CALHN Research Services

Investigator-Initiated Site Specific Assessment (SSA) Application Guide

Greater than low risk projects

Site Specific Assessment (SSA)

To ensure your SSA is eligible for review, it must meet CALHN Research Services eligibility requirements. Please use the checklist provided below.

For low-risk governance submissions use the CALHN Ethics and Governance Application (EGA) form and submit via email to Health.CALHNResearchLNR@sa.gov.au. Form available on the RAH website.

Submitting your SSA:

Refer to the Research GEMS user guides for step-by-step instructions.

For more information about CALHN requirements refer to the CALHN GEMS Guideline: Submitting An SSA For Investigator Initiated Studies.

Notify CALHN Research Services that your application/response has been submitted on GEMS and is ready for processing via email to Health.CALHNResearchGovernance@sa.gov.au

Contracts and Agreements

- All Clinical Trial related agreements are to be sent to Health.CALHNClinicalTrials@sa.gov.au
- Material Transfer Agreement (MTA), Data Transfer Agreement (DTA) and Research Collaboration agreements are to be sent to Health.CALHNResearchGovernance@sa.gov.au

Clinical Trials (CALHN Sponsored)

The Therapeutic Goods Administration (TGA) must be notified of clinical trials of unapproved therapeutic goods via the Clinical Trial Notification (CTN) scheme or the Clinical Trial Approval (CTA) scheme. If you intend to conduct an investigator-initiated clinical trial of an unapproved therapeutic good and CALHN is the sponsor, please refer to the information on the TGA website "Which clinical trial scheme should I choose" to determine if a CTN or a CTA is required.

If a **CTN** is required, please contact CALHN Research Services via Health.CALHNClinicalTrials@sa.gov.au. For investigator-initiated research, where CALHN will assume the role of sponsor, the CTN will be lodged by CALHN Research Services, however it is the responsibility of the investigator to provide the information required for the CTN and pay the associated fee incurred by the TGA.

If a **CTA** is required, please follow the TGA CTA instructions.

Clinical Trial (External Sponsor)

Refer to the CALHN Clinical Trial Submission Checklists on RAH website.

Please note: Clinical Trial Research Agreements (CTRA) are submitted via email to Health.CALHNClinicalTrials@sa.gov.au

SSA Submission Checklist for Researchers

All forms, templates and information below can be found on the RAH website.

1. Relevant Departmental Approval/s	
☐	This project has been discussed with all relevant Head of Departments (HoD) and Allied Health/Nursing Leads, and they have indicated their support/approval. – Consider services like imaging, pathology, pharmacy, medical records, and other services/departments/wards where resources will be required for this project. – Please ensure all resources you require from each department (e.g. to provide staff, service/s, investigators etc) have been discussed with the unit in advance, and are well described in Part C: Departments and Services – Upload the HoD support as an attachment in Part F of the SSA form. – Please note: Investigators cannot not approve their own research. Approval is required from the person they report to. – Head of Department Declaration Template
☐	CALHN Media and Communications approval (if applicable) *Required if advertisements will be displayed at CALHN sites.*
2. Site Team Supporting Documents	
☐	CALHN Study Team Declaration (email is sufficient) Template available here
☐	Curriculum Vitae(s) *Ensuring that current workplace is clearly documented.* *Valid for 2 years.*
☐	GCP Certificate(s) *Valid for 3 years.* *Mandatory for Clinical Trials.* *Further information available here.*
☐	National Police Check (NPC) - Non-SA Health Investigators (*if applicable*) *Required for non-SA Health Investigators that will be on a CALHN site.*
☐	CALHN Confidentiality Deed - Non-SA Health Investigators (*if applicable*) Template available on request, contact Health.CALHNResearchGovernance@sa.gov.au
3. Site Costing and Funding	
☐	In Kind Support

	– Investigator initiated projects supported by in kind support must provide a summary of hours and resources required for the project and the relevant Clinical Program Delivery Manager's approval (email is sufficient).
☐	Internal Departmental Funding – Submit the relevant financial approvals and the site study budget to Health.CALHNResearchGovernance@sa.gov.au
☐	Grant – If any CALHN investigators are listed as chief investigators on the grant application provide a copy of the application and award letter (or provide the CALHN MyIP reference number for the grant agreement). – If funds will be paid to CALHN submit a budget to Health.CALHNResearchGovernance@sa.gov.au.
☐	External Funding (e.g. University) – If funds will be paid to CALHN, contact CALHN RGO via Health.CALHNResearchGovernance@sa.gov.au to determine if an agreement is required for transfer of funds.
4. For projects where the ethics application has been approved outside of GEMS, please also upload the following:	
☐	Ethics Approval Letter and any subsequent amendment approval letters **The letter/s must list each of the sites at which the study will be undertaken.*
☐	HREC approved Master Participant Information Sheet(s) and Consent Form(s) (PICFs)
☐	All HREC approved documentation, including advertising material.
☐	Site Specific Document(s) including PICFs.
☐	Radiation Safety Approval (*if applicable*)
☐	Insurance Certificate (if applicable)
5. University Study (if applicable)	
☐	Confirmation of Insurance *We require confirmation that the relevant specific project is covered by the University's insurance arrangements. A Certificate of Currency from the university is not the correct document.*
☐	Relevant lead approval *For studies conducted at the University of Adelaide endorsement from the relevant university lead (i.e. medical dean) is required*

6. Services (if applicable)	
☐	Submit the quote or fee waiver (email is sufficient) (i.e. SA Pathology and/or SA Pharmacy)
☐	Service Agreement with external vendors (i.e. private radiology, consultants) *An agreement will be required if CALHN is paying or receiving money.* *Contact CALHN Research Services if an agreement is required via email to Health.CALHNResearchGovernance@sa.gov.au*
7. Clinical Trial (CALHN Sponsored)	
☐	CTN (if applicable) *The Australian clinical trial sponsor must notify the TGA of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good prior to commencement of the use. The notification form must be submitted online and accompanied by the relevant fee.*
	CTA (if applicable)
☐	CTA Part 1: Application submitted to TGA by Principal Investigator (PI)
☐	CTA Part 2: Notification of the conduct of a trial under the CTA scheme submitted to CALHN Research Services by PI to health.CALHNClinicalTrials@sa.gov.au *Part 2 must be completed and **submitted to TGA within 28 days** of either the commencement of each new trial or the addition of a new site in an ongoing CTA trial.*
8. Additional requirements for Investigator Initiated and/or Collaborative Trials	
☐	Research Collaboration Agreement *Written agreements for investigator-initiated applications are not usually required however in some circumstances when the research involves an external organisation, an agreement may be requested.*
☐	Material Transfer Agreement (MTA) *If your research involves a transfer materials or samples to an external site and does not require a CTRA or other collaboration agreement an MTA may be required.*
☐	Data Transfer Agreement (DTA) *If your research involves a transfer of data to an external site and does not require a CTRA or other collaboration agreement an DTA may be required.*
CALHN Research Office Reference Number - MyIP	
Once you submit your project to CALHN Research Services, a specific identifier known as MyIP will be assigned to it. A reference number will be allocated to your SSA and any associated agreements. It is important to note that this reference number is in addition to your GEMS reference number. **Please note:** the MyIP is required for correspondence within CALHN.	

For more information

CALHN Research Services
T: (08) 7117 2228
E: Health.CALHNResearchGovernance@sa.gov.au