

# Guidelines for Submissions (Agreements and Site Specific Assessments)

## Overview

These guidelines will provide CALHN Clinical Trial Units with the necessary information to submit agreements and site-specific assessments for review by CALHN Research Services.

## Contracts

- All Clinical Trial related agreements are to be sent to the following email address:
  - [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au)
- **Note:** Do not send (or cc in) any agreement directly to CALHN Research Services staff members. The generic email address provided above is actively monitored, categorised, reviewed and actioned.
- Do not copy in CALHN Research Services personal email addresses' to introduce or action a request with a sponsor or external party.
- **Fees & Invoicing Information:** Please ensure you send the Sponsor/Local Sponsor a copy of the CALHN Invoicing Fee Form (Ethics & Governance) available for download [here](#) and the SA Health Research Ethics and Governance Fee Schedule available [here](#). **Note:** The IT/Software Fee is only visible on the invoicing fee form as it is a CALHN specific fee and not yet available on the SA Health Fee Schedule.

## New Clinical Trial Research Agreements:

- For a Clinical Trial Research Agreement to be reviewed, submit the following listed documents:
  - Clinical Trial Research Agreement – in word version
  - Excel Budget Spreadsheet – if this has been provided
  - Standard Form of Indemnity (except CRG's and non-medicines Australia agreements)
  - HREC Review only Indemnity – (only required if a multi-site study where CALHN is the Reviewing HREC)
  - Quotes – Pharmacy, Imaging, Radiology, Pathology – If applicable
  - Copy of the Protocol
- If this information is not provided, a request for further information will be sent back.

## Amendments to Clinical Trial Research Agreements:

- For Amendments to the Clinical Trial Research Agreement, submit the following documents:
  - Amendment/Variation agreement in word version
  - HREC approval letter – if related to protocol amendment or change of PI
  - Quotes – if adding any services not previously included

## Novation Agreements:

- Where a party is being replaced (e.g. Sponsor / Local Sponsor) a novation agreement is required.
- Please provide the following:
  - Novation agreement in word version
  - Effective date of change to new party
  - HREC acknowledge/approval of change of sponsor

## Confidentiality/Non-Disclosure Agreements:

- For Confidentiality/Non-Disclosure Agreements, provide the following:
  - Contract in word version
  - Name of PI who will be undertaking feasibility (unless master/non-study specific agreement)

## Master Services Agreements:

- If you require the services of an external provider there must be a services agreement in place in order to pay for the services, as this is a treasury requirement.
- Provide the following information:
  - Name and address of entity/business/trading name of service provider
  - ABN

- Address and contact for notices
- Phone number and contact email address of service provider
- Insurance Certificate (Clinical trials or Medical Indemnity Insurance)
- **Note:** the work order template in schedule 1 of the Master Services Agreement is not to be signed, as it is only a template which must remain within the document.

## Work Orders

- Provide the following information:
  - Study details (e.g. title, protocol number, Sponsor, MYIP)
  - Term of services (commencement and expiration date)
  - Protocol Requirement for Clinical Services (state relevant section of protocol)
  - List of services being provided
  - Fees of the service provided (and state whether they are GST free, inclusive or exclusive)

## Site Specific Assessments

- All Site Specific Assessments are to be completed via Research GEMS available [here](#).
- For guidance in creating a Site Specific Assessment Application, visit the RAH website for more information, located [here](#) and download the “CALHN Clinical Trial GEMS Project Registration and SSA Submission Guidelines”.
- External HREC - Once the Reviewing HREC has approved the study, you will be able to submit your SSA via GEMS.
- CALHN HREC – You can submit the Site Specific Assessment Application, however the status will not be ‘Eligible’ until HREC approval has been obtained.
- Research GEMS requires the following documents to be uploaded as a minimum on all Site Specific Assessment Applications:
  - HREC Approval letter
  - HREA
  - Protocol
- All study documentation (as listed in the checklist) can be uploaded either into Research GEMS in the upload section or in the relevant Clinical Trial Unit sub-folder on the Share Drive. Indicate which method has been used in your submission email.
- Once submitting your application via Research GEMS, please send an email to [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au) in the following format:

Dear CALHN Research Services,

<Clinical Trial Unit Name> has now submitted an SSA for the below study:

<b>Project Title</b>	XXX
<b>Protocol:</b>	XX
<b>Principal Investigator:</b>	XX
<b>Program Directory:</b>	RAH/TQEH: XXXX: XXXXX
<b>HREC Reference Number:</b>	202X/HREXXXXX / or External HREC Number
<b>SSA Reference Number:</b>	202X/SSAXXXXX
<b>CALHN Reference Number:</b>	MYIPXXXXX

\*indicate whether you have uploaded via GEMS or Share Drive

Thanks

<email signature>

- The following documents and information are required for an eligible SSA application:

Documentation Checklist	Uploaded
Signed - CALHN Invoicing Fee Form (Ethics & Governance) – Available for download <a href="#">here</a>	<input type="checkbox"/>
Head of Department/Supporting Head of Department (HoD) Approval/Declaration <ul style="list-style-type: none"> <li>Discuss your application with the HoD prior to submitting</li> <li>The declaration can be sent via GEMS</li> </ul> Download form <a href="#">here</a> (select this downloadable document: CALHN Research Department Head and Medical Lead Declaration (CT))	<input type="checkbox"/>
Medical/Nursing/Allied Health Lead Approval/Declaration <ul style="list-style-type: none"> <li>Discuss your application with the appropriate lead prior to submitting</li> <li>This declaration can be sent via GEMS</li> <li>How to select the correct lead is available in guidelines located <a href="#">here</a> (document to download: CALHN Clinical Trial GEMS Project Registration and SSA Submission Guidelines)</li> </ul>	<input type="checkbox"/>
Study Team declaration <ul style="list-style-type: none"> <li>This is required for all study team members (e.g. coordinators, investigators etc)</li> <li>This field is not available on GEMS and will be required to be uploaded on the Clinical Trials Share Drive</li> <li>The Study Team declaration can either be submitted for each individual study or an annual form with new staff members added when participating in studies</li> </ul>	<input type="checkbox"/>
Study Team CV's & GCP Certificates <ul style="list-style-type: none"> <li>Uploaded to relevant folders on Clinical Trial Share Drive</li> </ul>	<input type="checkbox"/>
Credentialing of Investigators <ul style="list-style-type: none"> <li>Medical Officers, Allied Health and Nurse Consultants must be credentialed to practice as an Investigator for each CALHN site</li> <li>You can check credentialing <a href="#">here</a> (note: you can only access this website if you are a SA Health employee)</li> <li>If credentialing is required or expired, contact: &lt;insert email address&gt;</li> </ul>	<input type="checkbox"/>
Lead Human Research Ethics Committee (HREC) Approval Letter	<input type="checkbox"/>
Lead HREC Approval Letter with CALHN Study Site listed (RAH or TQEH)	<input type="checkbox"/>
HREA Form	<input type="checkbox"/>
Study Protocol	<input type="checkbox"/>
Product Information e.g. Investigator Brochure or Device Manual	<input type="checkbox"/>
Master Participant Information Sheet and Consent Form(s)	<input type="checkbox"/>
CALHN (Site Specific) Participant Information Sheet and Consent Form(s)	<input type="checkbox"/>
Certificate of Currency	<input type="checkbox"/>
Pathology/Imaging/Pharmacy Quotes	<input type="checkbox"/>
VELOS Budget Form	<input type="checkbox"/>
Radiation Report / Radiation Safety Report	<input type="checkbox"/>
TGA CTN notification	<input type="checkbox"/>
Institutional Biosafety Committee Approval Letter (If applicable)	<input type="checkbox"/>
OGTR Genetically Modified Organism License (If applicable)	<input type="checkbox"/>
NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) Letter (If applicable)	<input type="checkbox"/>
NHMRC Cellular Therapies Advisory Committee (CTAC) Letter (If applicable)	<input type="checkbox"/>