Review of new and existing pre-agreed sponsor specific clauses for standard Medicines Australia Clinical Trial Research Agreements

Approved Process for Queensland Health, New South Wales Ministry of Health and Department of Health Victoria.

Rationale: To standardise, streamline and circumvent unnecessary duplication in the review of sponsor specific clauses for use in Clinical Trial Research Agreements (CTRAs) agreed by the Southern and Eastern Border States:

a) Schedule 7 of Standard Medicines Australia CTRA for Commercially Sponsored Trials;
b) Schedule 7 of Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor;
c) Schedule 7 of Standard Medical Technology Association of Australia CTRA; and
d) Schedule 4 of Standard Collaborative or Cooperative Research Groups CTRA.

Scope: This process only applies to the review of new and amendments to existing pre-agreed Sponsor specific clauses submitted for consideration, in participating states, for use in the standard CTRAs. Sponsors will not be required to submit previously agreed clauses for re-review.

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 Services / Area Health Service / etc]

Review process:

Step 1: Sponsor prepares a submission for review using the approved Review Template. Go to: http://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp. Where appropriate, the proposed clause must reference the relevant standard CTRA 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 representative.

**Step 4:** The participating states will notify the Sponsor of the final agreed clauses with a version number and date, and which of the standard CTRAs for which they are to be used.

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amendments to pre-agreed clauses are re-reviewed, the sponsor will be notified that the previously agreed clauses are superseded and replaced by the new agreed clauses, but that existing contracts using the superseded clauses are valid until the end of that contract.

**Step 5:** The agreed clauses will be distributed to all jurisdictions [Institutions / Health Services / Area Health Services / etc] within 3 business days of the sponsor being notified [as per Step 4].

**Contact Details:**

Submissions and queries relating to review of schedule 4/7 clauses should be made to:

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