

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.

Scope

This guideline will help to achieve the following:

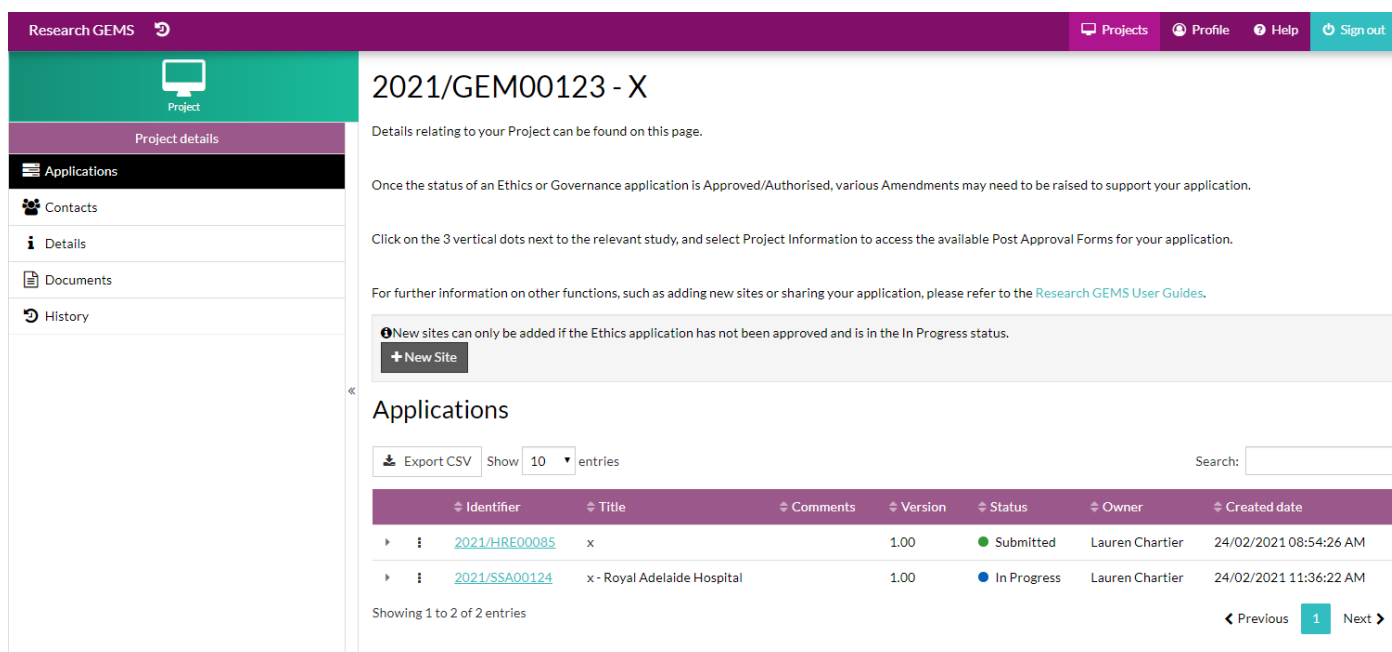
- Submit an external ethics SSA application
- Understand the process of applications from start to authorisation

Definitions & Acronyms

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

Site Specific Assessment

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



The screenshot shows the Research GEMS application interface. The top navigation bar includes 'Research GEMS', 'Projects', 'Profile', 'Help', and 'Sign out'. The main content area is titled '2021/GEM00123 - X' and contains instructions for users. Below the instructions is a 'New Site' button. The 'Applications' section features an 'Export CSV' button, a 'Show 10 entries' dropdown, and a search box. A table lists two applications:

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

- 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

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Submitting an SSA for Investigator Initiated Studies



- 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) at each site
- 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) by clicking the '+'
- 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/ Allied Health/ Nursing Lead first. Which Lead you select will depend on whether your study is Clinical, Allied Health or Nursing.
You do not need to add all three.
 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
- 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, and upload into Research GEMS with the SSA** as supporting documentation
 4. Then fill in section C4&5
- iv. Add any Supporting Departments the same way as the Head of Department

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Part B: Site Team

Site project team members details
(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services

Part D: Recruitment, Records, Tissue and Data

Part E: Site Costing and Funding

Part F: Attachments – Site Specific Documents

Part G: Declaration

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

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

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

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

C1. Department *

No department head can be found for the selected department.

C2. Department Head Name

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

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

Lead

v. Naming conventions can be seen here:

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Part B: Site Team

Site project team members details
(1) Jan-Louise Durand, Associate Investigator

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

C1. Department *

RAH: Acute and Urgent Care: Geriatrics

Glenside: Mental Health: Inpatient Mental Health

Hampstead: Neuroscience & Rehabilitation: General Rehabilitation

Hampstead: Neuroscience & Rehabilitation: SA Brain Injury Rehabilitation Service

Hampstead: Neuroscience & Rehabilitation: SA Spinal Cord Injury Services

RAH: Mental Health: Allied Health

RAH: Acute & Urgent Care: Allied Health

RAH: Acute & Urgent Care: Medical

RAH: Acute & Urgent Care: Nursing

RAH: Acute and Urgent Care: Acute Assessment Unit(s)

RAH: Acute and Urgent Care: Burns Service

RAH: Acute and Urgent Care: Emergency Department

RAH: Acute and Urgent Care: General Medicine

RAH: Acute and Urgent Care: Geriatrics

RAH: Acute and Urgent Care: Patient Flow & RAH/TQEH Afterhours

RAH: Acute and Urgent Care: Trauma Service

RAH: Cancer: Adolescents & Young Adults

RAH: Cancer: Allied Health

RAH: Cancer: Haematology

RAH: Cancer: Medical

User Guides SA Health Internet Hospital Research Foundation

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

- Answer questions 'Yes' or 'No' from D1 to D11
- Selecting 'Yes' will prompt some further questions to be populated

F. Part E – Site Costing and Funding

- Fill in sections E1 to E2 with appropriate details regarding costing/funding details for the project

2021/SSA00124 - x - Royal Adelaide Hospital

Part A: Project-Wide Information	✓
Part B: Site Team	✓
Site project team members details	(1) Lauren Chartier, Associate Investigator
Part C: Departments and Services	✓
Part D: Recruitment, Records, Tissue and Data	✓
Part E: Site Costing and Funding	
Part F: Attachments – Site Specific Documents	
Part G: Declaration	

Part E: Site Costing and Funding

For complex projects such as Clinical Trials, a detailed project costing using a template may be required by the site in order to ensure that the costs of carrying out research are fully covered, and/or that the costs are transparent so that the financial implications can be assessed based on sound information.

Please contact your local research office to discuss - they may have a standard budget template to be used.

If any supporting department (e.g. Pharmacy or Pathology) has generated its own detailed budget (more detailed than the information included in any contract/agreement) that has been acknowledged and agreed to, please upload at Part F.

E1. Are there any financial costs to the site associated with the project? *
 Yes No

E1.1. What is the total estimated cost for this site in SAUD *

E1.2. Do you have a local study costings template or detailed site budget prepared? *
 Yes No

E1.3. Will funding be provided to the site for this research? *
 Yes No

E2. Are there any non-financial costs (e.g. local resource allocations) associated with the project? *
 Yes No

Site Funding

Type of funding *	Funder name *	Amount of funding for the site (\$) *	Confirmed? *	Estimated in-kind support (\$) *	Confirmed? *
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No

G. Part F – Attachments/Site Specific Documents

- i. The HREA document will be automatically attached to this section
- ii. As HREA and Protocol documents were previously uploaded to the project registration you do not need to upload them again at this stage
- iii. Upload any site-specific Participant Information Sheet and Consent Forms (if the study was reviewed/approved by an external HREC), CV's of all team members, budget and any other relevant documentation
- iv. Check that the documents did come across from the project registration as it should appear as below
- v. Then click 'Next'

2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

Part A: Project-Wide Information	✓
Part B: Site Team	✓
Site project team members details	(1) Jan-Louise Durand, Associate Investigator
Part C: Departments and Services	✓
Part D: Recruitment, Records, Tissue and Data	✓
Part E: Site Costing and Funding	✓
Part F: Attachments – Site Specific Documents	
Part G: Declaration	

Part F: Attachments – Site Specific Documents

Document Title: Hrea-1-10-FEB-2021

Document type: Ethics application (HREA or other) [Clear content selection \(GEMS steps.docx\) \[Open\]](#)

Document type *	Document descriptor *	Document version *	Document date *
Ethics application decision notif	Approval Letter	1	10/02/2021

[Clear content selection \(Research GEMS.docx\) \[Open\]](#)

Maximum file size is 20.00 MB

Next

H. Part G – Declaration

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Submitting an SSA for Investigator Initiated Studies

- i. As the PI must 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 and 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)

Research GEMS [Decisions](#) [Projects](#) [Profile](#) [Help](#) [Sign out](#)

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Part A: Project-Wide Information ✔

Part B: Site Team ✔

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services ✔

Part D: Recruitment, Records, Tissue and Data ✔

Part E: Site Costing and Funding ✔

Part F: Attachments – Site Specific Documents ✔

Part G: Declaration

Part G: Declaration

G1 Declaration by the Principal Investigator responsible for the site

By clicking the button below I confirm that:

1. the information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site;
2. all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any emergencies and contingencies related to the research that may arise;
3. I will ensure all team members receive any additional relevant training as required;
4. I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Office and, that this will not be before evidence is received by them (provided by me) of ethics approval by an appropriate Human Research Ethics Committee (HREC);
5. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the Responsible Conduct of Research (as amended) and, where applicable, Note for Guidance on Good Clinical Practice.
6. If authorised to undertake this project at Royal Adelaide Hospital (this site),
 - a. I will inform the Research Office if the research project ceases before the expected date;
 - b. I will discontinue the research at this site if the HREC withdraws ethical approval;
 - c. I will adhere to the conditions of authorisation stipulated by the authorising authority at this site including any monitoring/reporting requirements;
 - d. I will discontinue the research at this site if the authorising authority withdraws authorisation;
7. I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit and monitoring purposes, AND
8. I understand that information relating to this research, and about me as an investigator, will be held within SA Health information systems and other local data collections. This information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cwth) and relevant laws in the States and Territories of Australia.

Name of Principal Investigator
Siana Dimond
Siana.Dimond@sa.gov.au

[Preview](#) [Save](#) [Previous](#)

- ii. Once you click save, a pop-up box will appear which states the below:

Application saved
✕

Your progress on 2021/SSA00063 has been saved. Saved applications will be listed on the 'Applications' page.

✕ Close

- 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

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Projects

GEMS is structured with the following hierarchy: Project>>>Applications>>>Post-approval/authorisation Amendments, Reports and Safety Notifications - listed below are all the projects you currently have access to.

In order to submit an application (ethics and/or site-governance), you must first register the project - you can do that here by selecting the *+New Project* button below.

Project Registration will determine whether a new HREA is required for consideration by a HREC operating within SA Health services and if SSA will need to be generated for research to be undertaken at sites with SA Health. The details entered at registration pre-populate those subsequent applications.

Below are your projects. Click the link to open and manage your project.

[+ New Project](#)

Export CSV Show 10 entries Search:

Title	Identifier	Status	Ethics approved	Expiry date	Principal organisation	Overdue milestones	Revision milestones	Total milestones
Evaluation of Research Office	2021/GEM00076	Registered	10 Feb 2021	10 Feb 2026	SA Health	0	0	0

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Submitting an SSA for Investigator Initiated Studies



- iv. Once PI has logged in, they need click on the 'Title' (Project that is applicable for the submission)
- v. Then click SSA application that you are the PI for (your/their site)
- vi. Click the blue Identifier title of your application – this will only let you choose your own site to submit. You will not be able to submit other PI's SSA's
- vii. This will then take the PI directly to Section G – Declaration, where the PI needs to select 'Complete SSA'

Research GEMS

2021/SSA00063 - Evaluation of Research Office - Royal Adelaide Hospital

Part A: Project-Wide Information ✓

Part B: Site Team ✓

Site project team members details

(1) Jan-Louise Durand, Associate Investigator

Part C: Departments and Services ✓

Part D: Recruitment, Records, Tissue and Data ✓

Part E: Site Costing and Funding ✓

Part F: Attachments – Site Specific Documents ✓

Part G: Declaration

Part G: Declaration

G1 Declaration by the Principal Investigator responsible for the site

By clicking the button below I confirm that:

1. the information provided is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site;
2. all members of the research team at this site have the appropriate qualifications, training, experience and facilities to conduct the research as set out in this application and to deal with any emergencies and contingencies related to the research that may arise;
3. I will ensure all team members receive any additional relevant training as required;
4. I will not start this research project at this site until I have received confirmation of site authorisation in writing from the Research Office and, that this will not be before evidence is received by them (provided by me) of ethics approval by an appropriate Human Research Ethics Committee (HREC);
5. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (as amended) and the Australian Code for the Responsible Conduct of Research (as amended) and, where applicable, Note for Guidance on Good Clinical Practice.
6. If authorised to undertake this project at Royal Adelaide Hospital (this site),
 - a. I will inform the Research Office if the research project ceases before the expected date;
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7. I understand and agree that project files and documents and research records and data may be subject to inspection by delegates of the authorising authority at this site (generally the Research Governance Officer) for audit and monitoring purposes, AND
8. I understand that information relating to this research, and about me as an investigator, will be held within SA Health information systems and other local data collections. This information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cwth) and relevant laws in the States and Territories of Australia.

Name of Principal Investigator
Siana Dimond
Siana.Dimond@sa.gov.au

Complete SSA

- viii. This will then submit the SSA
- ix. A pop-up box will appear (as below), you can download all documents from the SSA and then click 'Next'

Application submission

Select the application attachments you wish to download:

[All application forms and attachments \(.zip\)](#)

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

> Next

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

✓ Application submission

The application **2021/SSA00063** has been successfully generated.

Your application has been successfully submitted. Thank you for your application.
 To continue please click the close button.

◀ Back
✕ Close

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

Research GEMS

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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](#).

i 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	Modified date
2021/HRE00085	x		1.00	● Submitted	Lauren Chartier	24/02/2021 08:54:26 AM	24/02/2021 11:36:09 AM
2021/SSA00124	x		1.00	● Submitted	Lauren Chartier	24/02/2021 11:36:22 AM	24/02/2021 01:55:42 PM

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Hints / Tips / Key Points

SSA Application

SSA Application	The coordinator/research personnel can add information to the SSA, however only the PI will be able to submit the SSA
Part A: Project Wide Information	<ul style="list-style-type: none"> This section will be prefilled- the information will be taken from your project registration Ensure all the details are correct
Part B: Site Team	<ul style="list-style-type: none"> Add site team members and administrative staff. Please add staff in who will also be actioning post-approval monitoring For all clinical trials, please nominate one associate investigator (AI) who will act as a back-up/substitute for the site PI if they are not able to be contacted. You will not be able to proceed to the next step without adding an AI. Please note: You must add in an AI to progress forward with the site application. You can select the PI again if there is none.
Part C: Departments & Services	<ul style="list-style-type: none"> This is where you will add the 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	<ul style="list-style-type: none"> Fill in sections D1 to D11 with appropriate details regarding recruitment, records, tissue and data for the project
Part E: Site Costing & Funding	<ul style="list-style-type: none"> Fill in sections E1 to E2 with appropriate details regarding costing/funding details for the project
Part F: Attachments/Site Specific Documents	<ul style="list-style-type: none"> The HREA, HREC Approval and Protocol should be automatically attached from the Project Registration. Check that the documents are attached. Upload CV's, site-specific documents, budget etc
Part G: Declaration	<ul style="list-style-type: none"> Only the PI will be able to submit the SSA PI's will not be able to submit SSA's assigned to another PI

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.CALHNRResearchGovernance@sa.gov.au