CALHN
Ethics and Governance (EGA) Application Form

This form should be used when applying for ethical and/or governance review of low/negligible research projects eligible for review by the Central Adelaide Local Health Network (CALHN) Expedited Review Panel.

Researchers are advised that formal determination of eligibility for expedited review is made by CALHN Research Services, and are **strongly encouraged to read the Expedited Review Application guidelines prior to submitting an application**. Available on the RAH Website (rah.sa.gov.au/research/for-researchers/health-medical-research-project-submissions/expedited-review).

★ *The NHMRC National Statement on Ethical Conduct in Human Research 2023 defines low risk research as "research where the only foreseeable risk is one of discomfort". Discomfort may include minor side-effects of medication, discomfort related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.*

Submit application to Health.CALHNResearchLNR@sa.gov.au

Part A
Study-wide information

A1 Project Title

A2 Coordinating Principal Investigator

A3 Project Summary

A4 Regulatory Approvals

Reviewing Human Research Ethics Committee (HREC)

> Select one

Reviewing animal ethics committee

> Select one

Reviewing institutional biosafety committee

A5 Project Category

> Select one

A5.1 Is this a Laboratory Study or Registry Study?

> Select one

A5.2 Clinical Trial (If N/A proceed to A6)

How does this meet the criteria for the low-risk pathway?

What is the clinical trial type?

What is the clinical trial phase?

> Select one

What is the sponsor type?

> Select one

A6 Project Sponsor (Institution responsible for protocol/results ownership)

A7 CALHN Site Activity

A8 Anticipated project duration

A9 Consumer Engagement

Have investigators accessed consumer engagement during the development and review of the study? If yes, provide details.

A10 Principal Investigator

For CALHN sites, a CALHN Principal Investigator is preferred. Note: Students cannot be PI's.

Title/ Name/ Surname	
Position	
Department	
Employing Institution	
Site	
Institutional Email Address	
Phone Number	

A11 Administrative Contact

Name	
Contact Details	

A12 Student Involvement (If N/A proceed to Part B)

Student Name	
Educational Institution	
Study Program/Degree Type	> Select one
Is the student accessing Electronic Medical Records?	> Select one
Clinical Supervisor(s)	
Academic Supervisor(s)	

Responsibilities and duties for the study

Is the student using the outcomes of this project for their thesis or has this project been designed specifically for the purpose of their degree? If yes, provide details.

Part B
Participating networks/sites/services

B1 Sites and/or Private Sites

SA Health Local Health Network	Site / Service(s)	Department(s)	Site Principal Investigator

Part C
Project information

Data Collection

C1.1 Data to be collected

> Select one

C1.2 Patient records to be accessed

- Electronic Medical Records
- Casenotes
- Departmental Database
- Research Database – provide original ethics approval and consent form
- Statewide Database
- Not Applicable
- Other (please provide details)

C1.3 List the names of databases that will be accessed

C1.4 List investigators that will be accessing existing records

C1.5 Data Identifiability Category

> Select one

C1.6 s95 Guidelines — Commonwealth Agency/ies

Will data be collected from a Commonwealth agency? If yes, list the commonwealth agency/ies

C1.7 s95a Guidelines — Private Sector

Will data be collected from a private sector agency? If yes, list the private sector agency/ies

C1.8 Will CALHN data be transferred to another site? If yes, provide details.

C2 Specimen Collection

> Select one

C2.1 Specimens to be collected

C2.2 Institution that owns existing specimens

C2.3 Institution that will own new specimens

C2.4 Will CALHN samples be transferred to another site? If yes, provide details.

C3 Consent Process

Method of consent

Part D
Site costing and funding

Funding Type

D1.1 How will this project be supported?

- In-Kind Support (D1.2)
- Internal Departmental Funding (D1.3)
- External Funding - Select one (D1.4)
- If other, please provide details

D1.2 In-Kind Support

Provide a summary of personnel, hours (FTE) and resources required from CALHN.

D1.3 Internal Departmental or Operational Funding

Relevant financial endorsement and budget must be provided. Please append.

Provide the details of the institution and department providing funding.

D1.4 External Funding

Will funds be paid to or from CALHN?

> Select one

If grant funded, is there a CALHN investigator named on the grant application?

> Select one

If yes, list the CALHN investigators named on the grant application

The grants team will need to be contacted at Health.CALHNResearchGrants@sa.gov.au

Please provide the name and type of grant

Part E
Declaration

Declaration by all research personnel involved in the project.

> *Email declaration is sufficient stating "I approve to the terms and conditions of the declaration in the EGA form".*

I/we certify that:

1. All information in this form is truthful and as complete as possible.
2. The protocol contains all required information for comprehensive ethical and scientific review.
3. I/we have read and understand the requirements of the NHMRC National Statement on Ethical Conduct in Human Research 2023 (the National Statement) and the Australian Code for the Responsible Conduct of Research 2018 (the Code). Hyperlinks needed for these documents see here: nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023 and nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
4. I/we have read and understand the requirements of the Research Ethics and Governance Policy 2023. sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/governance/policy+governance/policies/research+ethics+and+governance+policy
5. The research project will be undertaken in compliance with the approved proposal, and conducted in keeping with conditions of ethical approval and local governance, and subject to any changes subsequently approved.
6. All records will be maintained and stored in accordance with common law, legislative, ethical, and current best practice requirements.
7. I will maintain the confidentiality, integrity, privacy and security of information in accordance with the SA DPC PC012 Information Privacy Principles, Instructions and Privacy Committee Proclamation, SA Health Privacy Policy Directive, and Australian Privacy Principles 2014.
8. Any confidential information, including but not limited to personal information of research project participants, CALHN patients, and CALHN staff will remain confidential and will not be disclosed to any third party except as required by law.
9. The project will be conducted in accordance with International Council for Harmonisation and NHMRC standards.
10. I/we have no conflicts of interest or have disclosed any conflicts of interest to the ethics review committee and CALHN Research Services and will manage them in accordance with the National Statement and the Code.
11. I/we will only commence this research project after obtaining ethics approval and governance authorisation has been obtained.

SA Health Employees

Name	Main duties	Local Health Network	Signature
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		

Non-SA Health Employees

A Confidentiality Deed must be provided for any non-SA Health investigators. Non-SA Health investigators going onto an SA Health site, or accessing SA Health participants must also provide a National Police Check and a CALHN Confidentiality Deed.
CALHN Confidentiality Deed

Name	Main duties	Employer/Institution	Signature
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
	> Select one		
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	> Select one		
	> Select one		

Part F
Project endorsement

Declaration by Head of Department (or equivalent)

Investigators are required to obtain endorsement from the department overseeing or supporting the project. The appropriate endorser will vary depending on the nature of the project and should be the Principal Investigator's Head of Department (or equivalent), and/or the department providing the necessary resources for the project.

Email declaration is sufficient, with approval containing the below statements.

Investigators cannot endorse their own research. If an investigator also serves as the head of their department (or holds an equivalent position), endorsement is required from the person they report to (i.e. Medical Lead).

F1 Project Title

I certify that:

1. I have read the referenced project application.
2. I have discussed this project and the resource implications with the principal investigator.
3. The principal investigator and other investigators involved in the project have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision has been arranged.
4. There are suitable and adequate facilities and resources for the project to be conducted, and they are available for the duration of the project.
5. The research project has been costed appropriately and there are sufficient funds to cover the costs of conducting research.
6. My signature indicates that I support this project being carried out using the required resources, based on the information provided by the principal investigator.

Name

Position > Select one

CALHN Department

CALHN Clinical Program/Statewide Service

Signature

Date

Part G
Data Custodian approval (if applicable)

G1 Project title

G2 Data set name

Email declaration is sufficient, with approval containing the below statements.

I certify that:

1. I have discussed this research project and the resource implications for CALHN: Data Custodian with the Principal Investigator
2. The Principal Investigator has submitted their protocol and provisional approval has been granted for them to access the data required.

Name

Signature

Date

Part H
Checklist

H1 Mandatory documents

- [ ] Protocol
- [ ] Declaration by investigators (Part F)
- [ ] Declaration by the Head of Department (or equivalent) (Part G)
- [ ] Endorsement from department business manager *(Studies with Departmental / Operational Funding only)*
- [ ] Curriculum vitae for each investigator *(if not submitted in the previous 12 months)*
- [ ] Good Clinical Practice Certificate *(Mandatory for Clinical Trials Only)*
- [ ] National Police Check *(Mandatory for all students and for Non-SA Health investigators on a CALHN site. Must be within 3 years)*
- [ ] Confidentiality Deed *(Mandatory for Non-SA Health investigators)*

H2 Supporting documents (if applicable)

- [ ] Declaration of interests (email is sufficient)
  "Under the Code, a conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests"
- [ ] Participant information sheet/consent form
- [ ] Data collection sheet *(REDCap is mandatory for data management purposes for all CALHN studies)*
- [ ] Questionnaire/survey
- [ ] Advertising materials
- [ ] Regulatory approvals
- [ ] Lead HREC Approval, Approved Documents and Amended Approval (Governance Only Submissions)
- [ ] Budget (if applicable)
- [ ] Grant award letter and/or grant agreement
- [ ] Data custodian declaration(s) (Part H)
- [ ] Specimen custodian declaration

Submit your application form along with all required documentation as per the instructions on the RAH website under the heading Expedited Review Panel: rah.sa.gov.au/research/for-researchers/health-medical-research-project-submissions/expedited-review

Thank you