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 Sponsors 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.**

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

**Organisation or Sponsor: [name], [mailing address], [email], [phone]**

**Local Sponsor: [name], [mailing address], [email], [phone]**

**Contract to which these proposed amendments apply *(delete those which do not apply)*:**

Standard CTRA, CRO CTRA, CRG CTRA, (Phase IV CTRA), MTAA CIRA

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

**Date of Submission to SEBS:**

**Are there pre-agreed clauses already in place for this Sponsor, for use with this contract? Y / N *(Please check with your legal team or the Medicines Australia website)***

**If “Yes”, please explain why the previously approved clauses are not being used:**

**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:

| **Current Clause** | **Proposed Amendment** | **Sponsor Justification** | **Review Response** |
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