Clinical Trial Research Agreements

Note: These pages are being updated and revamped in preparation for the release and implementation of the Research Governance Policy Framework - please be aware that information may be incomplete or be a placeholder for a future/final version. If you need any assistance please contact research.governance@health.tas.gov.au.

Medicines Australia and Medical Technology Association of Australia

Tasmania endorses and encourages the Medicines Australia Clinical Trial Research Agreement (CTRAs) and the Medical Technology Association of Australia Clinical Intervention Research Agreements (CIRA) standardised research agreements for use within the Tasmanian public health services.

Southern Eastern Border States (SEBS) panel

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 public health service organisations who are parties to the agreements. For further information or to submit an application for amendment refer to the Medicines Australia website.

Access to SEBS Approval Clause Letters is available for authorised DoH/THS staff, contact Marissa Bastion at research.governance@health.tas.gov.au.

Tasmania Specific Clauses

Treasurer's Instruction C-1, *Contracts – Disclosure and Confidentiality in Government Contracting*, issued under the *Financial Management Act 2016* (Tas) ("TI C-1") prohibits the inclusion of confidentiality provisions in contracts where the Tasmanian Crown is a party unless the Head of Agency (HoA) grants approval. This prohibition applies only to the terms and conditions of the contract itself. The purpose of this policy is to not unduly fetter public scrutiny of contracts.

The Medicines Australia CTRAs and the Medical Technology Association of Australia CIRA do not contain confidentiality provisions. Tasmanian CTRAs have amendments inserted at 'Special Conditions' (either Schedule 4 or Schedule 7 depending upon the contract type) to provide clarity and ensure full compliance with TI C-1.

Pursuant to Section 1.2 of TI C-1 a confidentiality provision may be sought. The Sponsor must make application in writing to the Department of Health (the Department) requesting the contract be confidential and outlining the sections of the contract that are to be made confidential or demonstrating that disclosure is commercially sensitive to the contracting party. The request for approval from the exemption needs to go before the Procurement Review Committee (PRC), who if in support then makes a recommendation to the HoA. The application is to be forwarded to Dr Jodi Glading, Deputy Chief Medical Officer, email: Jodi.johnson-glading@health.tas.gov.au.

The following CTRAs contain the Tasmanian Special Conditions:

- Standard MA CTRA (8-March-2017) with Tasmanian Special Conditions
- Collaborative Research Group MA CTRA (8-March-2017) with Tasmanian Special Conditions
- Contract Research Organisation Acting as Local Sponsor MA CTRA (8-March-2017) with Tasmanian Special Conditions
- Phase 4 MA CTRA (8-March-2017) with Tasmanian Special Conditions
- Phase 4 Contract Research Organisation Acting as Local Sponsor MA CTRA (8-March-2017) with Tasmanian Special Conditions
- Standard MTAA CIRA (May 2017 - Amended 2018) with Tasmanian Special Conditions

Current Research in Tasmania

A non-exhaustive list of research activities being conducted in Tasmania. To have your study included, please contact research.governance@health.tas.gov.au.

This document is under review, please contact us for more information.