

Clinical Trial Research Agreement for Public Health Organisations (Commercial Entities)

Document Number PD2009_033

Publication date 05-Jun-2009

Functional Sub group Clinical/ Patient Services - Research

Summary This policy sets out the clinical trial research agreement that is required for use in clinical trials that are conducted in NSW public health organisations and sponsored by a commercial entity (pharmaceutical and medical device companies, and contract research organisations).

Replaces Doc. No. Clinical Research: Standard Clinical Trial Research Agreement for NSW Public Health Organisations [PD2008_039]

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, NSW Ambulance Service, NSW Dept of Health, Public Health Units, Public Hospitals

Audience Research Governance Officers, Human Research Ethics Committees, researchers, clinical, admin

Distributed to Public Health System, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals

Review date 05-Jun-2014

File No. 04/4850-7

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

CLINICAL TRIAL RESEARCH AGREEMENT FOR NSW PUBLIC HEALTH ORGANISATIONS (COMMERCIAL ENTITIES)

This Policy Directive replaces PD2008_039.

Purpose

1. This policy directive sets out the clinical trial research agreement that is required for use in clinical trials that are conducted in NSW public health organisations and sponsored by a commercial entity (pharmaceutical companies and contract research organisations).

Background

2. Each clinical trial sponsored by a commercial entity and conducted in a NSW public health organisation must be governed by a clinical trial agreement.
3. Two forms of standard clinical trial research agreement have been negotiated with Medicines Australia for use in clinical trials that take place in public health organisations:
 - a) Clinical Trial Research Agreement - Medicines Australia Standard Form; and
 - b) Clinical Trial Research Agreement – Medicines Australia Form: Contract Research Organisation acting as the Local Sponsor.
4. Both forms of standard agreement allow for inclusion of sponsor-specific operational requirements in Schedule 7 of the agreement.
5. NSW Health will, at regular intervals, review clauses for inclusion in Schedule 7 of the standard agreement for individual commercial entities that are to be used for multiple sites on an on-going basis. Research governance officers of public health organisations will be notified of clauses that have been reviewed and pre-approved by NSW Health.

Application

Clinical Trial Research Agreement – Medicines Australia Standard Form

6. Clinical Trial Research Agreement – Medicines Australia Standard Form (Commercially Sponsored CTRA) should be used when a pharmaceutical company is sponsoring a clinical trial that is to be conducted in a NSW public health organisation. The sponsoring pharmaceutical company must be an Australian entity.
7. Commercially Sponsored CTRA should also be used for clinical trials where a pharmaceutical company subcontracts another party (for example, a contract research organisation) but remains as the sponsor of that trial.

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8. Commercially Sponsored CTRA can be downloaded from the Medicines Australia website: <http://www.medicinesaustralia.com.au/pages/page39.asp>

NSW Health will inform research governance officers of public health organisations when a new version of Commercially Sponsored CTRA that has been approved by NSW Health becomes available.

Clinical Trial Research Agreement – Medicines Australia Form: Contract Research Organisation acting as the Local Sponsor

9. Clinical Trial Research Agreement – Medicines Australia Form: Contract Research Organisation acting as the Local Sponsor (CRO Sponsored CTRA) should be used when a contract research organisation engaged by a pharmaceutical company is sponsoring a clinical trial that is to be conducted in a NSW public health organisation. The sponsoring contract research organisation must be an Australian entity.

10. CRO Sponsored CTRA can be downloaded from the Medicines Australia website: <http://www.medicinesaustralia.com.au/pages/page39.asp>

NSW Health will inform research governance officers of public health organisations when a new version of CRO Sponsored CTRA that has been approved by NSW Health becomes available.

Review of clinical trial research agreements

11. Where a commercial entity uses the Commercially Sponsored CTRA or CRO Sponsored CTRA for a clinical trial without alteration the public health organisation should accept this agreement without further review.
12. Where a commercial entity uses the Commercially Sponsored CTRA or CRO Sponsored CTRA with the addition only of clauses in Schedule 7 that have been reviewed and pre-approved by NSW Health, the public health organisation should also accept this agreement without further legal review.
13. Public health organisations still have the ability to negotiate specific additional operational terms and conditions for particular clinical trial agreements with the sponsoring commercial entity, where required.
14. Public health organisations must obtain independent legal advice where a commercial entity:
- uses its own clinical trial agreement; or
 - uses the Commercially Sponsored CTRA or CRO Sponsored CTRA but makes non-trivial/significant alterations or addition to it other than the addition of pre-approved Schedule 7 clauses.

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This advice should be at the expense of the sponsor company.

15. Where legal advice is to be obtained in accordance with paragraph 14, the sponsor should first be informed of this policy directive and a written undertaking should be obtained from the sponsor to pay the legal costs incurred for review of the non-standard agreement.

Implementation

This policy takes effect on **1 June 2009**.

Enquiries regarding this policy should be directed to the NSW Health Research and Ethics Branch (02) 9391 9427.

Professor Debora Picone AM
Director-General