

Frequently Asked Questions (FAQ's)

What is Research GEMS?

Research GEMS is a new system that was implemented across SA Health in December 2020 to manage research ethics and governance applications.

Research GEMS allows researchers to complete Human Research Ethics Application (HREA) and Site Specific Assessment (SSA) forms, monitor approval progress as well as submit post approval activities and monitoring to their local Research Office. Additional functionality, such as Low and Negligible Risk research (LNR) applications will be introduced to Research GEMS in the next release.

What benefits does Research GEMS provide?

Research GEMS enables a more consistent and streamlined process for research applicants who wish to conduct research within SA Health. The benefits include:

Streamlining of processes

- Common application and post approval monitoring forms across Research Offices
- Researchers will have greater clarity on application requirements, approval/authorisation process and post approval-monitoring requirements.
- Reduction in duplication of effort for Researchers

Streamlined approval

- Local site approval/endorsement, ethics approval and governance authorisation will all be managed within Research GEMS
- SA Health Human Research Ethics Committee decisions will be shared with SA Health sites
- Amendments and annual reports approved by a SA Health HREC will be automatically shared with SA Health sites

Visibility

Researchers will have greater visibility over their research projects, and can:

- Track the progress of their application
- Access all of their applications and approved/authorised research studies in one location
- View post approval monitoring requirements and receive automated reminders

Greater oversight

- Improved visibility and greater reporting on research being conducted, enabling strategies to be put into place to attract more research projects to South Australia
- Improved oversight of projects being conducted at SA Health sites
- Monitoring of application processing times and metrics, to enable further process improvement

How do I access Research GEMS?

Research GEMS can be accessed on a computer, tablet or mobile device by going to <https://gems.sahealth.sa.gov.au/>

How can I get a Research GEMS account?

Applicants can register for a Research GEMS account by clicking on 'Register Now' on the Research GEMS login page (<https://gems.sahealth.sa.gov.au/>)

If you receive the error message 'Something went wrong' when registering for an account, an account may already exist with your email address. Researchers with an active research project as of late November 2020 were migrated to Research GEMS. Try resetting your password by clicking on 'Reset your password' link on the Research GEMS login page.

I cannot login to Research GEMS

If you are having difficulty logging into Research GEMS, you can reset your password by clicking on 'Reset your password' link on the Research GEMS login page (<https://gems.sahealth.sa.gov.au/>).

You will receive an email advising how to reset your password. If you do not received the email, check your junk or spam folder before contacting the Research GEMS team for assistance on gems@sa.gov.au

I want to conduct a research project within SA Health, where do I start?

The best place to start is by contacting the Research Office located at the LHN, Statewide Service or Department for Health and Wellbeing where you want to conduct the study. The Research Office will discuss your project in further detail and provide guidance on the way forward. Research Office contact details are located on the [SA Health website](#).

Once you are ready to begin your HREA (ethics) and SSA (governance) application, you should register your project on Research GEMS. Further details on the project registration process can be found in the [user guide](#).

What is project registration?

Each human research project has a project in Research GEMS and is identified with a GEMS number, such as 2021/GEM00123.

Project registration is completed once per study, and is designed to guide the researcher through the ethical and governance process within SA Health. Following completion of the project registration, application forms will be generated for ethics and governance approval as required depending on answers provided in the initial project registration.

Further details on the project registration process can be found in the [user guide](#).

How can I submit a HREA in Research GEMS?

The first step is to register your project in Research GEMS which will determine if you need to complete a HREA. Once your project has been registered a HREA will be automatically generated if required, ready for completion by the CPI. The HREA is identified with a HRE number, such as 2021/HRE00456.

Further details on the HREA process can be found in the [user guide](#).

How can I submit a SSA in Research GEMS?

The first step is to register your project in Research GEMS and either provide your NMA ethical approval or complete the HREA. Once this has occurred, a Site Specific Application (SSA) will be automatically generated for each SA Health site identified in the project registration form, ready for completion by the PI. Site applications are identified with a SSA number, such as 2021/SSA00789.

Further details on the site application process can be found in the [user guide](#).

How do I obtain the site-specific approvals required for my SSA application in Research GEMS?

As part of the SSA process various site-specific approvals are required. These site-specific approvals are now managed through Research GEMS and are referred to as Head Of Department (HOD) approvers. The PI will nominate the required approvers in Part C of the SSA form in Research GEMS in order to begin the HOD approval process. A [guide is available](#) to assist the PI in selecting the appropriate approvers for each site. Prior to submitting the SSA, researchers are encouraged to contact each involved department to discuss their application and the involvement/resourcing required.

Following submission of the SSA form the HOD approvers will be requested to review the application and provide support electronically via Research GEMS. Once all HOD approvers have provided support to the application, the Research Office will commence their review.

I have ethics approval from a NMA ethics committee and want to conduct the study within SA Health, how do I manage this in Research GEMS?

You will need to register your project in Research GEMS. When completing the project registration you will be asked to identify which ethical committee you have applied to/received approval from. Identify the NMA ethics committee from this list, provide the NMA ethics identifier and continue through the project registration. You will be required to provide a copy of your application, documents and approval letter as part of the registration process.

Further details on the project registration process can be found in the [user guide](#).

I am applying for ethical approval from another South Australian based NHMRC certified HREC, how do I manage this in Research GEMS?

Ethical approval from another South Australian based NHMRC certified HREC (Bellberry) is accepted for some SA Health sites, for some studies.

In the first instance, contact the Research Office associated with each of the SA Health sites to confirm whether they accept HREC approvals from Bellberry, and that your study is eligible. Once you have obtained confirmation the ethics approval is acceptable to all involved SA Health sites you can begin registering your project in Research GEMS.

When completing the project registration you will be asked in Part A to identify which HREC you have applied to/received approval from. Identify the relevant Bellberry HREC from the list at A3, provide the Bellberry ethics identifier and continue through the project registration. You will be required to provide a copy of your application, documents and approval letter as part of the registration process.

Further details on the project registration process can be found in the [user guide](#).

How can I submit a Low and Negligible Risk (LNR) application for expedited review?

Functionality is currently under development to enable submission of LNR applications in Research GEMS and will be introduced to Research GEMS in the next release.

In the meantime, contact your local Research Office for details on the LNR application process. Research Office contact details are located on the [SA Health website](#).

How do I track the progress of an application?

Communication is sent from Research GEMS throughout the review process to keep you informed of the progress of your application. You can also login to Research GEMS to review the current status of your application. Information on each status can be found in the [user guide](#).

If your SSA application has not progressed from 'Completed pending HOD' after one week, it is recommended that you contact the HOD directly to discuss your application. Details on how to view outstanding HOD approvals can be found in the [user guide](#).

I submitted an application but need to make a modification, how can I do that?

Research GEMS allows you to create a new version of an application that has been submitted but not yet under review, by clicking on the three dots next to the application identifier, and selecting 'New version'. If your application has commenced review please contact your Research Office, if the application is too far progressed you may be required to lodge an amendment following approval. Research Office contact details are located on the [SA Health website](#).

I am missing an approved research study

Research projects that were approved within SA Health as of late November 2020 were migrated to Research GEMS. If you are missing a project, please contact the relevant Research Office for assistance. Research Office contact details are located on the [SA Health website](#).

I can view an application but am unable to edit

Projects in Research GEMS have varying levels of access, you may have access to view a project but not edit privileges. If you require access to edit an application or project, please contact the CPI (ethics) or PI (site) requesting edit access.

Details on how to share access to an application and project can be found in the [user guide](#).

I can edit an application but am unable to submit

Research GEMS has been designed to align with ICH GCP Guidelines supporting the responsibilities of the CPI and PI. As a result the CPI is required to submit the ethics application and post approval monitoring forms and the PI is required to submit the site application and post approval monitoring forms.

Other research project team members can edit and prepare the application ready for submission by the CPI (ethics) or PI (site).

If the submit button does not appear for the CPI or PI, check that every question has been completed and that the CPI/PI had entered the correct email address under the Project Team Details section.

I can view a project but am unable to lodge a post approval monitoring form

By default, the CPI can submit post approval monitoring forms on the Ethics project and the PI can submit on the Site project. Access to edit these forms can be shared with other members of the research project team, please contact your CPI/PI who can share the project with you enabling you to prepare post approval monitoring forms ready for submission by the CPI (ethics) or PI (site) in accordance with ICH GCP Guidelines.

Details on how to share access to an application and project can be found in the [user guide](#).

I want to share my application and/or project with another person

As the CPI (ethics) and PI (site) you can share your research project with members of the research project team. Sharing access enables other team members to edit applications and post approval monitoring ready for submission by the CPI (ethics) and PI (site). Details on how to share an application and/or project can be found in the [user guide](#).

Who can I contact if I require assistance?

For technical assistance or queries relating to an application, the application approval process and post approval monitoring please contact the Research Office relevant to your project. Research Office contact details are located on the [SA Health website](#).

For technical assistance include the project identifier, details of the issue and describe any error message in your email. It can also be useful to attach screenshots of the issues.

I have more than one GEMS account and want all my research projects under one account

Contact the Research GEMS team on gems@sa.gov.au to request your accounts be merged, include details of all of your accounts.

Can I provide feedback on using Research GEMS?

Yes, all feedback is welcome and is important for the ongoing support and enhancement of Research GEMS. Please send feedback to the Research GEMS team on gems@sa.gov.au.