Central Adelaide Local Health Network
Research Services

# Guidance and Checklist
# Collaborative Research Groups & Phase IV

## Overview

The Clinical Trial Research Agreement (CTRA) for Collaborative or Cooperative Group (CRG) Clinical Trial Research Agreements and the CTRA for Phase 4 Clinical Trials (Medicines) can be downloaded from the Medicines Australia website located here.

Also refer to the "CALHN Guideline for Clinical Trial Budgets, Payments & Invoicing" found on the website here. CALHN Research Services must review all CTRAs, please email them to Health.CALHNClinicalTrials@sa.gov.au.

## Checklist

| **Front Page** | **Yes** | **No** |
|---|---|---|
| Is the Institution Party name: 'Central Adelaide Local Health Network Incorporated (ABN 96 269 526 412)'?<br><br>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?<br><br>Are these details correct? | ☐ | ☐ |
| Are the Study Name and 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.<br>Please inform the Sponsor that this is not permitted.<br>All proposed changes to the agreement are to be detailed separately in Schedule 4. | ☐ | ☐ |
| **Schedules** | **Yes** | **No** |
| **Schedule 1: Key Information** | | |
| Is the Study Name correct? | ☐ | ☐ |
| Is the Study Site Correct?<br>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?<br>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"<br><br>Is all of the medical equipment provided by the Sponsor/CRG TGA-approved?<br><br>If TGA-approved, is the equipment being sourced from the local Australian Sponsor as defined on the Australian Register of Therapeutic Goods (ARTG)?<br><br>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? | ☐ | ☐ |
| **Schedule 2: Payments** | | |
| Are the amounts, terms and conditions of payment adequate for the purposes of the Study?<br>Refer to the "CALHN Guideline for Clinical Trial Budgets, Payments & Invoicing" found on the website here.<br>For further queries please contact CALHN Research Services. | ☐ | ☐ |
| Are the amounts specified exclusive of GST? | ☐ | ☐ |
| Is the currency in Australian dollars?<br>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? | ☐ | ☐ |
| **Schedule 3: Study Protocol Identification** | | |
| Are all of the details complete and correct? | ☐ | ☐ |
| **Schedule 4: Special Conditions** | | |
| Have any Special conditions been included?<br>If no, please insert "NIL"<br><br>CALHN Research Services has approved a number of Schedule 4 provisions submitted by individual sponsors.<br><br>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.<br><br>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.<br><br>Often the Sponsor or CRG will provide Insurance and Indemnity for the study.<br>Include these as:<br>Schedule 4a: Indemnity Agreement<br>Schedule 4b: Insurance Certificate | ☐ | ☐ |