

Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)

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Functional Sub group Clinical/ Patient Services - Research

Summary 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 collaborative or cooperative research group.

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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 administration

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

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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This Policy Directive may be varied, withdrawn or replaced at any time.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 (COLLABORATIVE OR COOPERATIVE RESEARCH GROUPS)

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 collaborative or cooperative research group.

Background

2. Each clinical trial sponsored by a collaborative or cooperative research group and conducted in a NSW public health organisation must be governed by a clinical trial agreement.
3. A standard clinical trial research agreement has been negotiated for this purpose: Clinical Trial Agreement: Collaborative or Cooperative Research Group (CRG) Studies – Standard Form (CRG Sponsored CTRA).
4. CRG Sponsored CTRA allows for inclusion of sponsor-specific operational requirements in Schedule 4 of the agreement.
5. CRG Sponsored CTRA can be downloaded from the Medicines Australia website at: <http://www.medicinesaustralia.com.au/pages/page39.asp>

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

Application

6. Where a collaborative or cooperative research group uses the CRG Sponsored CTRA for a clinical trial without alteration the public health organisation should accept this agreement without further review.
7. Public health organisations still have the ability to negotiate specific additional operational terms and conditions for particular clinical trial agreements with the sponsoring collaborative or cooperative research group, where required.
8. Public health organisations should consider obtaining independent legal advice where a sponsoring collaborative or cooperative research group:
 - uses its own clinical trial agreement; or
 - uses the CRG Sponsored CTRA but makes non-trivial/significant alterations or addition to it other than the addition of operational clauses in Schedule 4.

Title: Clinical Trial Research Agreement for NSW Public Health Organisations (Collaborative or Cooperative Research Groups)

9. Where legal advice is to be obtained in accordance with paragraph 8, public health organisations should inform the sponsor of this decision first and negotiate the payment of the costs for the legal advice, acknowledging that not all CRGs will be in a position to meet the costs for legal advice.

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