Medicines Australia and Medical Technology Association of Australia Commercial Research Agreement - Standard Form Checklist

The Standard CTRA for Sponsor and Contract Research Organisation (CRO) Clinical Trial Research Agreements can be downloaded from the Medicines Australia website: http://medicinesaustralia.com.au/issues-information/clinicaltrials/clinical-trials-research-agreements/

The Medical Technology Association of Australia (MTAA) Commercially Sponsored Clinical Investigation Research Agreements can be downloaded at: http://www.mtaa.org.au/policy-initiatives/clinical-investigations

Also refer to the "Clinical Research Agreement Guidelines" at http://www.rah.sa.gov.au/ under the "Research" tab.

Front Page	
Is the name of the Institution "**Central Adelaide Local Health Network Incorporated (ABN 96 269 526 412)**"? Also refer to the document "Parties and Signatories to a CALHN Research Agreement" for further details on contracting parties at http://www.rah.sa.gov.au under the "Research" tab	Yes ☐
Are the Institution contact details correct?	Yes ☐
Has the full legal name of the Sponsor/Local Sponsor been listed, and their ABN and contact details provided? Are these details correct?	Yes ☐ Yes ☐
Are the Study Name details/Clinical Investigation Plan name and number correct?	Yes ☐ N/A ☐
Is the date of Agreement entered as "when the last Party signs" or "when both parties have signed" this agreement?	Yes ☐
Body Of The Agreement (page 2 to Signature page)	
Please confirm that no changes have been made to the Body of the Agreement. Please inform the Sponsor/Local sponsor that this is not permitted. All proposed changes to the agreement are to be detailed separately in Schedule 7.	Yes ☐
Schedules	
Schedule 1: Key Information	
Schedule 1: Is the Study Name correct?	Yes ☐
Schedule 1: Is the Study Site Correct? It should be where the study is being conducted e.g. "Royal Adelaide Hospital" or "The Queen Elizabeth Hospital"	Yes ☐
Schedule 1: Target Number of Subjects/Participants: Are the numbers the same as stated in the ethics and SSA applications?	Yes ☐
Schedule 1: Recruitment Period: Are the dates correct?	Yes ☐
Schedule 1: Are the Principal Investigator details accurate and complete?	Yes ☐
Schedule 1: Are the HREC details correct? The HREC must be a NHMRC approved ethics committee e.g. "Royal Adelaide Hospital Human Research Ethics Committee"?	Yes ☐
Schedule 1: Equipment: If no equipment insert "NIL" Is all of the medical equipment provided by the Sponsor TGA-approved?	Yes ☐

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?	Yes ☐ NA ☐ Yes ☐ NA ☐
Schedule 1: Software: If no software insert "NIL" Is the software provided by the Sponsor approved by ICT?	Yes ☐ NA ☐
Schedule 1: Investigational Product (where applicable) details included?	Yes ☐ NA ☐
Schedule 1: Organisation. For CRO studies: are the name, address, phone/fax number details of the Organisation the Local Sponsor is representing in Australia provided?	Yes ☐ NA ☐
Schedule 2: Payments	
Schedule 2: Are the amounts, terms and conditions of payment adequate for the purposes of the trial? Refer to "Clinical Trial Budget Guidelines and Assistance" at http://www.rah.sa.gov.au under the "Research" tab. For further queries please contact the Research Finance Office Health.CALHNResearchFinance@sa.gov.au	Yes ☐
Schedule 2: Are the amounts specified exclusive of GST?	Yes ☐
Schedule 2: Is the currency in Australian dollars? All amounts must be listed in Australian dollars.	Yes ☐
Schedule 2: Will you receive a Start-Up fee if you haven't signed a Pre-Clinical Trial/Investigation Agreement?	Yes ☐ NA ☐
Schedule 2: Have you included HREC and Governance Fees?	Yes ☐ NA ☐
Schedule 2: Have you included other department costs e.g. Pharmacy, Radiology, non standard of care pathology – SA Pathology?	Yes ☐ NA ☐
Schedule 2: Are you able to comply with any requirements to complete CRFs within a specified period?	Yes ☐ NA ☐
Schedule 2: Are you able to meet any deadlines by which you are required to enrol the required number of study subjects/participants?	Yes ☐ NA ☐
Schedule 2: Are you satisfied with the definition of a "screen failure", the capped number of screen failures and compensation for screen failures?	Yes ☐ NA ☐
Schedule 2: Will you be reimbursed for the work associated with the preparation of any future amendment applications, SAE reporting, annual progress reports, archiving etc?	Yes ☐ NA ☐
Schedule 2: Have all study subject/participant visit payments been included?	Yes ☐ NA ☐
Schedule 2: Will Study Subjects be reimbursed for travel, meal and accommodation costs?	Yes ☐ NA ☐
Schedule 2: Have any "bonus" payments been offered which could be considered as an inducement to enrol additional participants?	Yes ☐ No ☐
Schedule 2: Have the invoicing and payment details been completed?	Yes ☐ NA ☐
Schedule 2: Are there any terms which you are unsure about?	Yes ☐ No ☐
Schedule 2: Has the budget been approved and signed by the Business Operations Manager of your clinical directorate?	Yes ☐
Schedule 2: Has the budget/Invoicing form been signed by the Sponsor?	Yes ☐
Schedule 3: Form Of Indemnity For Clinical Trials **For Sponsor/CRO CTRAs**	

Schedule 3: Has an unsigned Medicines Australia Form of Indemnity Agreement been attached? Wording should include: "The Sponsor agrees to execute and deliver to the Institution, as necessary, an indemnity in the form of the Medicines Australia Standard Form of Indemnity for Clinical Trials without amendment." If to be signed as a separated document include the words "Executed as a separate agreement"	Yes ☐ NA ☐
Schedule 3: Form Of Indemnity For Clinical Investigations **For Sponsor MTAA Clinical Investigations**	
Schedule 3: Has an unsigned MTAA Form of Indemnity Agreement been attached? Wording should include: The Sponsor agrees to execute and deliver to the Institution, as necessary, an indemnity substantially in the form of the Medical Technology Association of Australia Standard Form of Indemnity for Clinical Trials. If to be signed as a separated document include the words "Executed as a separate agreement" See "Form of Indemnity Agreement for Clinical Trials" found at http://www.rah.sa.gov.au under the "Research" tab.	Yes ☐ NA ☐
Schedule 4: Insurance Arrangements **For Sponsor / CRO CTRAs and MTAA Agreements**	
Schedule 4: Has a current insurance certificate been attached? Please check the expiry date. Delete the following wording: "Certificate of Insurance For a Study to be conducted in Victoria, the following details are mandatory; • Insurance provider • Insured Entity • Additional Insured • Clinical Investigation Plan/ CTN number • Limits of Liability in AUD/ Per occurrence amount and Annual Aggregate • Excess/ deductible/ Self insured risk Victorian Managed Insurance Authority Guidelines can be found at the VMIA website in the "Clinical Trials" section under "Public Healthcare": http://www.vmia.vic.gov.au/ For a Study to be conducted in any other State in Australia, the relevant insurance requirements within those States will be adhered to and documented in this Schedule" See "Insurance Cover Guidelines and Checklist" http://www.rah.sa.gov.au under the "Research" tab.	Yes ☐ NA ☐
Schedule 5: Guidelines For Compensation For Injury Resulting From Participation In A Company-Sponsored Clinical Trial. **For Sponsor / CRO CTRAs**	
Schedule 5: Has the following reference to the Medicines Australia Clinical Trials Compensation Guidelines been included? "The Sponsor / Local Sponsor will comply with the 16 January 2004 versions of the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Trial, which are set out at the following website:	Yes ☐ NA ☐

http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/ Note: The full document does not need to be inserted, however the correct reference must be cited.	
Schedule 5: Guidelines For Compensation For Injury Resulting From Participation In A Company-Sponsored Clinical Investigation. **For MTAA Agreements**	
Schedule 5: Has the following reference to the Medicines Australia Clinical Trials Compensation Guidelines been included? "The Sponsor will comply with the 8 April 2010 version of the Medical Technology Association of Australia (MTAA) Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Investigation, which are set out at the following website: http://www.mtaa.org.au/policy-initiatives/clinical-investigations Note: The full document does not need to be inserted, however the correct reference must be cited.	Yes ☐ NA ☐
Schedule 6: Study Protocol Identification **For Sponsor / CRO CTRAs**	
Schedule 6: Are the details complete and correct?	Yes ☐ NA ☐
Schedule 6: Clinical Investigation Plan Identification **For MTAA Agreements**	
Schedule 6: Are all of the details correct?	Yes ☐ NA ☐
Schedule 7: Special Conditions **For Sponsor / CRO CTRAs and MTAA Agreements**	
Schedule 7: Has only the SA Health approved wording been included? The CALHN Research Office has approved a number of Schedule 7 provisions submitted by individual commercial 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" at http://www.rah.sa.gov.au under the "Research" tab.	Yes ☐ NA ☐