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| **APPLICATION FORM FOR CONTRACT AMENDMENT(S)** |
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| The Sponsor/Local Sponsor is responsible for completion of this review template. All proposed amendments to the suite of Clinical Trial/Clinical Investigation Research Agreements must be inserted into this review template before being submitted to the Southern and Eastern Border States (SEBS) panel for review. Where a formal legal review is required, it will be at the Sponsor/Local Sponsor’s expense. A quote for the initial legal review will be obtained and forwarded to the Sponsor/Local Sponsor for consideration. **Please provide the invoicing details below as legal review will not commence until this information is provided.****Submit to:** MOH-SEBS@health.nsw.gov.au |
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| **SECTION A: SUBMISSION CONTACT POINT** |
|  |  |  |  |
| Company/Business |  | ABN: |  |
|  |  |  |  |
| Business Address: |  |
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| Contact Person: |  |
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| Email Address: |  | Phone Number: |  |
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| Email copy to: | Email Address |
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| Invoicing Details | Invoices are to be made out to: |
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| **SECTION B: STUDY DETAILS** |
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| Are the amendments for a specific single study or for multiple studies? | Single [ ]  | Multiple[ ]  |
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| If single study, enter the Study title |  |
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| Any additional Information |  |
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| **SECTION C: CONTRACT DETAILS** |
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| Contract type to which requested amendments will apply | Choose an item. |
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| Name of Choose an item. |  |
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| Name of Organisation | *If applicable* |
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| Are there pre-agreed clauses already in place for this Sponsor? | Yes [ ]  | No[ ]  |
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| If “Yes”, please explain why the clauses aren’t being used |  |
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| **SECTION D: APPLICATION ENDORSEMENT** |

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| Date of Submission to SEBS Panel | Select date |
| Sponsor Signatory Name |  |
| Sponsor Signatory Role |  |
| Signature  | *Print Name or insert signature (do not PDF document)* |

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| **DETAILS & INSTRUCTIONS** |
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| The New South Wales, Queensland, Victorian, Tasmania and South Australian Health Departments (the SEBS States), together with Medicines Australia and Medical Technology Association of Australia, have developed standard Clinical Trial Research Agreements (CTRAs) and Clinical Investigation Research Agreements (CIRAs) in order to provide template agreements that are fair and reasonable for both parties and provide certainty of application in the commercial trial environment in the jurisdictions. Some of the individual clauses have been the subject of long negotiation through this process.The SEBS panel will consider contract amendments that are intended to accommodate, as far as possible, company-specific clauses that clarify or add to the CTRAs/CIRAs. However, the SEBS panel will not accept amendments that:* are clearly contrary to, or attempt to modify, the core provisions of the CTRAs/CIRAs;
* 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/CIRAs;
* seek to override the applicability of the CTRAs/CIRAs;
* 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 and Medical Technology Association of Australia CIRAs, 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 panel 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/CIRA that seek to include the international Organisation as a principal contracting party in a tripartite arrangement. The SEBS panel 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** |
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| Current Clause | Copy and paste into this field the relevant section of the current CTRA/CIRA clause (including the clause numbering) you wish to amend. |
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| Proposed Amendment | Insert into this field the proposed wording exactly as you wish for it to appear in the final Schedule 4/7. Ensure you use highlights/tracked changes to display the differences from the original clause to the proposed new clause. Should this not be included, your application will be sent back to be corrected. |
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| Applicant Justification | Please provide in this field the rationale for why you wish to use the proposed amendment in favour of the current clause. |
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| SEBS Panel Response | Leave this field blank for SEBS to provide a response to your proposed amendments following its review. |

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| **AMENDMENTS** |
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| **EXAMPLE FOR MA CTRA STANDARD – FOLLOW AS DEMONSTRATED** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| 16.1 A notice, consent, approval or other communication (each a **notice**) under this Agreement must be:(1) delivered to the party’s address; or(2) sent by pre-paid mail to the party’s address; or(3) transmitted by facsimile to the party’s address. | 16.1 A notice, consent, approval or other communication (each a **notice**) under this Agreement must be:(1) delivered to the party’s address; or(2) sent by pre-paid mail to the party’s address; or(3) transmitted by facsimile or email to the party’s address. | Reviewed at September Meeting: Approved |
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| *Applicant Justification* | *The Sponsor is requesting to send notices under the Agreement via email.* |

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| **1** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| *Applicant Justification* |  |

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| **2** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| *Applicant Justification* |  |

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| **3** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| *Applicant Justification* |  |

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| **4** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| *Applicant Justification* |  |

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| **5** |
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| Current Clause | Proposed Amendment | SEBS Panel Response |
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| *Applicant Justification* |  |