Guidance and Checklist

Medicines Australia & Medical Technology Association of Australia Clinical Trial Research Agreements (CTRA) – Standard & CRO Form Checklist

Overview

For Clinical Trials involving medicines, Medicines Australia (MA) Clinical Trial templates can be downloaded from the MA website located here.

For Clinical Trials involving a device, the Medical Technology Association of Australia (MTAA) Clinical Investigational Research Agreements templates can be downloaded from the website here.

CALHN Research Services must review all Clinical Trial Research Agreements prior to execution, please email them to: Health.CALHNClinicalTrials@sa.gov.au. Please submit the following for review:

- 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 the requested documents are not provided, a request for further information will be sent back.

Checklist

Front Page	**Yes**	**No**
Is the Institution Party name: 'Central Adelaide Local Health Network Incorporated (ABN 96 269 526 412)'? Also refer to the document "Parties and Signatories to a CALHN Research Agreement" available for download on the website here for further details on contracting parties.	☐	☐
Are the Institutions contact details correct?	☐	☐
Has the full legal name of the Sponsor been listed, and their ABN and contact details provided? Are these details correct?	☐	☐
Are the Study Name details/Clinical Investigational Plan/Protocol Number correct?	☐	☐
Is the date of Agreement entered as "Date of the last Party to sign" or "when both parties have signed" this agreement?	☐	☐
Body of the Agreement (Page 2 to Signature Page)	**Yes**	**No**
Please confirm that no changes have been made to the Body of the Agreement. Please inform the Sponsor that this is not permitted. All proposed changes to the agreement are to be detailed separately in Schedule 7.	☐	☐
Schedules	**Yes**	**No**
Schedule 1: Key Information		
Is the Study Name correct?	☐	☐
Is the Study Site Correct? It should be where the study is being conducted e.g. "Royal Adelaide Hospital" or "The Queen Elizabeth Hospital"	☐	☐
Target Number of Study Participants: Are the numbers the same as stated in the ethics and SSA applications?	☐	☐
Recruitment Period: Are the dates correct?	☐	☐
Are the Principal Investigator details complete and correct?	☐	☐
Are the Reviewing HREC details correct? The Reviewing HREC must be a NHMRC approved ethics committee e.g. "Central Adelaide Local Health Network Human Research Ethics Committee"?	☐	☒
Equipment: If no equipment insert "NIL"	☐	☒

Is all of the medical equipment provided by the Sponsor/CRG TGA-approved? If TGA-approved, is the equipment being sourced from the local Australian Sponsor as defined on the Australian Register of Therapeutic Goods (ARTG)? Will the equipment provided be tested and approved by Biomedical Engineering prior to use?		
Software: If no software insert "NIL" Is the software provided by the Sponsor approved by ICT?	☐	☐
Investigational Product (where applicable) details included?	☐	☐
Organisation (for CRO studies) – Has the Organisations name been provided? (Global Sponsor)	☐	☐
Schedule 2: Payments		
Are the amounts, terms and conditions of payment adequate for the purposes of the Study? Refer to the "CALHN Guideline for Clinical Trial Budgets, Payments & Invoicing" found on the website here. For further queries, please contact CALHN Research Services.	☐	☐
Are the amounts specified exclusive of GST?	☐	☐
Is the currency in Australian dollars? All amounts must be listed in Australian dollars.	☐	☐
Will you receive a Start-Up fee if you haven't signed a Pre-Clinical Trial/Investigation Agreement?	☐	☐
Have you included Reviewing HREC and Governance Fees (where applicable)?	☐	☐
Have you included the IT/Software Fee?	☐	☐
Have you included other department costs e.g. Pharmacy, Radiology, non-standard of care pathology – SA Pathology?	☐	☐
Are you able to comply with any requirements to complete CRFs within a specified period?	☐	☐
Are you able to meet any deadlines by which you are required to enrol the required number of Study Participants?	☐	☐
Are you satisfied with the definition of a "screen failure", the capped number of screen failures and compensation for screen failures?	☐	☐
Will you be reimbursed for the work associated with the preparation of any future amendment applications, SAE reporting, annual progress reports, archiving etc?	☐	☐
Have all Study Participant visit payments been included?	☐	☐
Will Study Participants be reimbursed for travel, meal and accommodation costs?	☐	☐
Have any "bonus" payments been offered which could be considered as an inducement to enrol additional Study Participants?	☒	☐
Have the invoicing and payment details been completed? Is the MYIP reference number included in the remittance advice?	☐	☐
Are there any terms which you are unsure about?	☐	☐
Has the Invoicing Fee form been signed off by the Sponsor/Local Sponsor?	☐	☐
Schedule 3: Form of Indemnity for Clinical Trials		
Has the form of Indemnity been filled in correctly and attached?	☐	☐
Schedule 4: Insurance Arrangements		
Has a current Insurance Certificate been attached? Please check the following: • Expiry date – this should be in date and not expired • Name of insured – this should be the Sponsor or Local Sponsor (can be additionally insured) • Level of cover – should be for an amount of not less than $10m, if the certificate is in a different currency, then equivalent to $10m AUD. • Type of cover – these types are acceptable: Clinical trials, product liability, professional indemnity/medical malpractice, public liability or additional or top up policies	☐	☐
Schedule 5: Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial		

MA: Does this state: Copy available online at: http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/ MTAA: Does this include the link? https://www.mtaa.org.au/clinical-investigations Note: the full document does not need to be inserted, but the correct website should be cited.	☐	☐
Schedule 6: Study Protocol Identification (MA) / Schedule 6: Clinical Investigation Identification Plan (MTAA)		
Are all the details correct and complete?	☐	☐
Schedule 7: Special Conditions		
Have any Special conditions been included? If no, please insert "NIL" CALHN Research Services has approved a number of Schedule 7 provisions submitted by individual sponsors. If there are additional "Special Conditions" requested they may need to be reviewed and approved by the Southern and Eastern Border States (SEBS) committee which meets monthly to consider CTRA amendments. Please refer to the document "SEBS Schedule 7 and 4 Special Conditions to a Clinical Research Agreement" available for download on the website located here. For more information in regards to the SEBS Committee, refer to the Medicines Australia website here.	☐	☐