

Research GEMS Demonstration

Presented by Siana, Eyllinee, Lauren and
Jan-Louise
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Introduction

- How to use the Research GEMS system (not specific project/ethics/governance questions)
 - Accounts & logging in
 - Project Registration
 - HREA
 - SSA Applications
- Session is recorded and will be made available via BHI intranet

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Accounts & Logging In

- Accounts were created for Principal Investigators if they are a PI for a commercially sponsored clinical trial
- If they have not set up their password, they need to click "Reset your password"
- If they have not been a Principal Investigator for commercially sponsored trials before they will need to 'Register Now'
- If you reset your password and don't receive an email (after a few hours) please contact CALHN Research Services

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HREA

- The HREA is the same form that was available on Online Forms/hrea.gov.au
- Research personnel can enter the HREA details, however, only the CPI will be able to submit the application
- Attach all study documentation to the HREA
- In section Q4.5 – select 'Greater than low risk review pathway'
- Note: Low/negligible risk (LNR) studies are **not** supported on GEMS at this time. Submission requirements for LNR studies are available on the BHI and RAH websites. Please contact CALHN Research Services if you are unsure if your study is low risk

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HREA

- CALHN Research Services will review the submission for eligibility (completeness)
- You will receive an email confirming eligibility or requesting additional changes/documentation
- To streamline ethics and governance (SSA) review, additional governance information may be requested at this time
- When eligible you will receive an email advising of HREC meeting date
- Requests for further information from the HREC meeting review of your submission will be sent to the PI and contact person via GEMS
- Response to requests for further information must be made via GEMS

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SSA

- SSA applications can be completed after a HREA has been submitted. You do not need to wait for ethics to be approved to begin your application
- Note: Governance (SSA) will not be approved until the application is eligible and ethics has been approved
- Research personnel can enter the SSA details, however, only the PI will be able to submit the application
- Study team declarations need to be downloaded from RAH website (located here) and uploaded in Part F

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SSA

- Medical Leads must approve applications via GEMS
- DO NOT upload any agreements to GEMS, these must be submitted to Health.CALHNResearchGovernance@sa.gov.au
- DO NOT enter any site monetary values
- If any site documents were missed during HREA submission, upload to the SSA
- The documents uploaded to the Project registration flows through to the HREA and SSA, however, the HREA and SSA documents are **not** linked

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SSA

- PI's can only submit their own site applications
- Email Health.CALHNResearchGovernance@sa.gov.au once you have submitted an SSA to ensure that we are capturing all applications

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SSA

- CALHN Research Services will review the submission for eligibility (completeness)
- PI and contact person will receive an email confirming eligibility or requesting additional changes/documentation
- Response to requested changes/additional documentation must be made via GEMS
- Once eligible, SSAs are sent to the appropriate delegate for authorisation
- Once authorised, a formal letter advising governance authorisation will be sent via GEMS

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Questions & Feedback

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CONTACT POINTS

Please contact the Research GEMS Project Team

- For all technical errors, issues & feedback - Gems@sa.gov.au

For all study/project related questions, please contact CALHN Research Services

- HREA Applications – Health.CALHNResearchEthics@sa.gov.au or 08 7117 2228
- SSA Applications (Investigator Initiated) Health.CALHNResearchGovernance@sa.gov.au or 08 7117 2228
- Low Risk Applications – Health.CALHNResearchLNR@sa.gov.au or 08 7117 2224

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