

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
- **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 in the following format:

Dear CALHN Research Services,

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

Project Title	XXX
Protocol:	XX
Principal Investigator:	XX
Program Directory:	RAH/TQEH: XXXX: XXXXX
HREC Reference Number:	202X/HREXXXXX / or External HREC Number
SSA Reference Number:	202X/SSAXXXXX
CALHN Reference Number:	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 here	<input type="checkbox"/>
Head of Department/Supporting Head of Department (HoD) Approval/Declaration <ul style="list-style-type: none"> Discuss your application with the HoD prior to submitting The declaration can be sent via GEMS Download form here (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"> Discuss your application with the appropriate lead prior to submitting This declaration can be sent via GEMS How to select the correct lead is available in guidelines located here (document to download: CALHN Clinical Trial GEMS Project Registration and SSA Submission Guidelines) 	<input type="checkbox"/>
Study Team declaration <ul style="list-style-type: none"> This is required for all study team members (e.g. coordinators, investigators etc) This field is not available on GEMS and will be required to be uploaded on the Clinical Trials Share Drive 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 	<input type="checkbox"/>
Study Team CV's & GCP Certificates <ul style="list-style-type: none"> Uploaded to relevant folders on Clinical Trial Share Drive 	<input type="checkbox"/>
Credentialing of Investigators <ul style="list-style-type: none"> Medical Officers, Allied Health and Nurse Consultants must be credentialed to practice as an Investigator for each CALHN site You can check credentialing here (note: you can only access this website if you are a SA Health employee) If credentialing is required or expired, contact: <insert email address> 	<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"/>