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.
- **Pathology/Imaging/Pharmacy Quotes:** Please ensure that you provide these along with the draft Clinical Trial Research Agreement

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	☐
Pathology/Imaging/Pharmacy Quotes	☐
Head of Department/Supporting Head of Department (HoD) Approval/Declaration • Discuss your application with the HoD prior to submitting • The declaration cant be sent via GEMS Download form here (select this downloadable document: CALHN Research Department Head and Medical Lead Declaration (CT))	☐
Study Team Declaration • 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	☐
Study Team CV's & GCP Certificates • Uploaded to relevant folders on Clinical Trial Share Drive	☐
Principal Investigator Declaration • You can download the form here	☐
Credentialing of Investigators • 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>	☐
Lead Human Research Ethics Committee (HREC) Approval Letter	☐
Lead HREC Approval Letter with CALHN Study Site listed (RAH or TQEH)	☐
HREA Form	☐
Study Protocol	☐
Product Information e.g. Investigator Brochure or Device Manual	☐
Master Participant Information Sheet and Consent Form(s)	☐
CALHN (Site Specific) Participant Information Sheet and Consent Form(s)	☐
Certificate of Currency	☐
VELOS Number	☐
Radiation Report / Radiation Safety Report	☐
TGA CTN notification	☐
Institutional Biosafety Committee Approval Letter (If applicable)	☐
OGTR Genetically Modified Organism License (If applicable)	☐
NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) Letter (If applicable)	☐
NHMRC Cellular Therapies Advisory Committee (CTAC) Letter (If applicable)	☐