

## Statement of Purpose for the Southern Eastern Border States (SEBS) Panel

### Representation

The Southern Eastern Border States (SEBS) panel has representatives from the health departments of New South Wales, Queensland, South Australia, Tasmania and Victoria. SEBS works to standardise, as far, as possible, the terms and conditions of the Medicines Australia Clinical Trial Research Agreements (CTRAs) in an effort to streamline the administrative management of contracts for sponsors and Health Services organisations who are parties to the agreements.

### Process for Submission to SEBS for Schedule 7 or 4 Special Conditions

The template CTRAs can be executed without the need for any amendments via Schedule 7 (or Schedule 4 in the case of the CRG, Phase IV CRO and Phase IV templates). This is preferable for SEBS jurisdictions, as there will be no requirement to involve the SEBS panel, and SEBS Institutions can accept the unmodified CTRAs without requiring further legal review and therefore imposing further delays.

The SEBS panel will consider CTRA amendments that are intended to accommodate, as far as possible, company-specific clauses that clarify or add to the CTRAs. However, the SEBS panel 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; and/or
- involve the Medicines Australia forms of indemnity that apply to commercially sponsored research.

A request template for amendment of a CTRA has been developed by the SEBS panel, which is available on the Medicines Australia [website](#).

The completed template to request CTRA Schedule 7 or 4 special conditions should initially be submitted to the nominated representative. One jurisdiction member will be appointed as the liaison officer for each request. The Sponsor/Local Sponsor requesting the contract variation will be informed that a jurisdiction representative will be in contact.

The SEBS panel meets monthly to consider the CTRA variation requests. These should be submitted by COB on the Monday 9 days prior to the meeting. Meetings are held on the Wednesday of the following week, to ensure that the request can be included on the panel's agenda.

## **SEBS Deliberation**

The SEBS panel will only provide advice on non-legal issues that relate to consistency with the content of CTRAs.

If the requesting party requires changes that need legal analysis or advice, SEBS will notify and ask the requesting party to allow SEBS to seek legal advice from a body that has relevant experience and has declared that no conflict of interest exists.

The requesting party may accept the quotation and payment for legal review or not. If accepted the requesting party will inform SEBS to proceed to legal review.

The legal firm engaged by a SEBS representative will then provide review of the SEBS submission and advice to SEBS

It is the sole responsibility of the requesting party to pay for legal advice directly to the legal firm engaged to do the work. The requesting party will be responsible for payment of any subsequent legal advice as agreed. Subsequent consideration by both SEBS and the requesting party will occur until a mutual agreement is reached or not.

An agreed schedule 7 or 4 will be included in a compiled list of special conditions held by each member jurisdiction. A formal letter to communicate the agreed schedule will be sent to the requesting party by each jurisdiction, separately.

Each jurisdiction will provide the compiled schedule 7 and 4 listing to the Research Governance Office at each health service.

## **Non-binding Process for Sponsors and Other Requesting Parties**

It will be entirely the choice of the Sponsor/Local Sponsor or other commercial party to use the SEBS centralised schedule 7 or 4 special conditions review process.

A Sponsor or other commercial party may choose to negotiate schedule 7 or 4 special conditions individually at each public health organisation that will conduct the research.