SEBS Schedule 7 and 4 Special Conditions to a Clinical Research Agreement

Review of New and Existing Pre-Approved Sponsor Specific Clauses for Approved Clinical Trial Research Agreements

This document is to be read in conjunction with the "Statement of Purpose for SEBS" and Template to request a Schedule 7 or Schedule 4 variation to a CTRA" documents located on the Medicines Australia website.

This process is approved for Queensland Health, New South Wales Department of Health, Victorian Medical Insurance Agency and South Australian Health.

Rationale: To standardise, streamline and circumvent unnecessary duplication in the review of sponsor specific clauses for use in Clinical Trial/Investigation Research Agreements approved by the Southern and Eastern Border States.

SA Health participates in a multi-jurisdiction review panel to consider amendments to the standard Medicines Australia CTRA agreements and the Medical Technology Association of Australia CIRA template agreement.

- Schedule 7 of 'Clinical Trial Research Agreement - Medicines Australia Standard Form';
- Schedule 7 of 'Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor';
- Schedule 7 of 'The MTAA Standard Clinical Investigation Research Agreement';
- Schedule 4 of 'Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies'; and
- Schedule 4 of 'Clinical Trial Research Agreement- Phase 4 Clinical Trial (Medicines)'

The Southern and Eastern Border States (SEBS) review panel meets monthly to consider CTRA and CIRA amendments.

Scope: This process only applies to the review of new and amendments to existing pre-approved Sponsor specific clauses submitted for consideration, in participating states, for use in approved standard agreements listed above.

Sponsors will not be required to submit previously approved clauses for re-approval.
The process covers review of clauses for on-going use by the Sponsor for clinical trials and other research projects conducted in participating states, and for one-off multi-site studies that involve at least one of the participating states.

Out of scope: This process does not cover review of sponsor specific clauses for one-off single site studies. In these instances, clauses are to be negotiated directly with the Institution/Health District/Area Health Service/Local Health Network/etc.

Review process:

Step 1: Sponsor prepares a submission for review using the approved review template attached to this document.
Where appropriate, the proposed clause must reference the relevant standard CTRA/CIRA clause that it will replace or amend. A justification must be provided for the inclusion of each of the proposed clauses.

Step 2: Sponsor submits the completed pro forma to the relevant authority in any one of the participating jurisdictions.

Step 3: The participating states will jointly review the submitted clauses. The timeline and cost of review will be dependent on the number and complexity of the clauses submitted for review. The sponsor will be provided with an estimate of timeline and cost before the review starts. During the review, if necessary, the states' legal representative will communicate directly with the sponsor's legal representative.

Step 4: The participating states will notify the Sponsor of approved clauses with a version number and date, and which of the standard CTRA/CIRA for which they are approved.

Where amendments to pre-approved clauses are approved, the sponsor will be notified that the previously approved clauses are superseded and replaced by the new approved clauses, but that existing contracts using the superseded clauses are valid until the end of that contract.

Step 5: A register of all endorsed CTRA/CIRA amendments will be maintained by SA Health's Office for Research Development.

SA Health approval letters for Schedule 7/Schedule 4 changes can be obtained from the SA Health Office For Research researchgovernance@health.sa.gov.au

Submissions and queries relating to the review of Schedule 7/4 Special Conditions to should be made through Health Ethics at NSW Office for Health and Medical Research:
Email: HEALTHETHICS@doh.health.nsw.gov.au Phone: (02) 9391 9228

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Southern and Eastern Border States Research Contract Amendment Review Template

The Sponsor is responsible for completion of this review template. All proposed amendments to the standard Clinical Trial Research Agreements must be *inserted* into this review template before being submitted to the Southern and Eastern Border States (SEBS) committee for review. Where a formal legal review is required, it will be at the Sponsor's expense. A quote for the initial legal review will be obtained and forwarded to the Sponsor for consideration. Please provide the invoicing details below **as legal review will not commence until this information is provided.**

Sponsor and Title of submission: [sponsor name] and if applicable, [study-related wording]

Organisation (applicable to CRO CTRA only): [name]

Local Sponsor (applicable to CRO CTRA only): [name], [mailing address], [email], [phone]

Contract to which these proposed amendments apply (delete those that do not apply):
Standard CTRA, CRO CTRA, CRG CTRA, Phase IV CTRA, MTAA CIRA

Are there pre-agreed clauses already in place for this Sponsor, for use with this contract? **Yes / No**
(Please check with your legal team or contact each State Health Department)

If "Yes", please explain why the previously agreed clauses are not being used:

Are these amendments specific for a single study or use for multiple studies? [Study specific] [Multiple studies]

Title of submission: [study specific amendments only]

Date of Submission to SEBS:
{submit the template in an MS Word doc so feedback may be incorporated in the one document}

Sponsor name and signature: _____ **Date:** _____
(Must be the signatory to the MA CTRA).

Invoicing details for Sponsor:

Company Name:		ABN:	
Company Address:		Contact Person:	
		Email:	

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Guidance for Amendments to the Medicines Australia template Clinical Trial Research Agreements (CTRAs)

The New South Wales, Queensland, Victorian and South Australian Health Departments (the SEBS States), together with Medicines Australia, have developed four standard Clinical Trial Research Agreements (CTRAs) in order to provide template agreements that are fair and reasonable for both parties and provide certainty of application in the commercial trial environment. Some of the individual clauses have been the subject of long negotiation through this process.

The standard CTRAs can be executed without the need for any amendments via Schedule 7. This is preferable for SEBS jurisdictions, as there will be no requirement to involve the SEBS Committee, and SEBS Institutions can accept the unmodified CTRAs without requiring further legal review and therefore imposing further delays.

The SEBS Committee will consider contract amendments that are intended to accommodate, as far as possible, company-specific clauses that clarify or add to the CTRAs. However, the SEBS Committee will not accept amendments that:

- are clearly contrary to, or attempt to modify, the core provisions of the CTRAs;
- seek to delete or substantially modify the essential clauses of the CTRAs. These include the provisions surrounding Publication, Confidentiality, Intellectual Property, Governing Law and Termination;
- merely restate (or "wordsmith") the existing provisions of the CTRAs;
- seek to override the applicability of the CTRAs;
- are contrary to government insurance arrangements or seek to require the Institution to have certain types of insurance. All Public Health Institutions in Australia have standard insurance arrangements that apply to the whole of the Government sector for each State;

The SEBS States have adopted the Medicines Australia indemnity position set out in the standard Medicines Australia Forms of Indemnity. No amendments to these Forms of Indemnity will be accepted.

The Medicines Australia CTRAs, in alignment with TGA regulation, require the Sponsor of a trial to be an Australian legal entity. Accordingly, and to minimise the legal risk on behalf of its Institutions, SEBS Committee policy is to agree only to Australian legal entities as contracting parties in any CTRA they negotiate. This includes not accepting proposed amendments to the CRO CTRA that seek to include the international Organisation as a principal contracting party in a tripartite arrangement. The SEBS Committee has agreed to standard wording for the extension of third party beneficiary rights to international Organisations.

The agreed wording is available on the Medicines Australia website:
http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/

Template Field Instructions:
Current Clause: Copy and paste into this field the relevant section of the current CTRA clause (including the clause numbering) you wish to amend.
Proposed Amendment: Insert into this field the proposed wording (including the clause numbering) exactly as you wish it to appear in the final Schedule 4/7.
Sponsor Justification: Please provide in this field the rationale for why you wish to use the proposed amendment in favour of the current clause.
Review Response: Leave this field blank for SEBS to provide a response to your proposed amendments following its review.

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Current Clause	Proposed Amendment	Sponsor Justification	Review Response