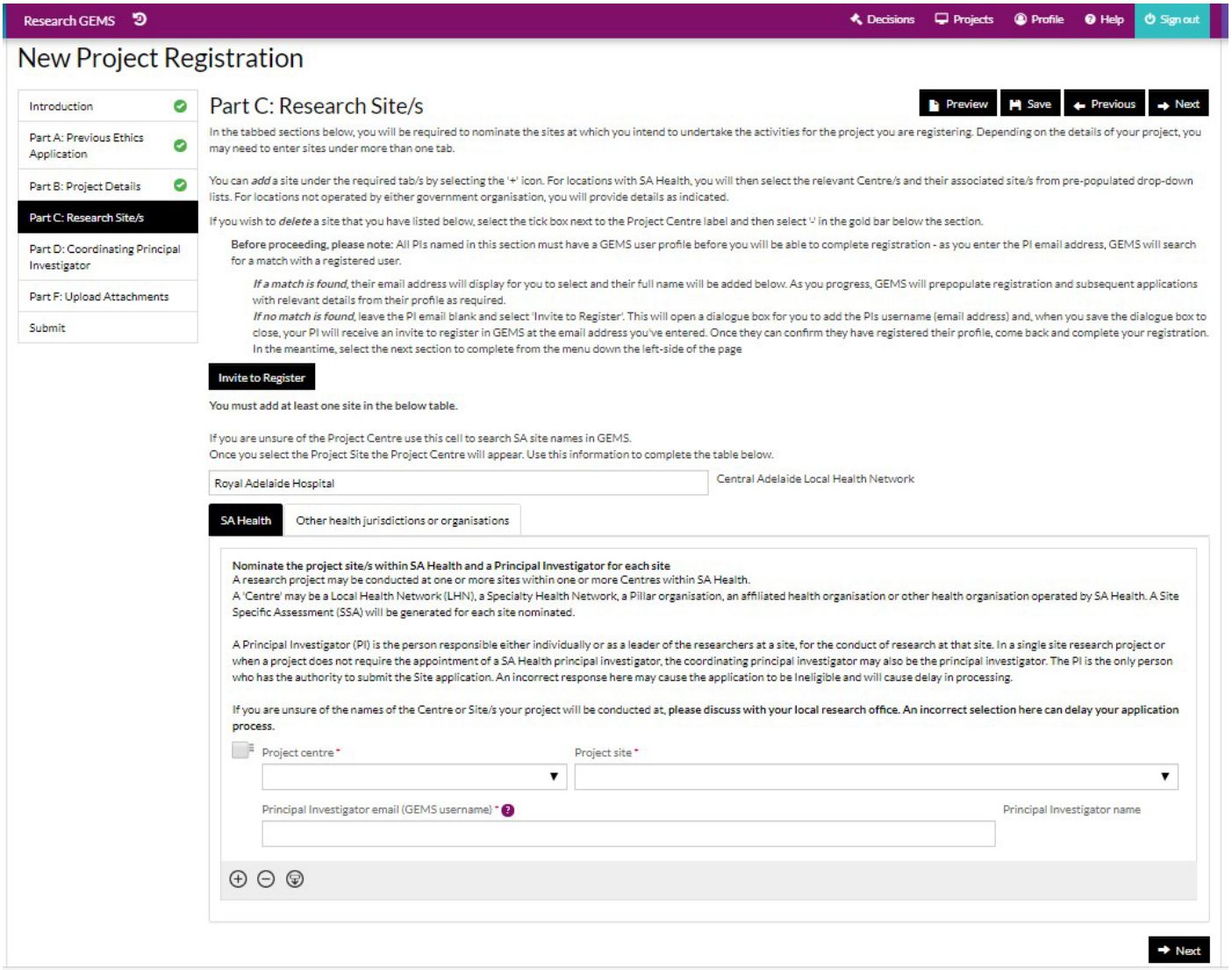
h. Part B: Project Details

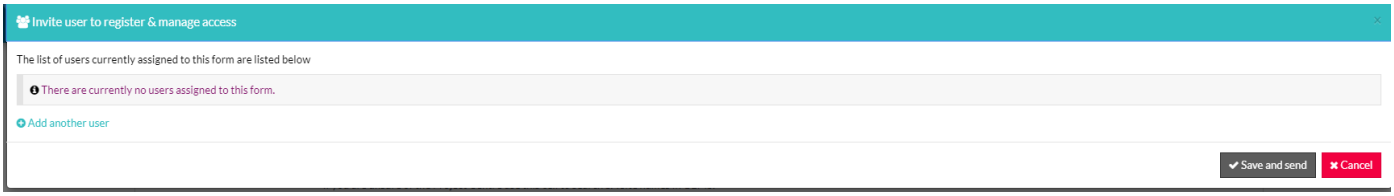
i. Fill in details related to your project > click next

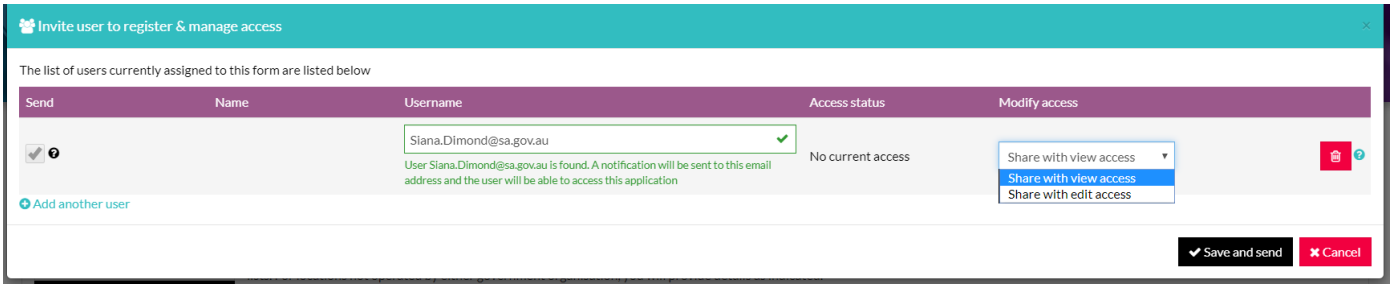
i. Part C: Research Site(s)

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

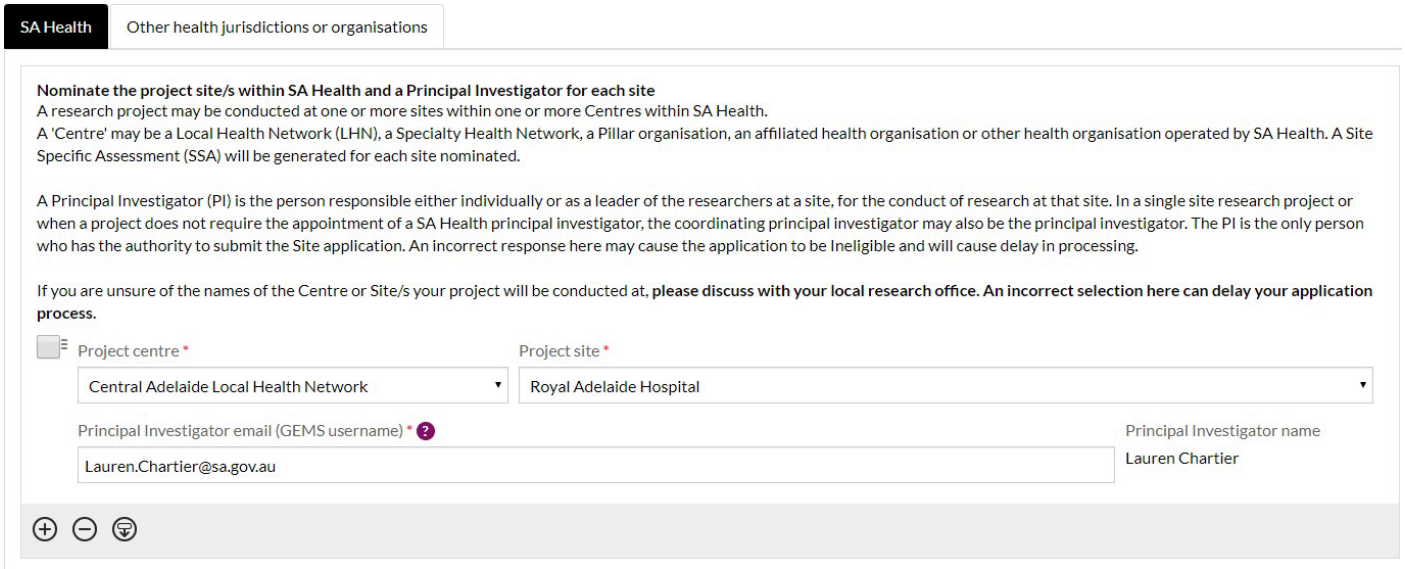






viii. Select the site you will be conducting the research at, when you begin to type the site should appear in the drop-down selector box. This will then pre-fill the local health network next to the site name,

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

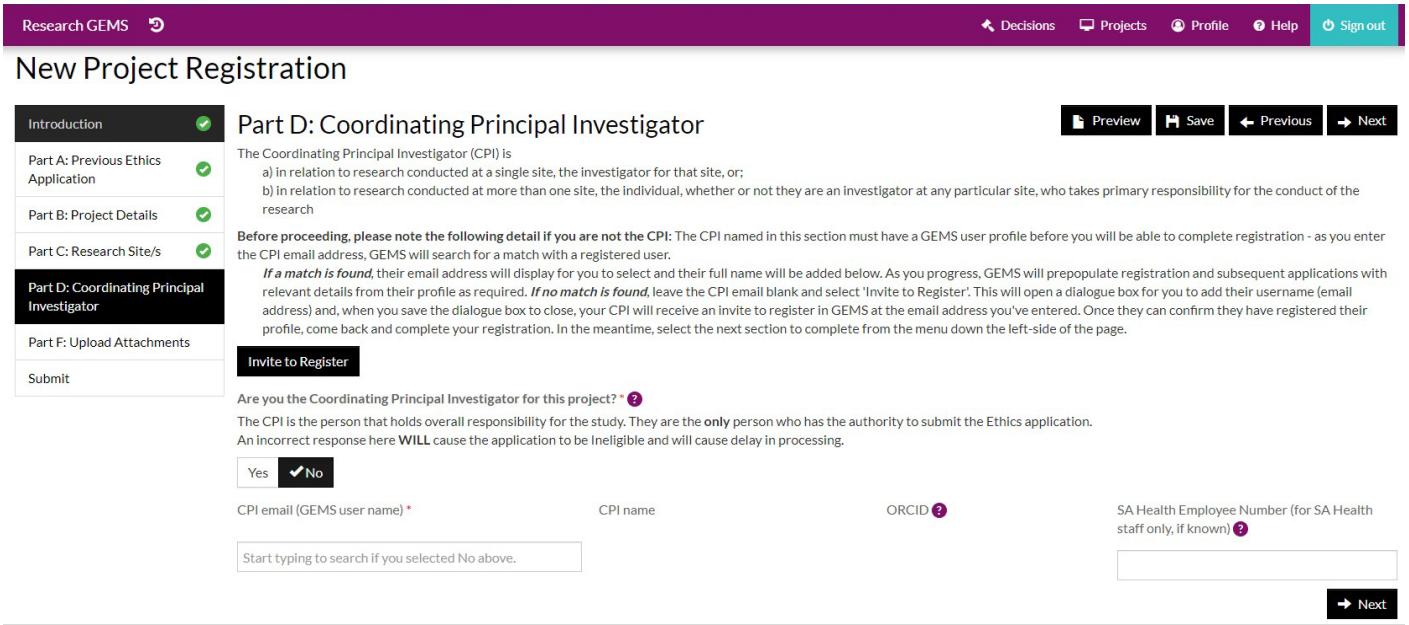
xi. You must always add your site and the PI in this section to be able to create any SSA's related to this application

xii. Then click next once you have finalised your sites and PI's

j. Part D – Coordinating Principal Investigator

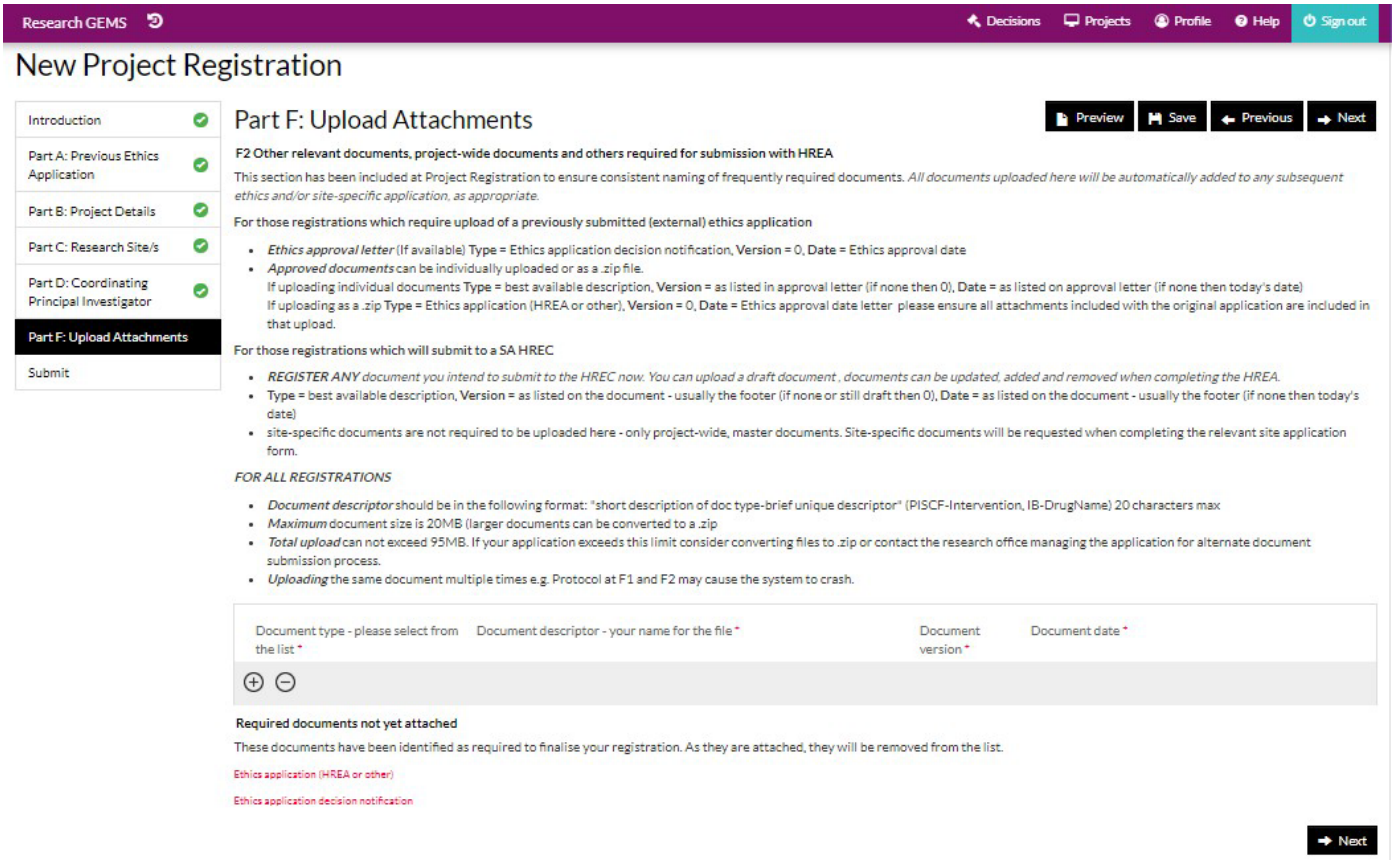
i. Click 'yes' if you are the CPI or 'no' if not the CPI

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
3. **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
iii. 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

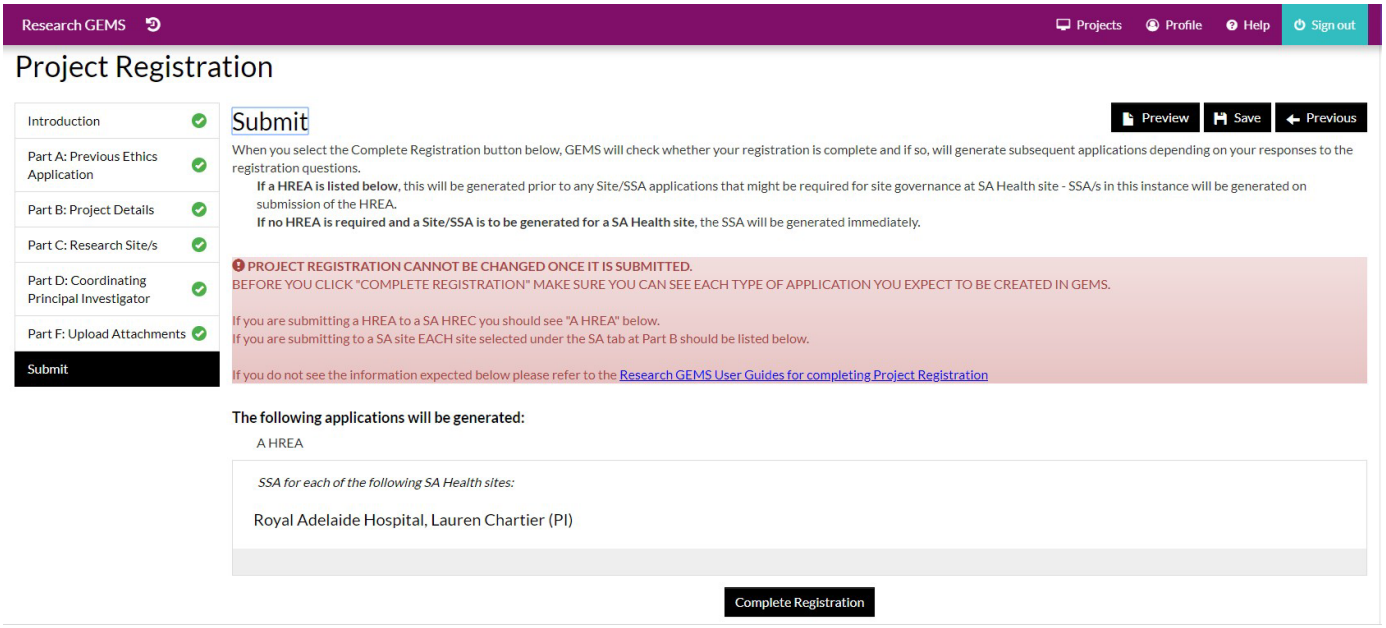


vi. Then upload the document by selecting “Select upload new” > Choose the file > Select the file > Open > Start Upload

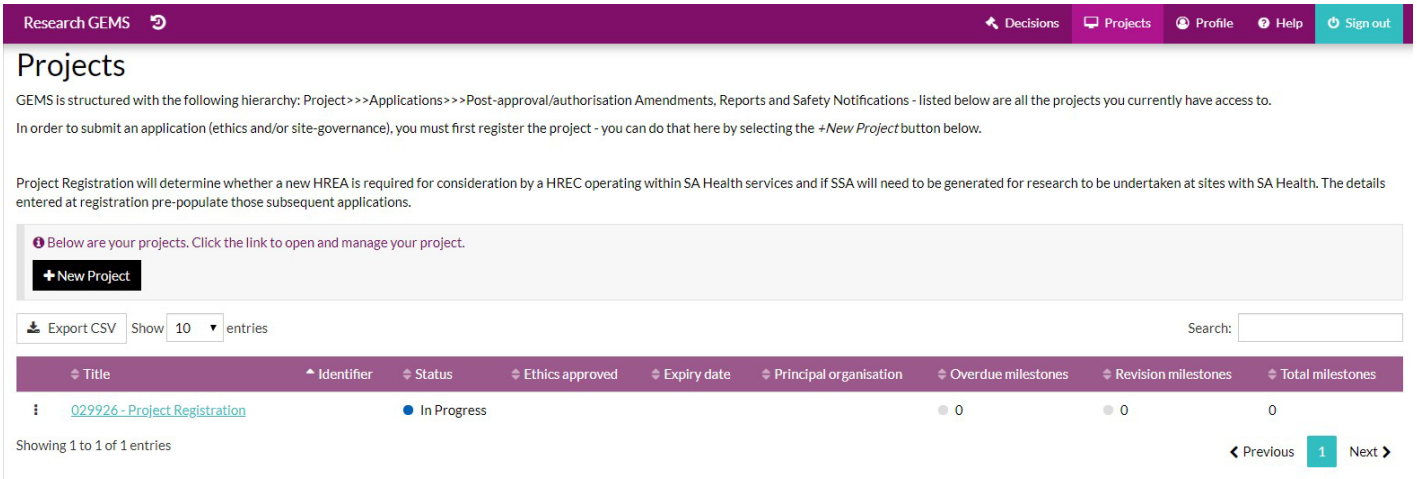
vii. Then click the (+) button to add upload additional documents via the same method

viii. Click ‘Next’ once all the documents have been uploaded

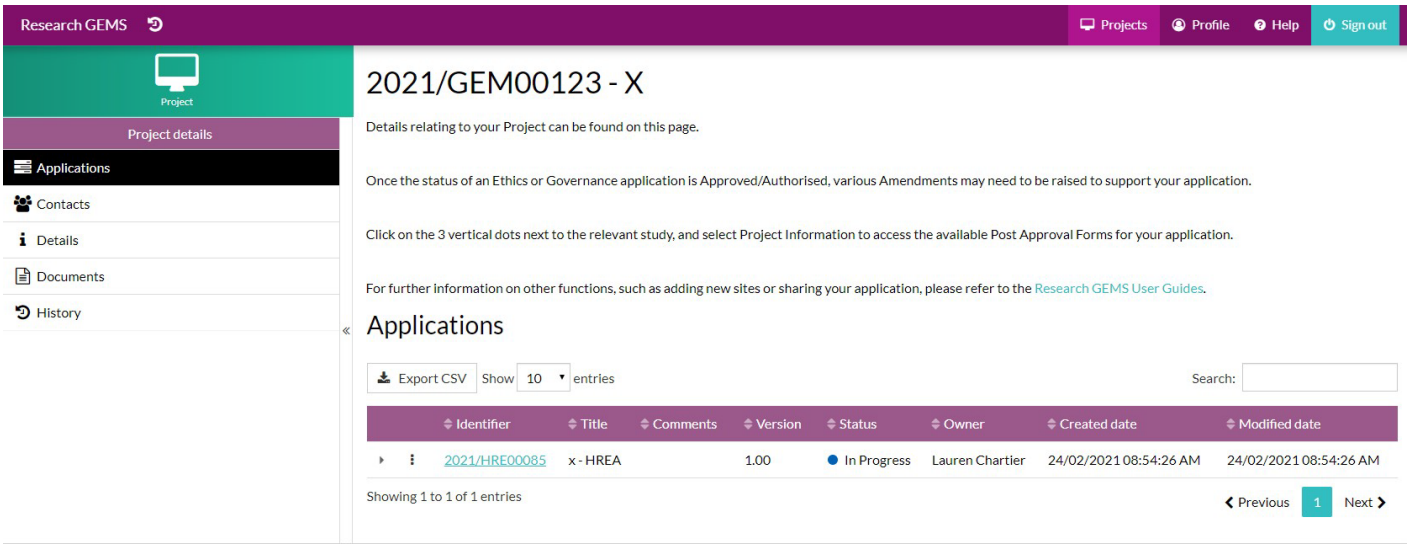
I. Submit



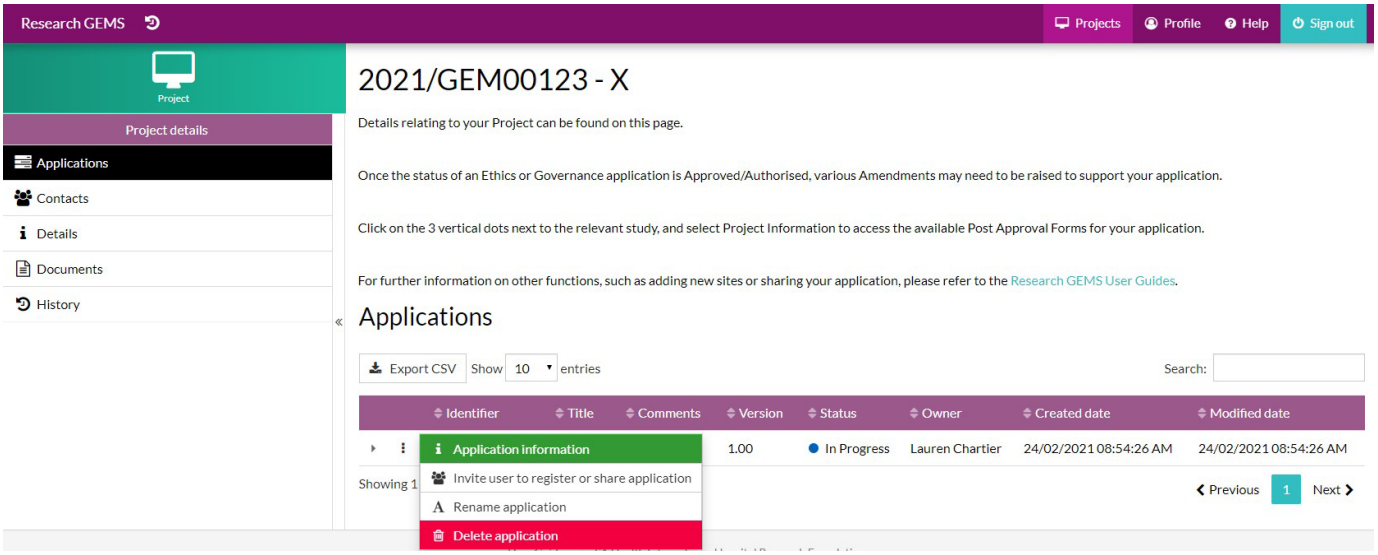
i. Please double check your project registration is correct before you submit it, as you **cannot** make edits to it once it has been submitted
ii. When satisfied the registration information entered is correct, click 'Complete Registration'
iii. Following submission, you will be returned to the Projects 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'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Documents
History
2021/GEM00123 - X
Details relating to your Project can be found on this page.
Once the status of an Ethics or Governance application is Approved/Authorised, various Amendments may need to be raised to support your application.
Click on the 3 vertical dots next to the relevant study, and select Project Information to access the available Post Approval Forms for your application.
For further information on other functions, such as adding new sites or sharing your application, please refer to the Research GEMS User Guides.
Applications
Export CSV
Show 10 entries
Search:
Identifier
Title
Comments
Version
Status
Owner
Created date
Modified date
Application information
Invite user to register or share application
Rename application
Delete application
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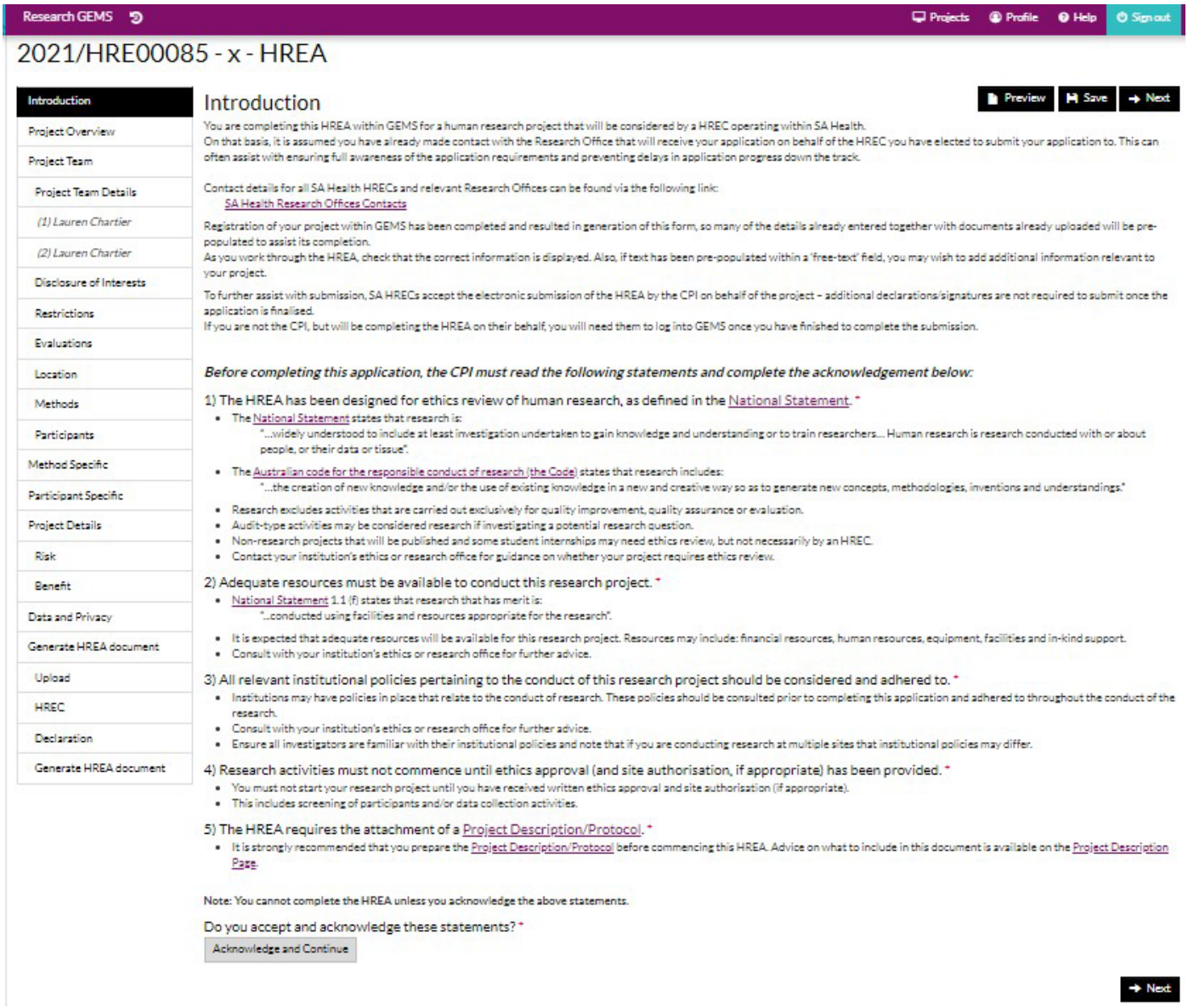
Showing 1
Previous
1
Next

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



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

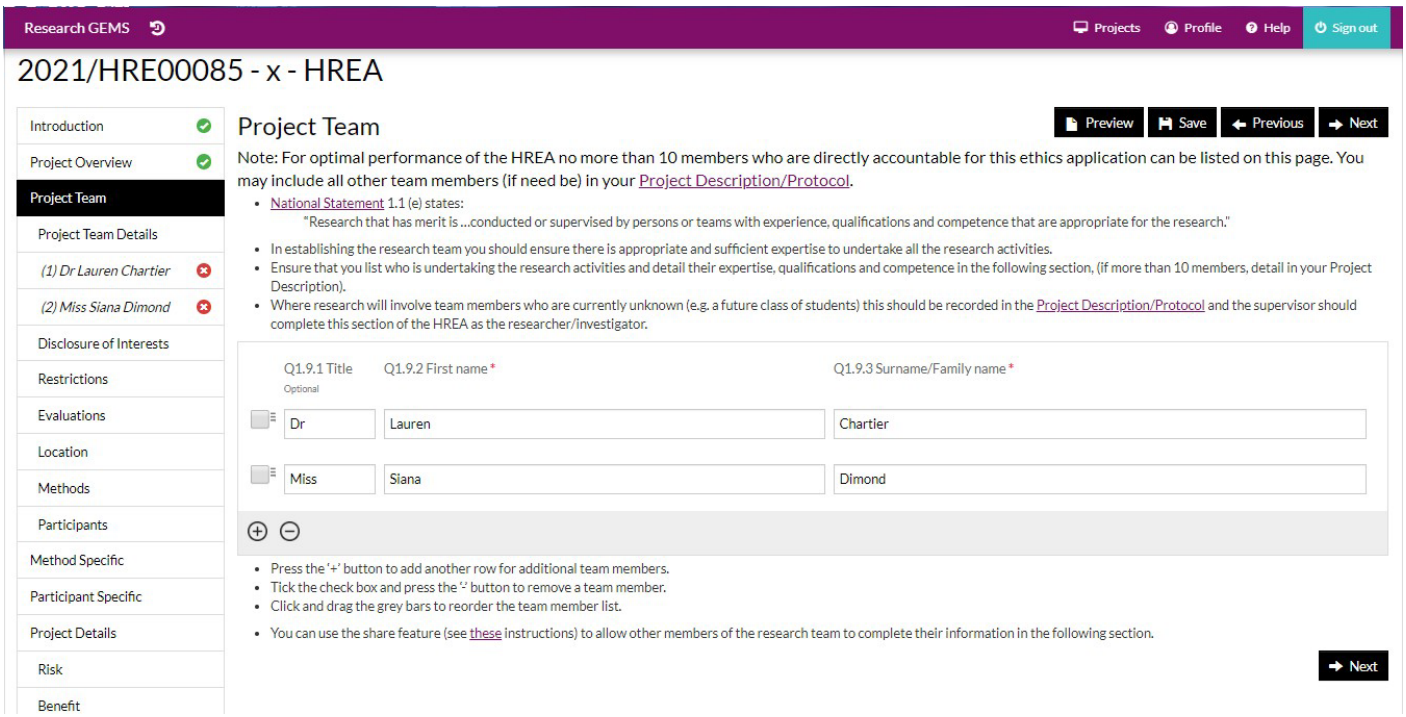
1. Project Overview

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

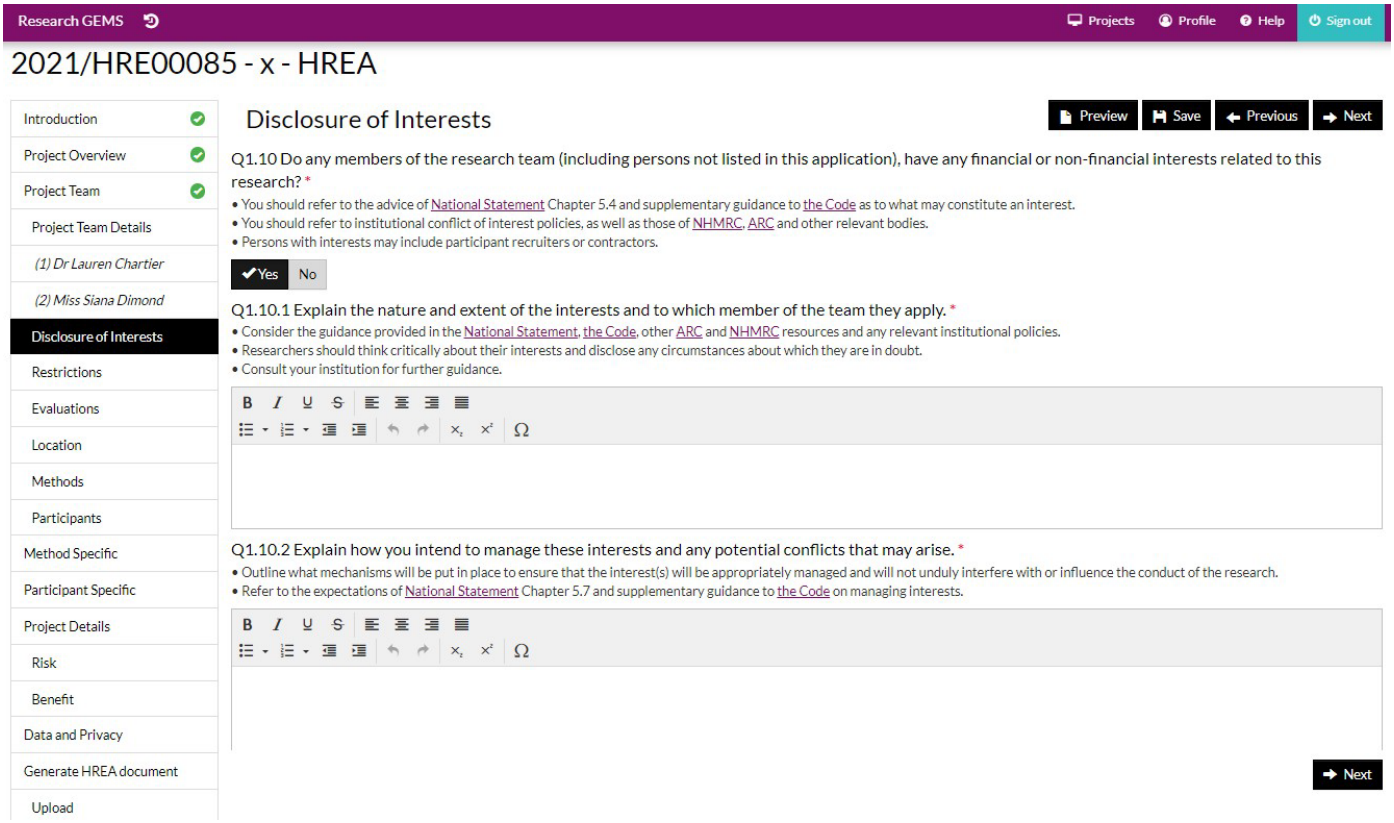
2. Project Team

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’



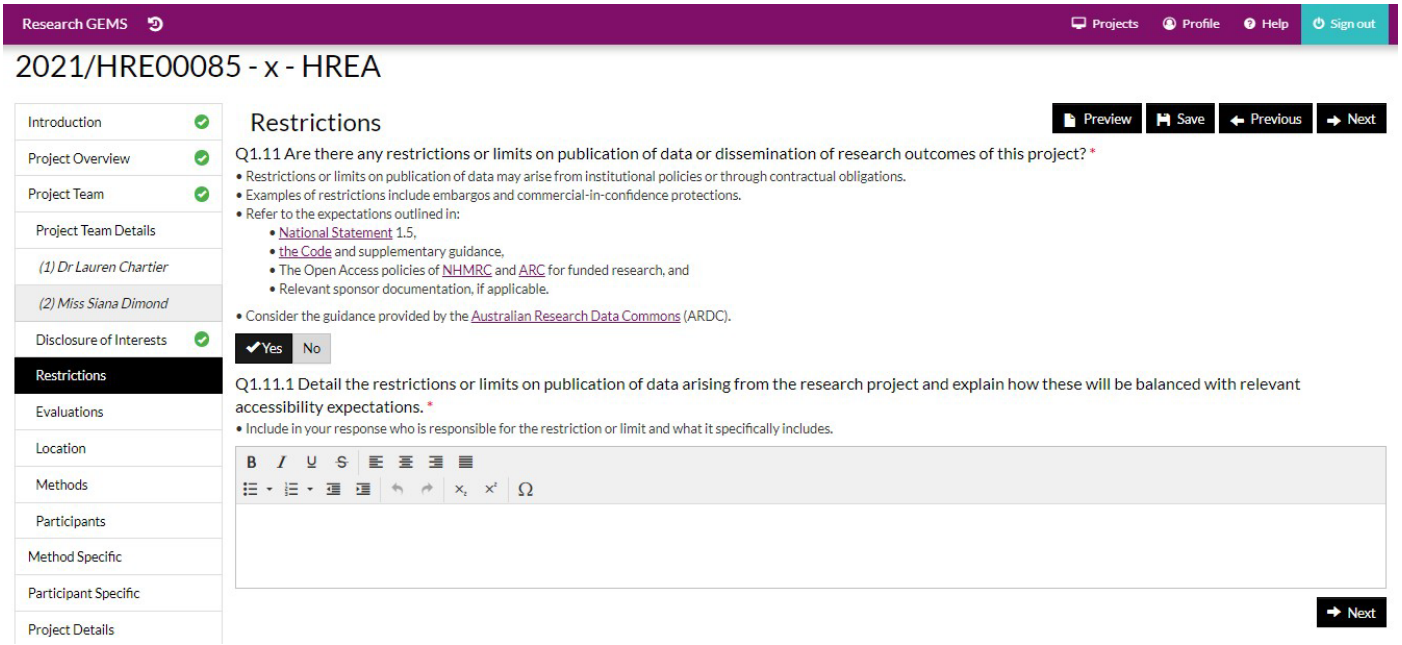
3. Disclosures of Interest

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



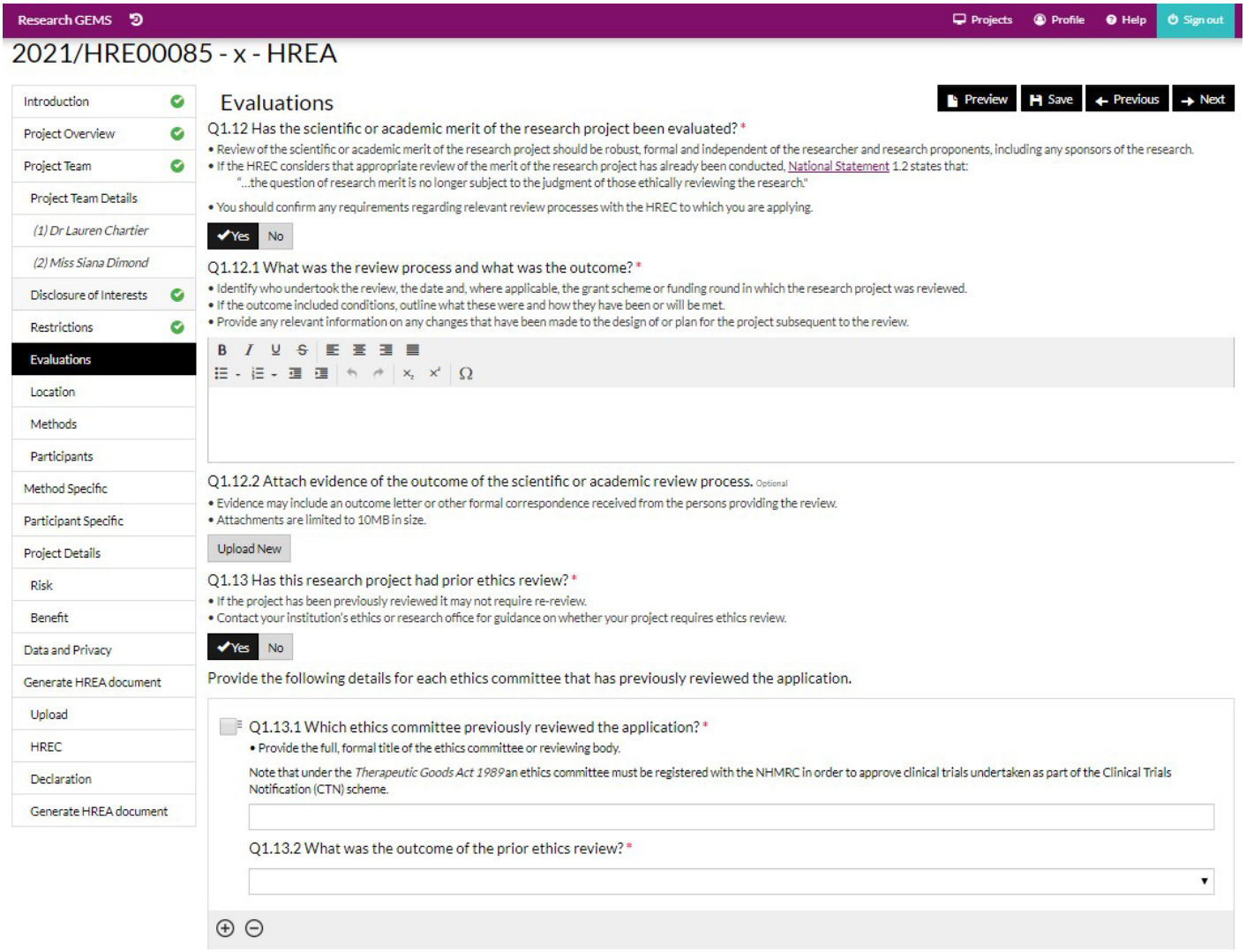
4. Restrictions

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

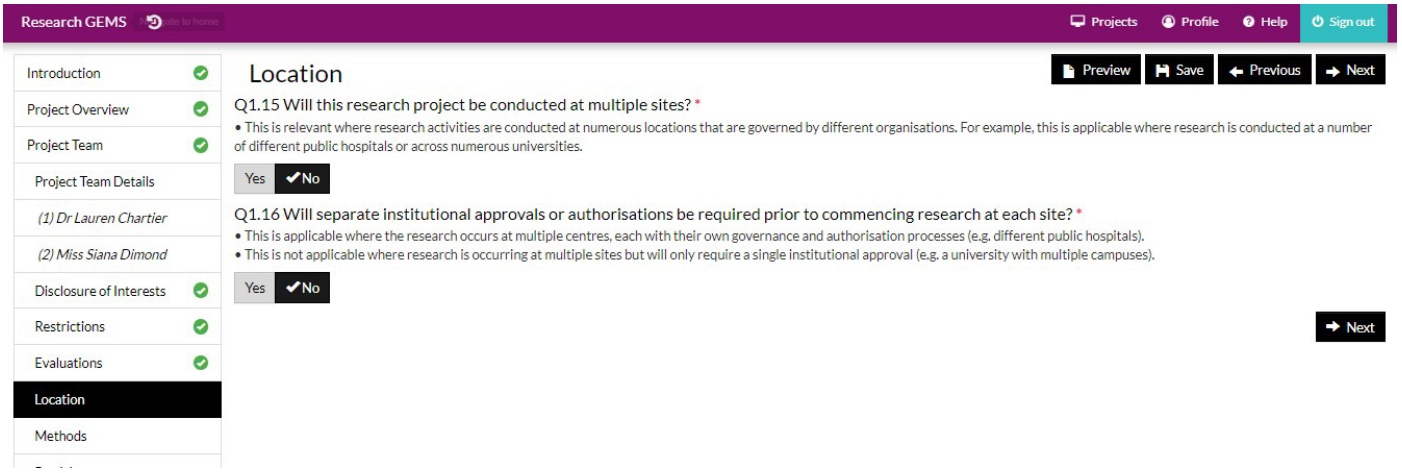
i. Select ‘No’ for Q1.12, Q1.13 and Q1.14 if there are no related evaluations or previous ethics review
ii. Q1.12 - selecting ‘Yes’ will prompt some additional questions related to the evaluations. You can also upload evidence or the outcome of this scientific evaluation, however, this is optional
iii. 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’



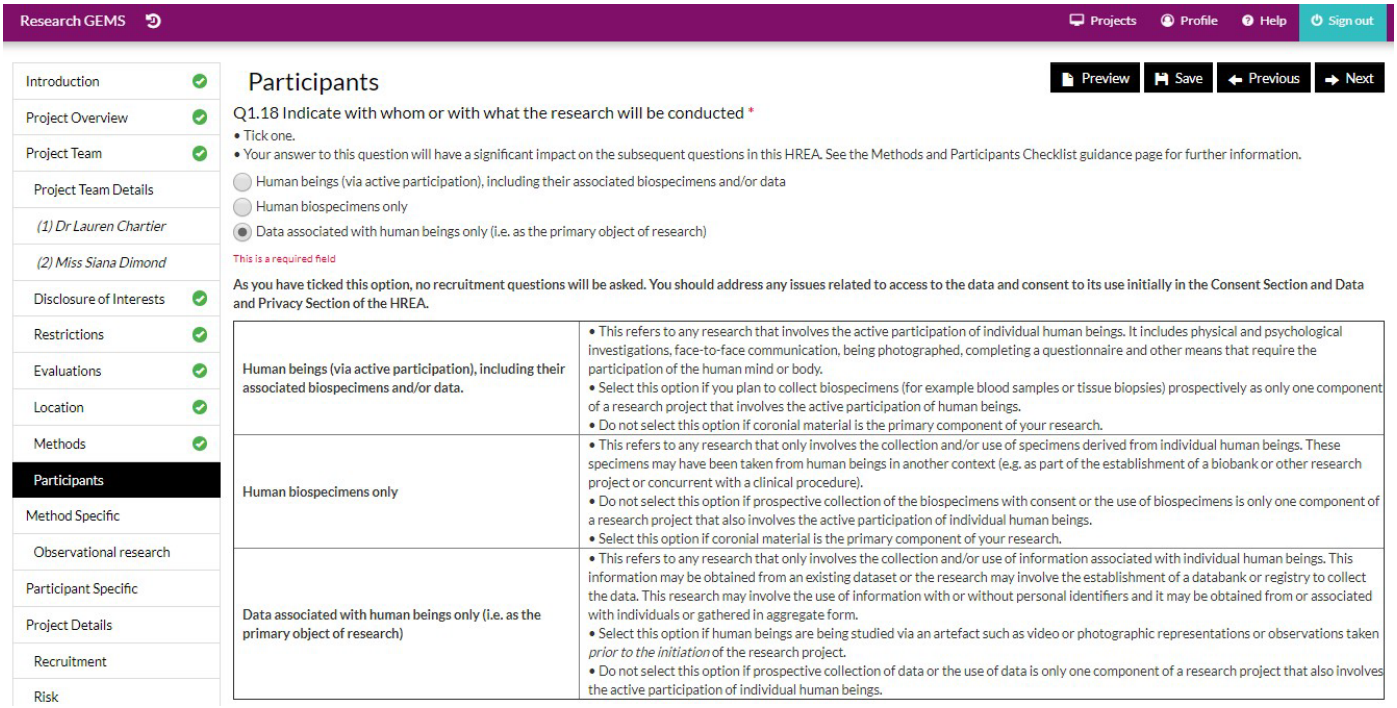
7. Methods

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

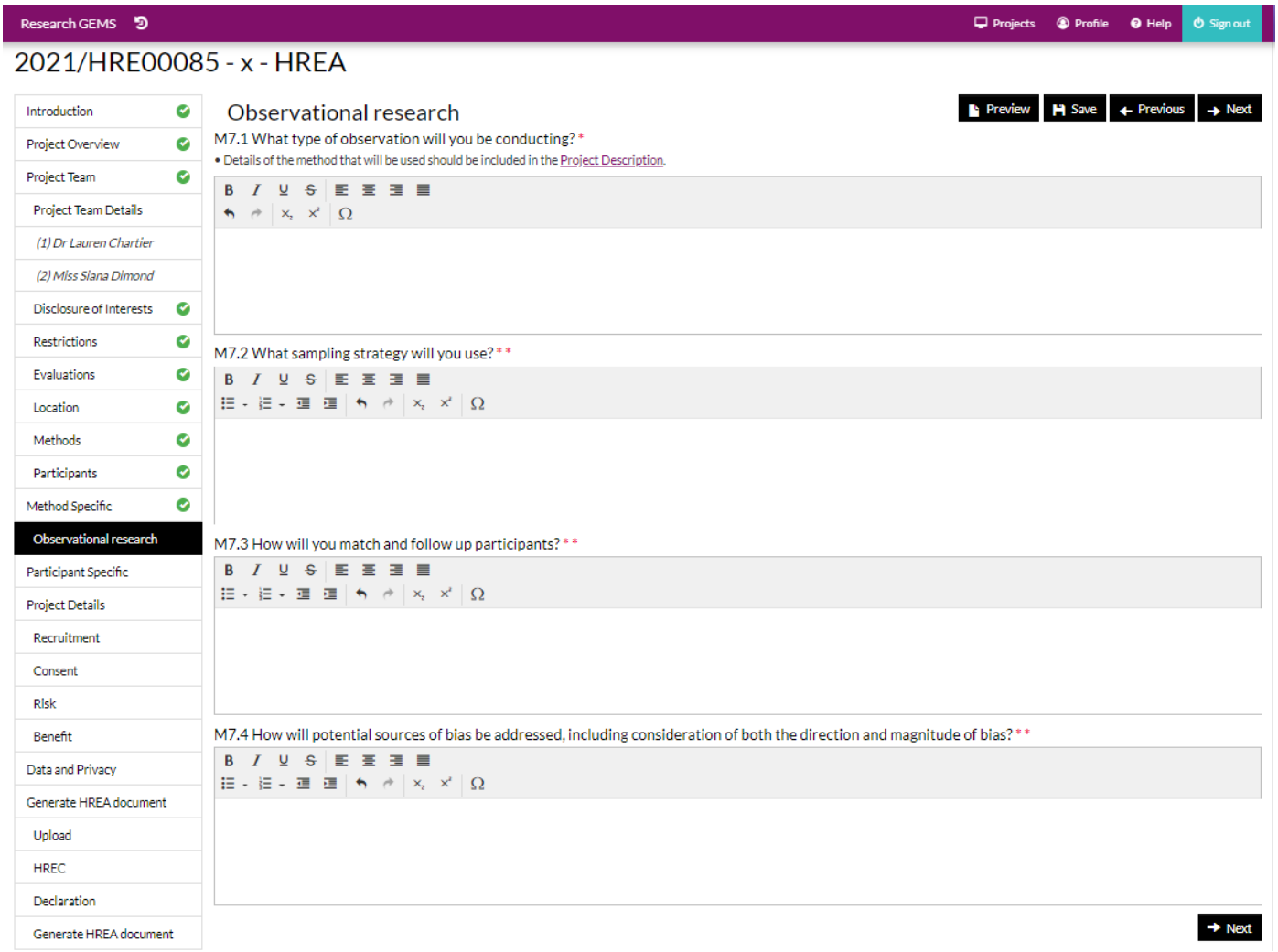


iii. Q1.18.1 – If all data collected is retrospective, select 'No'

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)

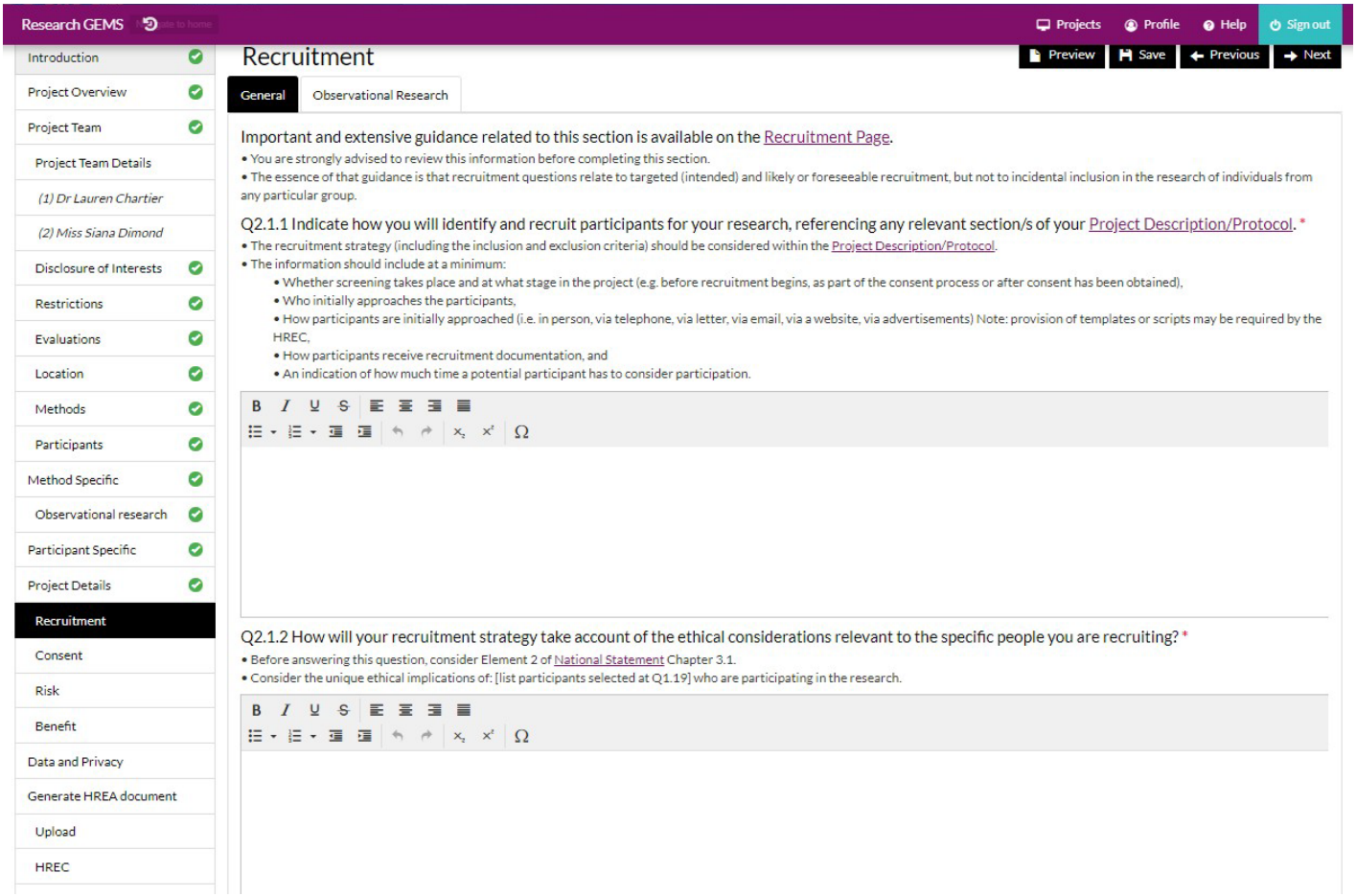


10. Participant Specific

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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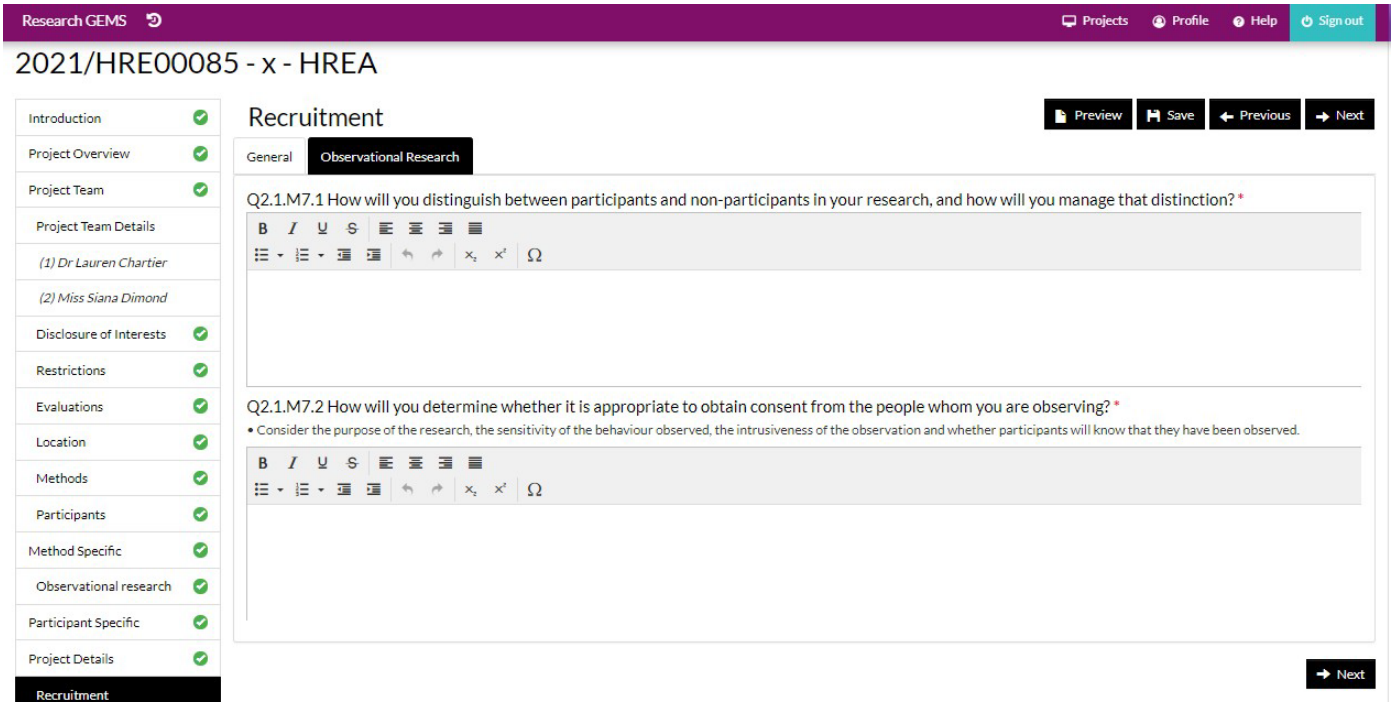
Upload
HREC
Recruitment
Preview
Save
Previous
Next
General
Observational Research
Important and extensive guidance related to this section is available on the Recruitment Page.
• You are strongly advised to review this information before completing this section.
• The essence of that guidance is that 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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Observational research
Participant Specific
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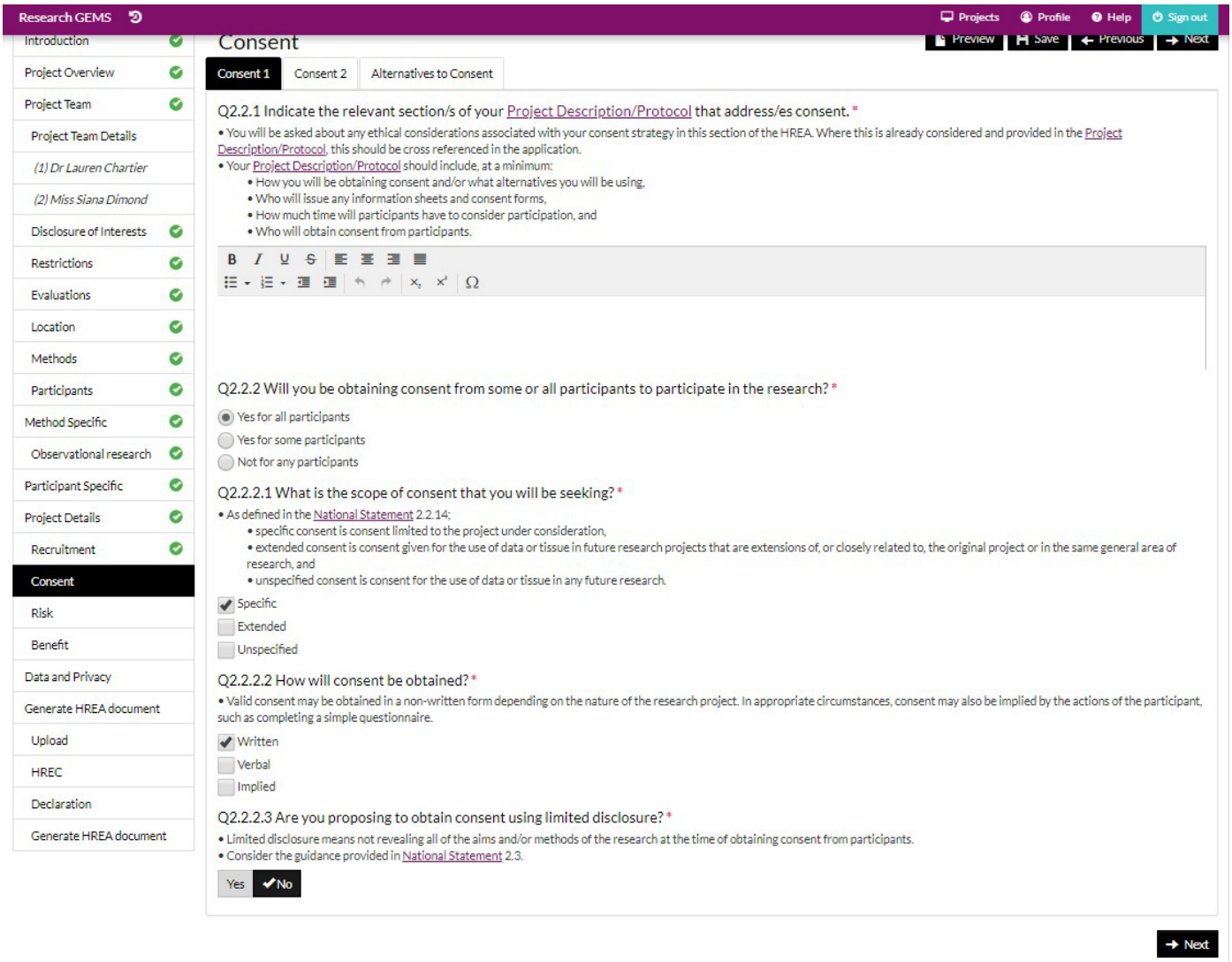
Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction? *
Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing? *
• Consider the purpose of the research, the sensitivity of the behaviour observed, the intrusiveness of the observation and whether participants will know that they have been observed.
Next

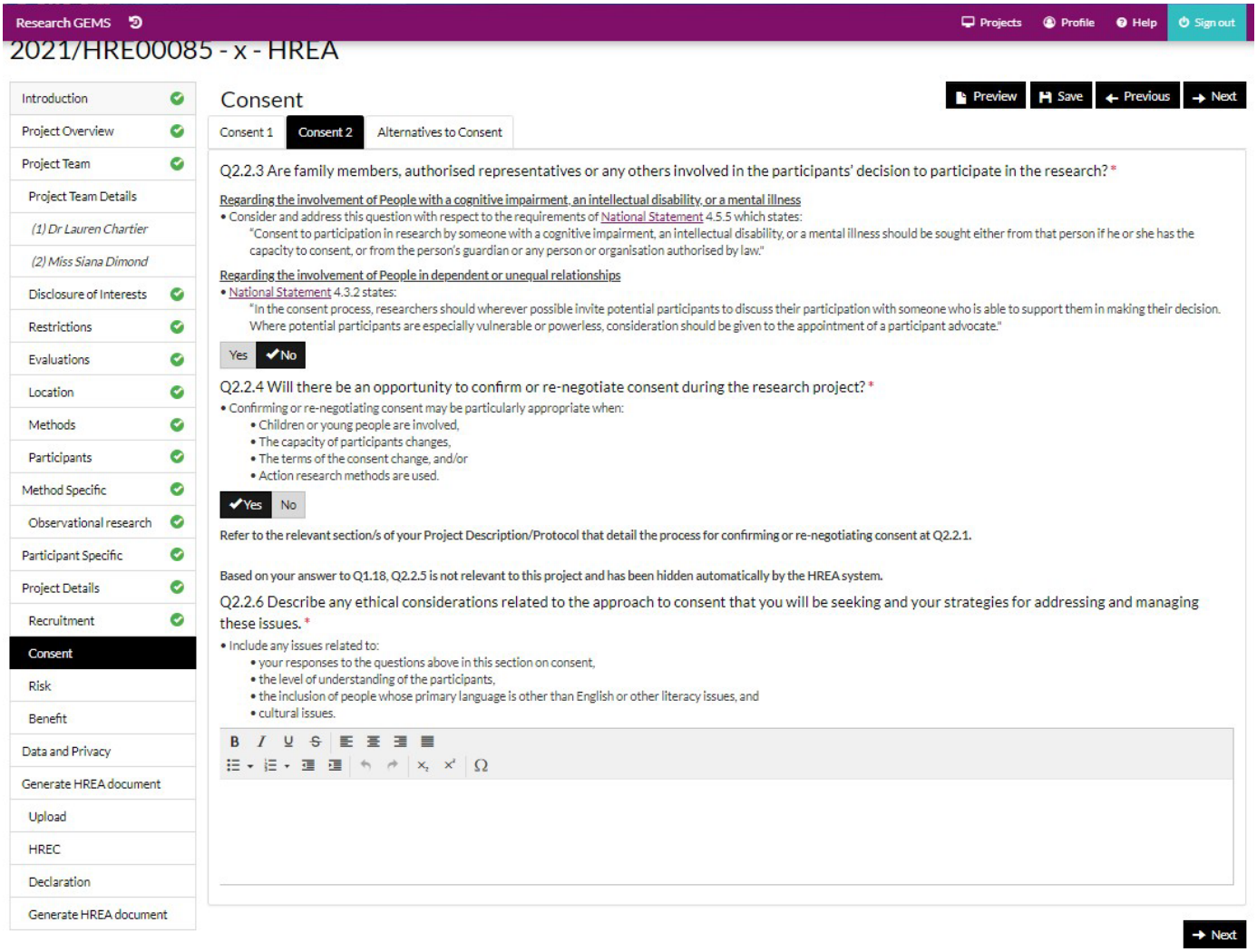
12. Consent

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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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
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Save
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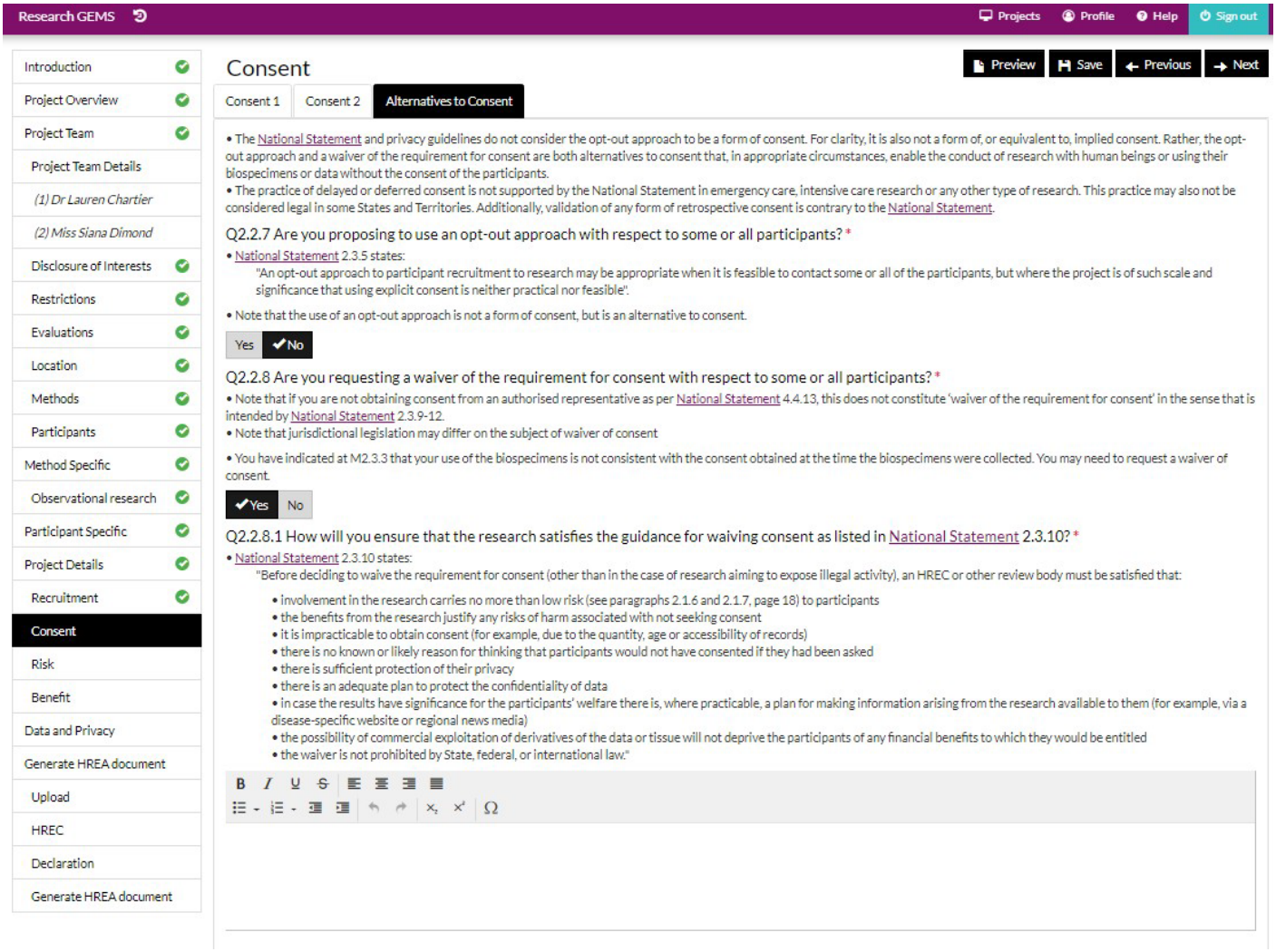
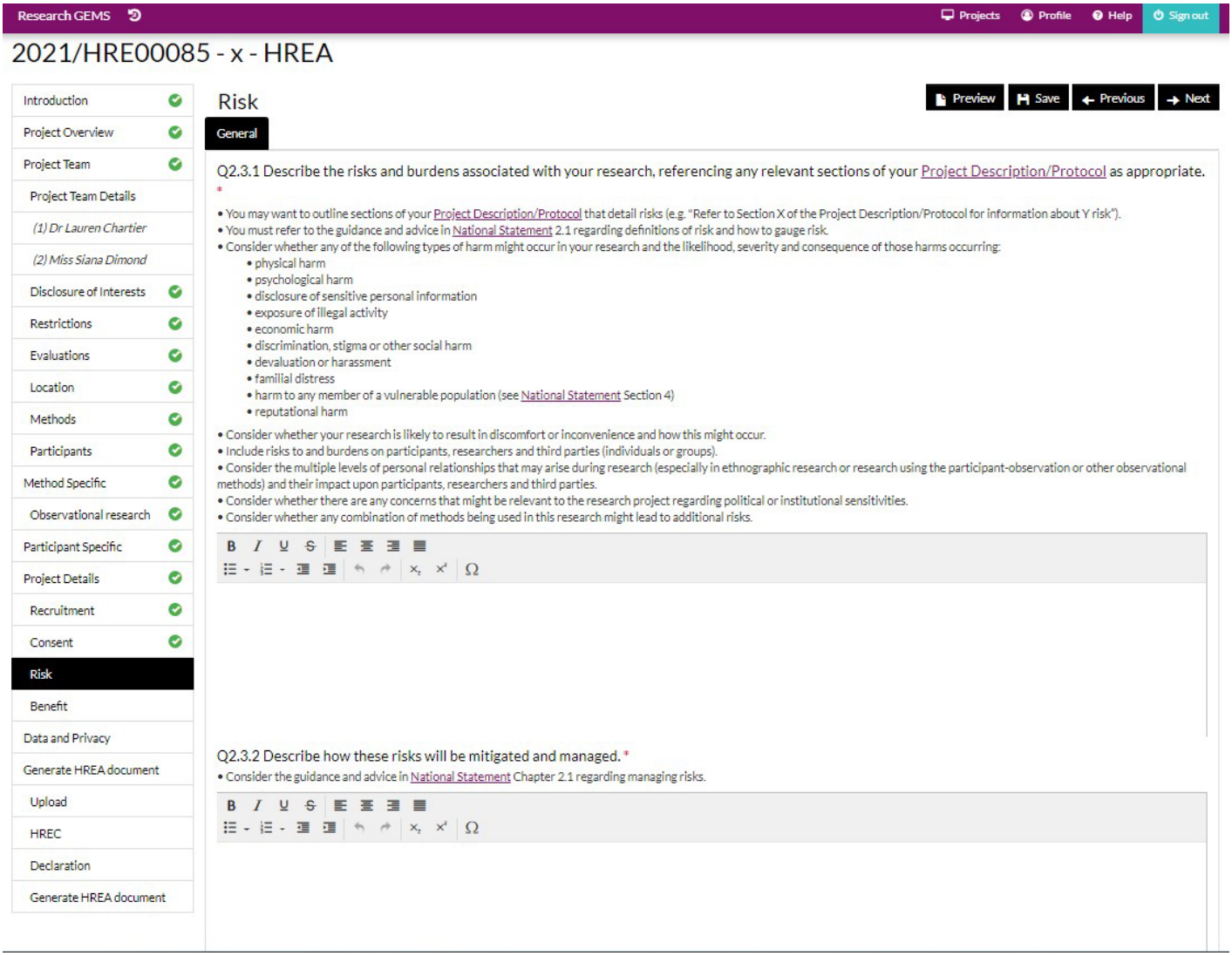
Consent 2
Alternatives to Consent
Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research? *
Regarding the involvement of People with a cognitive impairment, an intellectual disability, or a mental illness
• Consider and 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



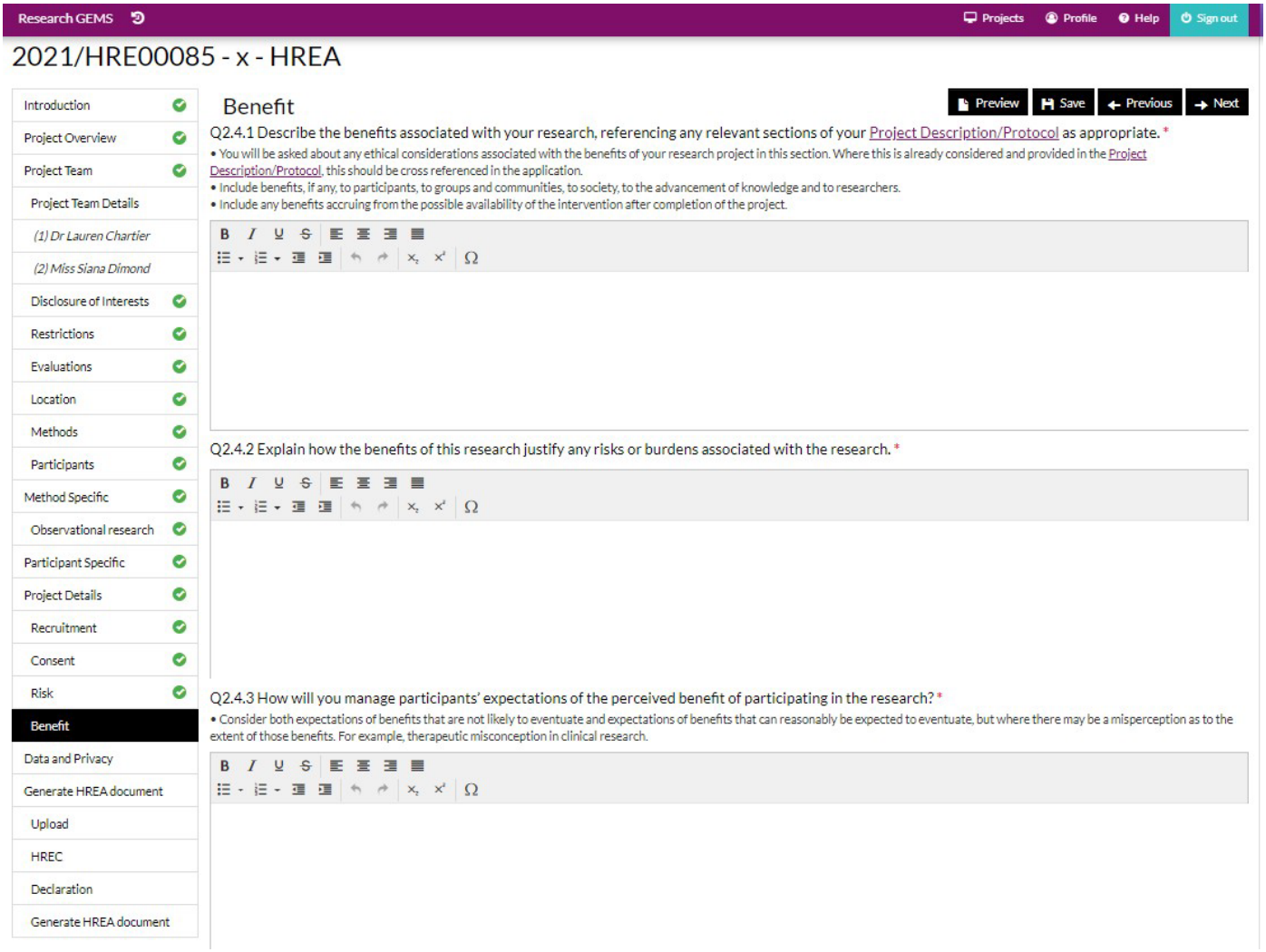
13. Risk

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



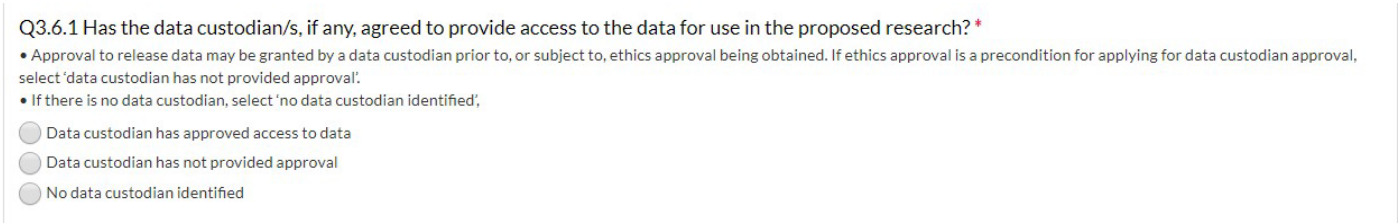
14. Benefit

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

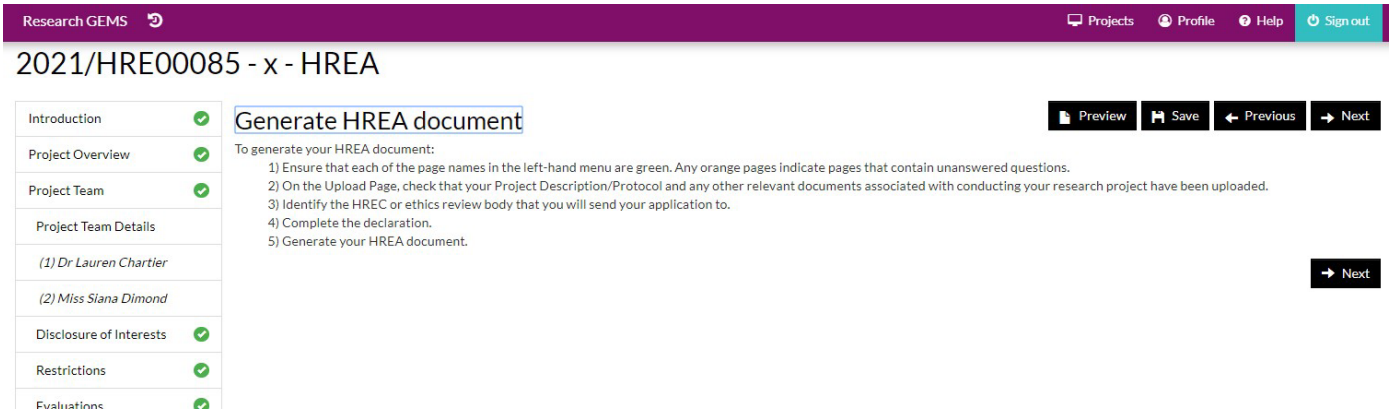
i. Data Characteristics - these questions are related to the type of data collected and used throughout the research project. i.e. Personal, health, identifiable, de-identifiable information
ii. Select all that apply
iii. Q3.6 – Selecting a database as a source of information will prompt Q3.6.1 relating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

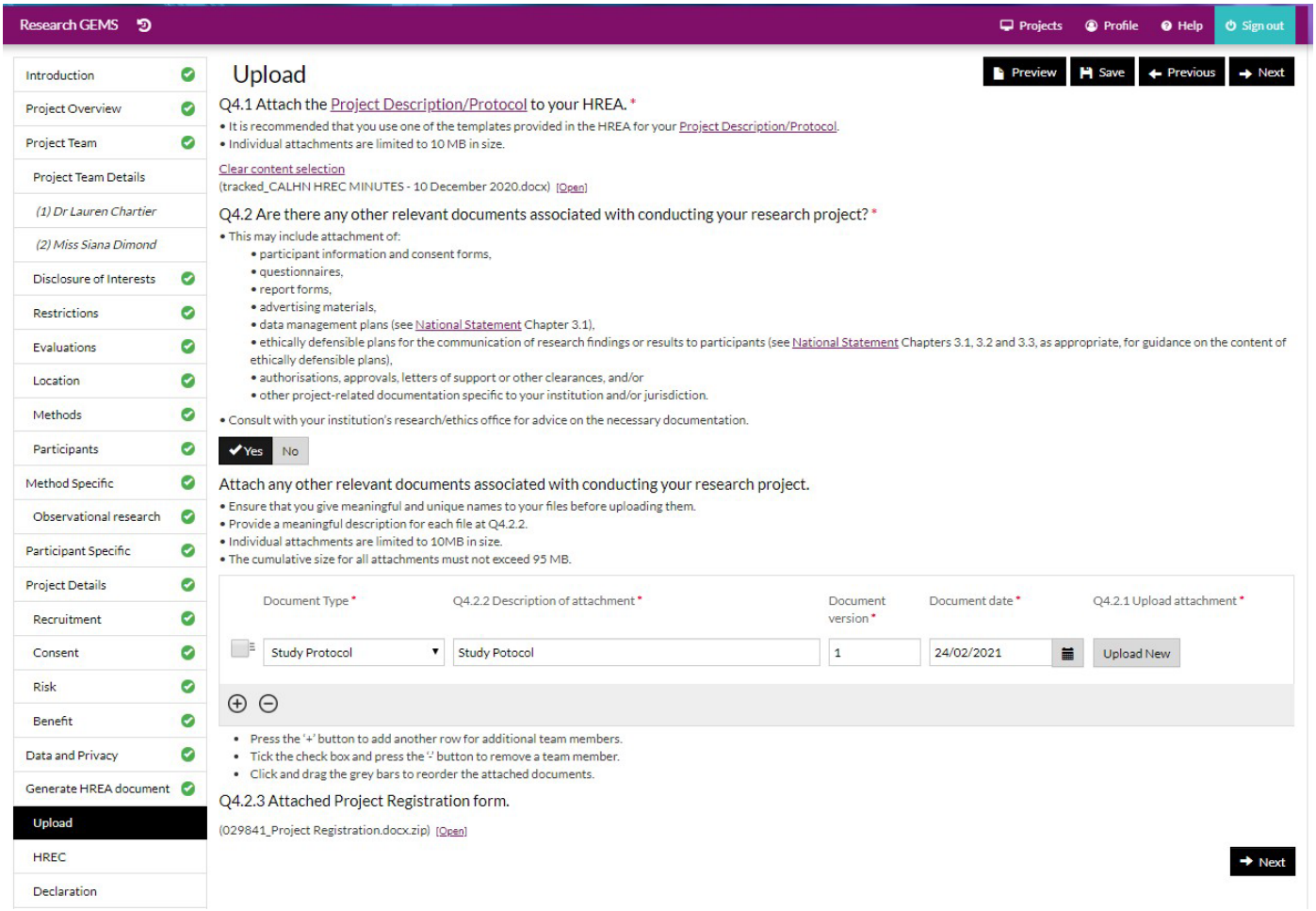
16. Generate HREA document

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'



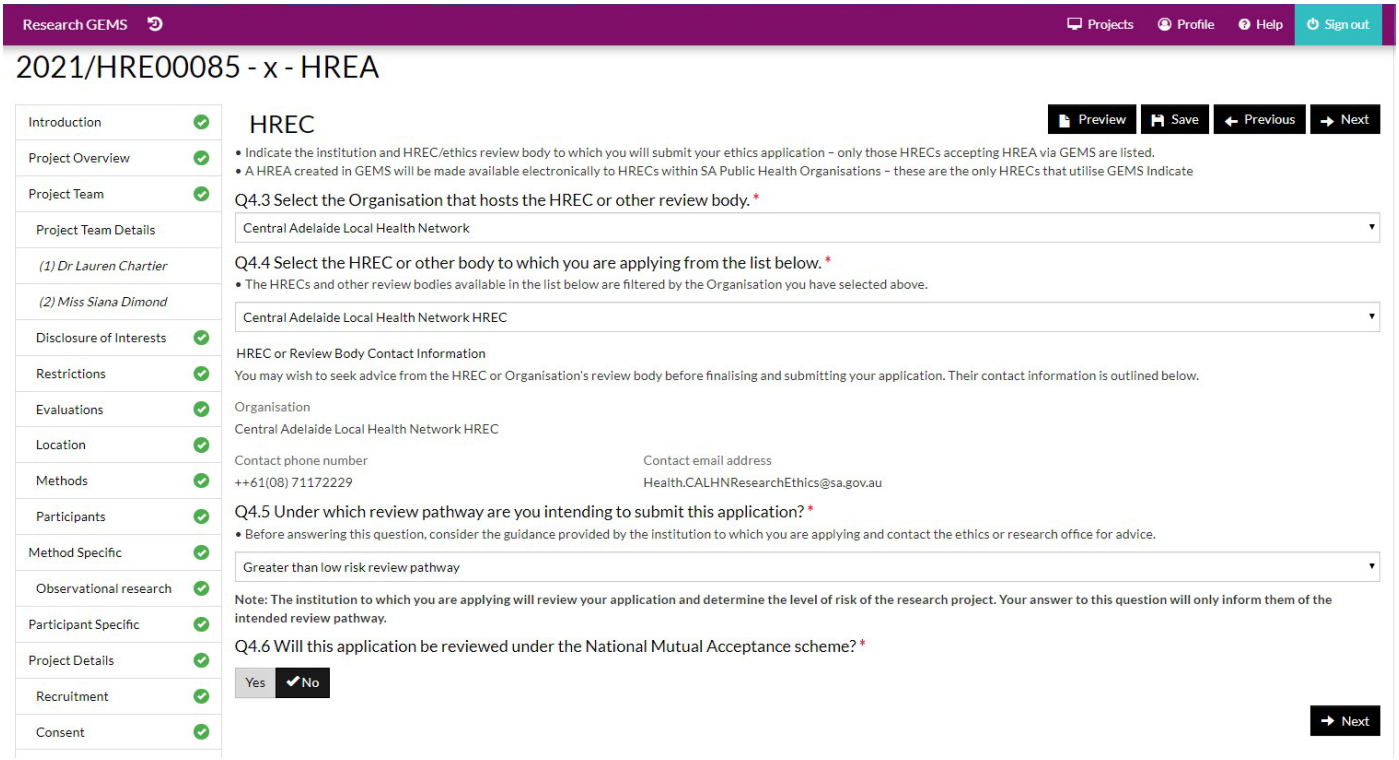
17. Upload

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>**



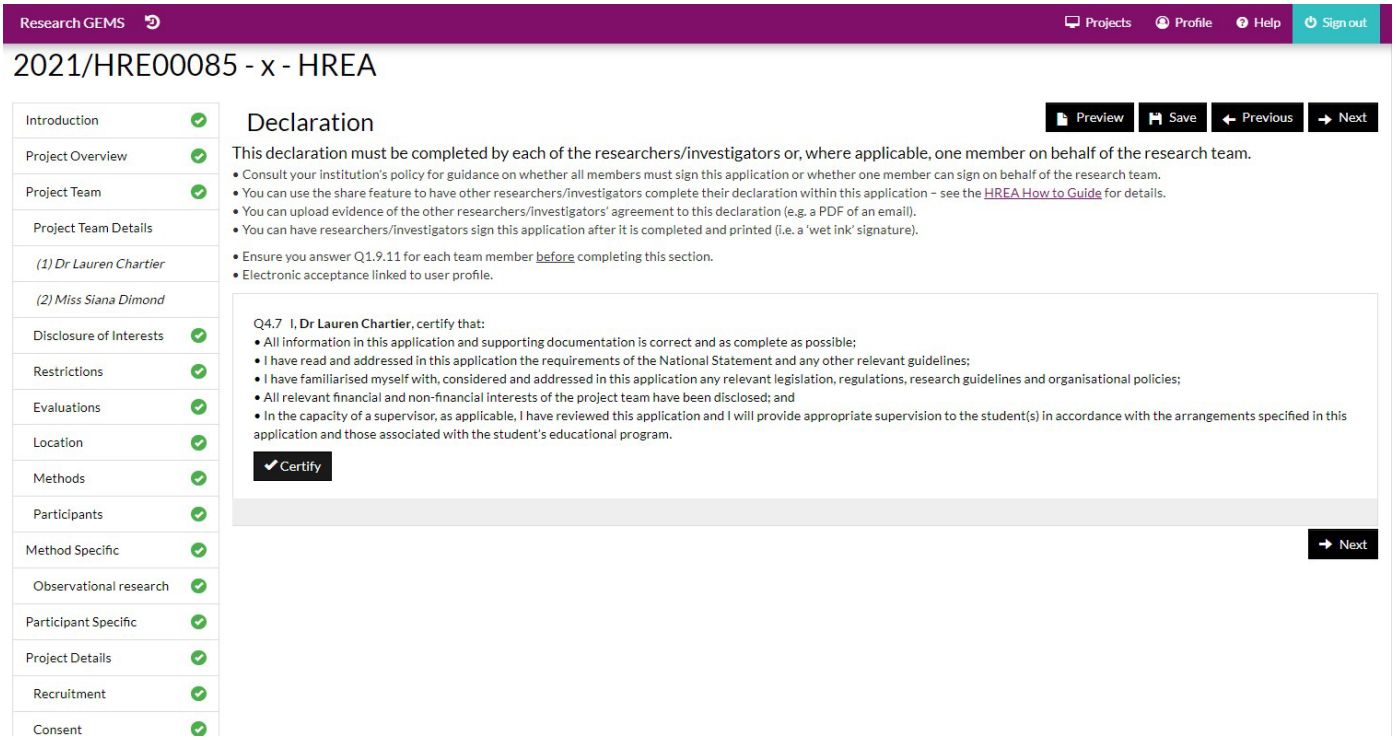
18. HREC

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

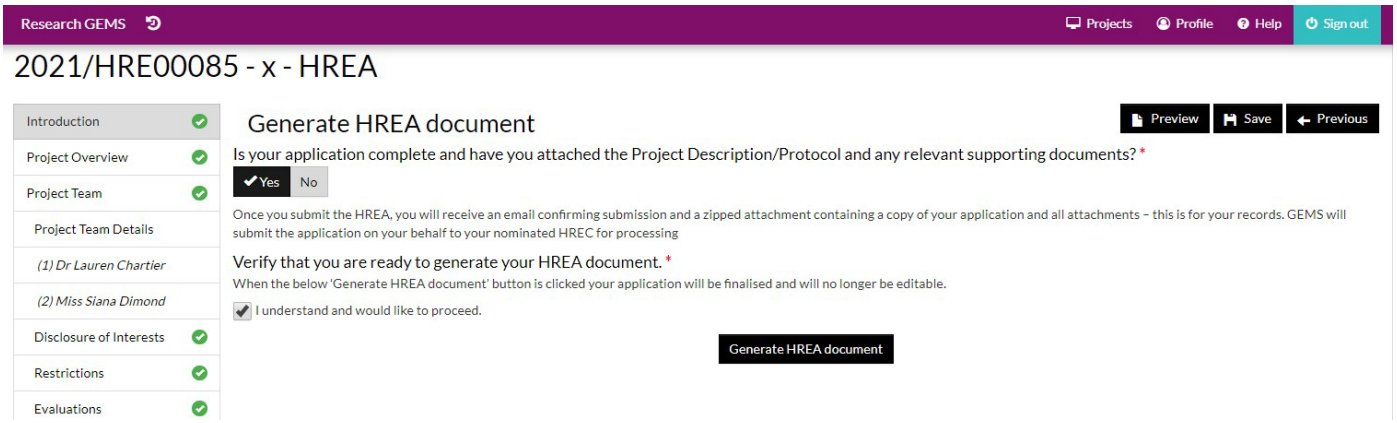
i. All study personnel will receive an email notification to complete this declaration page
ii. Select 'Certify'



20. Generate HREA document

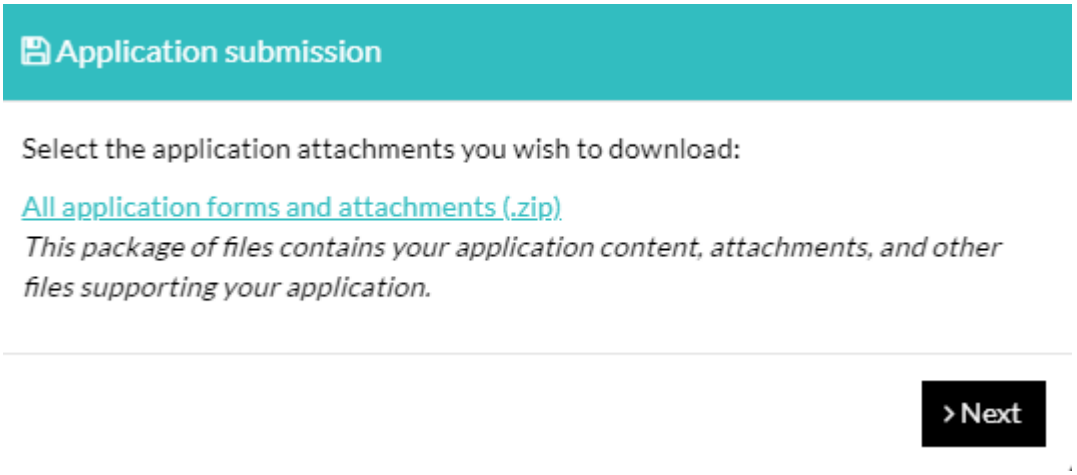
i. If all information is correct and attachments are uploaded, select 'Yes' and tick 'I understand and would like to proceed'

ii. Click 'Generate HREA document'

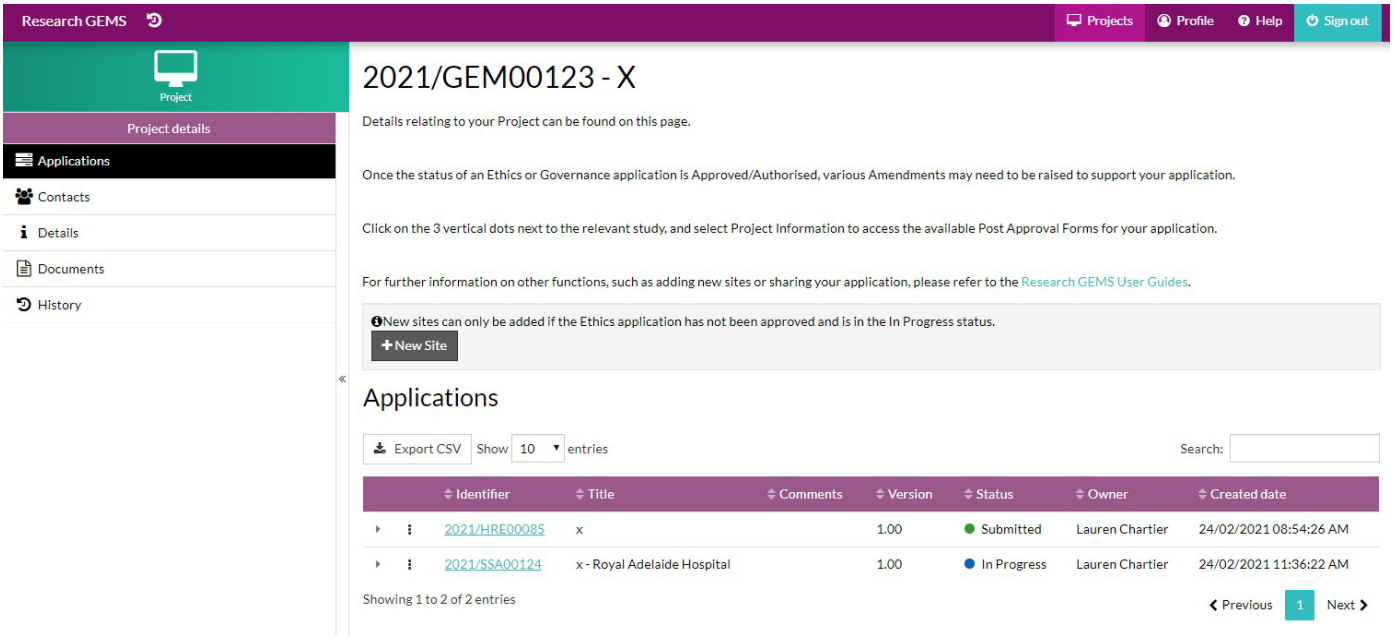


HREA Application is now submitted

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
5. For information and guidelines on how to complete an SSA, please refer to *Guideline: Submitting an SSA for Investigator Initiated Studies*.


Research GEMS
Projects
Profile
Help
Sign out
Project
Project details
Applications
Contacts
Details
Documents
History
2021/GEM00123 - X
Details relating to your Project can be found on this page.
Once the status of an Ethics or Governance application is Approved/Authorised, various Amendments may need to be raised to support your application.
Click on the 3 vertical dots next to the relevant study, and select Project Information to access the available Post Approval Forms for your application.
For further information on other functions, such as adding new sites or sharing your application, please refer to the Research GEMS User Guides.
New sites can only be added if the Ethics application has not been approved and is in the In Progress status.
+ New Site
Applications
Export CSV
Show 10 entries
Search:
Identifier
Title
Comments
Version
Status
Owner
Created date
2021/HRE00085
x
1.00
Submitted
Lauren Chartier
24/02/2021 08:54:26 AM
2021/SSA00124
x - Royal Adelaide Hospital
1.00
In Progress
Lauren Chartier
24/02/2021 11:36:22 AM
Showing 1 to 2 of 2 entries
Previous
1
Next

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 an 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 • 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: Health.CALHNResearchEthics@sa.gov.au or Health.CALHNResearchGovernance@sa.gov.au