SEBS Guidance - Schedule 4 & 7 Special Conditions to a Clinical Trial Research Agreement

Overview

The South Eastern Border States (SEBS Committee) is comprised of NSW, QLD, VIC, SA and TAS Health Departments, and together with Medicines Australia have developed five Clinical Trial Research Agreements (CTRAs). From time to time, sponsors may wish to make changes to the body of the CTRAs. To make changes to the template, they will need to submit a SEBS application. Amendments to the body of the CTRA are to be placed within Schedule 4 (CRG/Phase IV templates) and Schedule 7 (Standard & CRO templates).

If no amendments are being sought to any of the template CTRAs a SEBS review is not required. The SEBS Committee will consider CTRA amendments that are intended to accommodate (to an extent) company specific clauses that clarify or add to the CTRA. Please note that SEBS will not accept amendments that:

- Are clearly contrary to, or attempt to modify, the core provisions of the CTRAs;
- Seek or 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 arrangements that apply to the whole of the Government sector for each state.

Should you wish to make an amendment to submit to the SEBS Committee the template is available on the Medicines Australia website, found here.

Contact Points for SEBS Committee

- **Phone:** (02) 9461 7389
- **Email:** MOH-SEBS@health.nsw.gov.au

Please forward all contract variation requests (on the SEBS template) to the above email and the SEBS secretariat will appoint a Committee Member as the liaison officer for that request.

Meeting Dates SEBS Committee

Submission deadlines and meeting dates for the SEBS Committee are available on the Medicines Australia website located here.

Review Process

Step 1
Sponsor/Local Sponsor/CRG prepares a submission for review using the SEBS template and submits to the SEBS email address.
Step 2
Application is assigned to a meeting date and SEBS secretariat appoints a Committee Member/State/Jurisdiction as the liaison officer for the request.
Step 3
The application is jointly discussed at the meeting.
Step 4
Committee Member liaises with Sponsor/Local Sponsor/CRG to advise the outcome of the application.
Step 5
If the Sponsor/Local Sponsor/CRG is accepts the SEBS clauses, an approval letter is issued from SEBS jurisdictions to endorse the clauses.