



THE UNIVERSITY OF
MELBOURNE

Understanding and using the Medicine's Australia Clinical Trial Research Agreement

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Clinical Trial Research Agreements

- Medicines Australia have developed five Clinical Trial Research Agreements (CTRAs), that are available for use by any sponsor and/or institution for specific clinical trial scenarios.
- Clinical Trial Research Agreement – Medicines Australia Standard Form
- Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor
- **Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies**
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines)
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines) Contract Research Organisation acting as the Local Sponsor



Purpose and use of the CTRA

- Wide use across Australian universities and hospitals.
- Accepted template that does not often require amendments.
- Standard variations for certain grant funding.
- Clearly outlines responsibilities/obligations of the Institution (Study Site, through the Principal Investigator) and CRG (University).
- Acknowledges that the study will be conducted in the spirit of cooperation and collaboration.



Structure of the CTRA – the study

- 1. Interpretation

1. **INTERPRETATION**

1.1 In this Agreement:

Adverse Event has the meaning given in the TGA document “Access to Unapproved Therapeutic Goods – Clinical Trials in Australia” (October 2004) or replacement.

Affiliate means any company which (directly or indirectly) controls, is controlled by or is under common control with the CRG.

Agreement means this Agreement, including all the Schedules.

- 2. The Study

2. **THE STUDY**

2.1 The parties must comply with, and conduct the Study in accordance with the Protocol and any conditions of the Reviewing HREC. In addition the parties must comply with the following, as applicable:

- (1) any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;
- (2) the requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or its replacement and any



Structure of the CTRA – Obligations

- 3. Principal Investigator

3. PRINCIPAL INVESTIGATOR

3.1 Role of Principal Investigator

The Institution has authorised the Principal Investigator as the person responsible on a day to day basis for the conduct of the Study at the Study Site. The Principal Investigator does not have authority on behalf of the Institution to amend this Agreement or the Protocol.

3.2 Liability for Principal Investigator

- 4. Institution Obligations and Responsibilities

4. INSTITUTION OBLIGATIONS AND RESPONSIBILITIES

4.1 If the Principal Investigator leaves the Institution or otherwise ceases to be available then:

- (1) the institution must notify the CRG as soon as is practical;
- (2) the Institution must consult with the CRG and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both parties; and



Structure of the CTRA – Obligations and operations

- 5. CRG Obligations and Responsibilities

5. CRG OBLIGATIONS AND RESPONSIBILITIES

5.1 Prior to the Agreement being executed, the CRG or its designate must provide the Principal Investigator, and through the Principal Investigator the Institution and the Reviewing HREC, with all current and relevant information regarding the Investigational Product that is reasonably available to the CRG and required to justify the nature, scope and duration of the Study.

- 6. Payments
- 7. Provision of Equipment and Software
- 8. Investigational Product and Product Liability



Structure of the CTRA – Results

- 9. Confidentiality
- 10. Privacy
- 11. Liability and Insurance
- 12. Publications
- 13. Study results and intellectual property
- 14. Term and Termination
- 15. Disputes



Structure of the CTRA – Legal requirements

- 16. Applicable law
- 17. Notices
- 18. Waiver
- 19. Variation
- 20. Assignment
- 21. Entire agreement
- 22. Further documents
- 23. Severance
- 24. Relationship of the Parties
- 25. Force Majeure
- 26. Counterparts
- 27. Conflict



Schedule 2: Payments

- Tailor as appropriate i.e. payment on per participant basis or lump sum etc.
- If instalments, include how many and the deliverable that triggers an instalment payment.

EXAMPLE 1: Instalments

“The Institution will be paid a recruitment fee of AUD\$500 (excluding GST) per Study Participant (Participant Fee). The Participant Fee will be payable in two equal instalments of AUD\$250 (excluding GST) on completion of the deliverables described below in respect of a Study Participant:

Instalment 1: Completion of electronic Case Report Form from patient screening and enrolment.

Instalment 2: Completion of electronic Case Report Form for 12 months follow up data.”

EXAMPLE 2: Single payments

“A single payment of AUD\$1000 (excluding GST) will be made on signing of this agreement to facilitate the study set up. This payment covers study set up, completion of Case Report Forms, and the preparation and submission of any required ethics amendments.”



Schedule 3: Study Protocol Identification

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Full Title: _____

Version Number: _____

Date: / / _____

List of Key attachments: _____



Schedule 4: Special Conditions

- Examples of special conditions include
 - Grant funding clauses.
 - State based amendments (relevant for Western Australia).
 - Details of linked or sub-studies.
 - Other.



Thank you