

## Clinical Trial Research Agreements for Use in NSW Public Health Organisations

**Summary** This policy directive sets out the Clinical Trial Research Agreements approved for use in NSW Public Health Organisations.

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**Distributed to** Public Health System, NSW Ambulance Service, Ministry of Health

**Audience** Research office staff; researchers; Heads of Depts hosting and supporting research

## CLINICAL TRIAL RESEARCH AGREEMENTS FOR USE IN NSW PUBLIC HEALTH ORGANISATIONS

### PURPOSE

This policy directive sets out the Clinical Trial Research Agreements approved for use in NSW Public Health Organisations.

### MANDATORY REQUIREMENTS

Public Health Organisations must comply with the processes outlined in this policy directive for the use and review of approved Clinical Trial Research Agreements, for clinical trials to be conducted at sites under their control.

### IMPLEMENTATION

Chief Executives are required to ensure that requirements outlined in this policy directive are communicated to all staff involved in conducting clinical trials at sites under their control.

Research Governance Officers are required to:

- Follow the processes outlined in this policy directive for reviewing Clinical Trial Research Agreements (section 5); and
- Provide advice to investigators and sponsors seeking to submit an approved Clinical Trial Research Agreement, in accordance with this policy directive.

### REVISION HISTORY

Version	Approved by	Amendment notes
May 2011 (PD2011_028)	Deputy Director-General Population Health	Issue of policy which replaces <i>Clinical Trial Research Agreement for Public Health Organisations (Commercial Entities)</i> (PD2009_033) and <i>Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)</i> (PD2009_032)
June 2009 (PD2009_033)	Deputy Director-General Population Health	Policy replacing Clinical Research: Standard Clinical Trial Research Agreement for NSW Public Health Organisations PD2008_039
June 2009 (PD2009_032)	Deputy Director-General Population Health	New policy 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

### ATTACHMENTS

1. Clinical Trial Research Agreement for use in NSW Public Health Organisations: Procedures

***Clinical Trial Research Agreements for use in NSW  
Public Health Organisations***



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**Issue date:** May 2011

PD2011\_028: Attachment 1

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## 1 Background

### 1.1 About this document

Each clinical trial to be conducted at site(s) under the control of a NSW Public Health Organisation and sponsored by an entity external to that Public Health Organisation must be governed by a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial, in accordance with Policy Directive PD2010\_056 *Research - Authorisation to commence human research in NSW Public Health Organisations*.

NSW Health, together with key stakeholders, has developed a number of standard Clinical Trial Research Agreements.

This document sets out the approved Clinical Trial Research Agreements for use in Public Health Organisations and outlines the processes to be employed for the use and review of these Agreements.

### 1.2 Key definitions

**Principal Investigator** is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the project for site authorisation.

**Public Health Organisation** as defined by section 7 of the *Health Services Act 1997* (NSW) is a local health network, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services.

**Research Governance Officer** is the individual appointed within the Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

**Site** is a facility, location or service where the research is being conducted.

**Site authorisation** is the authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.

**Site-specific assessment** is a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

**Sponsor** of a clinical trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial.

### 1.3 Relationship to other NSW Health policies and guidelines

This policy directive should be read in conjunction with the following NSW Health policy directives and guidelines.

Policy Directive PD2010\_056 *Research - Authorisation to commence human research in NSW Public Health Organisations*

Policy Directive PD2011\_006 *Clinical Trials: Insurance and Indemnity*

Guideline GL2011\_001 *Research Governance in NSW Health Public Health Organisations*

## **2 Approved Clinical Trial Research Agreements**

Four Clinical Trial Research Agreements (CTRAs) have been approved for use in NSW Public Health Organisations.

1. Standard Medicines Australia CTRA for Commercially Sponsored Trials;
2. Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor;
3. Standard Medical Technology Association of Australia CTRA; and
4. Standard Collaborative or Cooperative Research Groups CTRA.

The CTRAs are designed for use by different sponsors of clinical trials: pharmaceutical companies; contract research organisations; medical device companies; and collaborative/cooperative research groups.

The organisation that executes the CTRA as sponsor must provide indemnity and evidence that it is covered by requisite insurance arrangements as set out in the relevant CTRA and which meet the requirements of PD2011\_006 *Clinical Trials: Insurance and Indemnity*.

For clinical trials to be conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration, the organisation that executes the CTRA as sponsor should also be identified on the CTN/CTX Form as sponsor.

### **2.1 Standard Medicines Australia CTRA for Commercially Sponsored Trials**

Standard Medicines Australia CTRA for Commercially Sponsored Trials should be used when a pharmaceutical company is sponsoring a clinical trial that is to be conducted at site(s) under the control of Public Health Organisations.

The sponsoring pharmaceutical company must be an Australian entity. This could be an Australian pharmaceutical company or an Australian subsidiary of an international pharmaceutical company.

Standard Medicines Australia CTRA for Commercially Sponsored Trials should also be used when a pharmaceutical company subcontracts another party (for example, a contract research organisation) to undertake certain clinical trial related activities/responsibilities but remains the sponsor of that trial.

The CTRA can be downloaded from the Medicines Australia website: <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>

### **2.2 Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor**

Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor should be used when a contract research organisation is

sponsoring a clinical trial that is to be conducted at site(s) under the control of Public Health Organisations.

The sponsoring contract research organisation must be an Australian entity. This could be an Australian contract research organisation or an Australian subsidiary of an international contract research organisation.

The CTRA can be downloaded from the Medicines Australia website: <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>

### **2.3 Standard Medical Technology Association of Australia CTRA**

Standard Medical Technology Association of Australia CTRA should be used when a medical device company is sponsoring a clinical trial that is to be conducted at site(s) under the control of Public Health Organisations.

The sponsoring medical device company must be an Australian entity. This could be an Australian medical device company or an Australian subsidiary of an international medical device company.

Standard Medical Technology Association of Australia CTRA should also be used when a medical device company subcontracts another party (for example, a contract research organisation) to undertake certain clinical trial related activities/responsibilities but remains the sponsor of that trial.

The CTRA can be downloaded from the Medical Technology Association of Australia website: <http://www.mtaa.org.au/pages/page283.asp>

The CTRA uses the term “clinical investigations” instead of “clinical trials”.

### **2.4 Standard Collaborative or Cooperative Research Groups CTRA**

Standard Collaborative or Cooperative Research Groups CTRA should be used when a collaborative or cooperative research group is sponsoring a clinical trial that is to be conducted at site(s) under the control of Public Health Organisations, and which satisfies the following criteria:

1. The research addresses relevant clinical questions and not pharmaceutical/device company or other commercial needs;
2. The collaborative or cooperative research group declares the nature of any sponsorship from any entity, including a pharmaceutical/device company, that may benefit commercially from the research outcomes; and
3. The collaborative or cooperative research group is the primary author and custodian of the clinical trial protocol.

Depending on the nature of commercial entity sponsorship to the collaborative or cooperative research group, Public Health Organisations may determine that another form of CTRA is more appropriate for the trial.

The sponsoring collaborative or cooperative research group must be an Australian entity. This could be an Australian collaborative or cooperative

research group or an Australian division of an international collaborative or cooperative research group.

The CTRA can be downloaded from the Medicines Australia website: <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>

### **3 Sponsor specific clauses**

The CTRAs are designed to allow inclusion of sponsor specific clauses through the nominated Schedule. This is at Schedule 4 for Standard Collaborative or Cooperative Research Groups CTRA and Schedule 7 for other CTRAs.

The Schedule is to be used for the introduction of sponsor specific operational requirements that are required to be executed in order to allow for the conduct of the clinical trial.

The Schedule should not be used to substantially amend the CTRA, or to introduce provisions that contradict or otherwise undermine the substantive provisions or intent of the CTRA, including:

- Drafting amendments;
- Clauses that seek to override the applicability of the CTRA;
- Clauses that are contrary to Government insurance arrangements;
- Clauses seeking to impose additional indemnities on parties or lessen an existing indemnity; and
- Clauses that are clearly contrary to the core provisions of the CTRA (e.g. publication, confidentiality, IP and termination provisions; compliance with foreign legal requirements).

### **4 Joint review of sponsor specific clauses**

NSW Department of Health, at regular intervals, will review sponsor specific clauses for inclusion in the nominated Schedule of CTRAs.

This section outlines the process for a joint review that the Department will undertake, together with Queensland Health and Victoria Managed Insurance Authority (VMIA), for sponsor specific clauses.

#### **4.1 Purpose**

The purpose of the joint review is to standardise, streamline and circumvent unnecessary duplication in the review of sponsor specific clauses for use in CTRAs approved by NSW Health, Queensland Health and VMIA.

#### **4.2 Scope**

This process only applies to the review of new and amendments to existing pre-approved sponsor specific clauses submitted for consideration, in participating states, for use in approved standard CTRAs.

Sponsors will not be required to submit previously approved clauses for re-approval.

The process covers review of clauses for on-going use by the sponsor for clinical trials conducted in participating states, and for one-off multi-site studies that involve at least one of the participating states.

The process does not cover review of sponsor specific clauses for one-off single site studies. In these instances, clauses are to be negotiated directly with the relevant site.

### **4.3 Review process**

The following steps are involved in the joint review:

1. Sponsor prepares a submission for review using the standard pro forma (see Annex 1). Where appropriate, the proposed clause must reference the relevant standard CTRA clause that it will replace or amend. A justification must be provided for the inclusion of each of the proposed clauses.
2. Sponsor submits the completed pro forma to the relevant authority in any one of the participating jurisdictions.
3. The participating states will jointly review the submitted clauses. The timeline and cost of review will be dependent on the number and complexity of the clauses submitted for review. The sponsor will be provided with an estimate of timeline and cost before the review starts. During the review, if necessary, the states' legal representative will communicate directly with the sponsor's legal representative.
4. The participating states will notify the sponsor of approved clauses with a version number and date, and which of the standard CTRA they are approved for.

Where amendments to pre-approved clauses are approved, the sponsor will be notified that the previously approved clauses are superseded and replaced by the new approved clauses, but that existing contracts using the superseded clauses are valid until the end of that contract.

5. The approved clauses will be distributed to all jurisdictions, including all NSW Health Research Governance Officers within 3 business days of the sponsor being notified as per Step 4.

### **4.4 Contact details**

Submissions and queries relating to review of schedule 4/7 clauses in NSW Health should be made to:

Research, Ethics and Public Health Training Branch  
NSW Department of Health  
Email: [healthethics@doh.health.nsw.gov.au](mailto:healthethics@doh.health.nsw.gov.au)  
Phone: 02 9391 9427  
Fax: 02 9391 9232

## **5 Review of Clinical Trial Research Agreements by NSW Public Health Organisations**

The CTRA must be submitted to the Research Governance Officer responsible for the proposed trial site by the Principal Investigator, as part of an application for site specific assessment, in accordance with Policy Directive PD2010\_056 *Research - Authorisation to commence human research in NSW Public Health Organisations*

Research Governance Officers should initiate review of CTRAs at the earliest possible opportunity, following submission by the Principal Investigator.

Where the CTRA is submitted without any alteration, Public Health Organisations should accept this Agreement without further review.

Where the CTRA is submitted with the addition only of sponsor specific clauses that have been reviewed and approved by NSW Department of Health, Public Health Organisations should also accept this Agreement without further review.

Public Health Organisations, however, have the ability to reject any sponsor specific clauses reviewed and approved by the Department for operational purposes. Public Health Organisations also have the ability to negotiate specific additional operational terms and conditions for a CTRA for a particular trial.

Public Health Organisations should obtain independent legal advice where the sponsor:

- uses an agreement other than one of the approved CTRAs; or
- uses the CTRA but makes non-trivial/significant alterations or additions to it other than the addition of sponsor specific clauses that have been reviewed and approved by NSW Department of Health.

Where independent legal advice is to be obtained, the sponsor should first be informed of the pending review.

Where the sponsor is a commercial entity, the legal advice should be at the expense of that commercial entity. A written undertaking should be obtained from the sponsor to pay the legal costs incurred for the review of the submitted agreement.

Where the sponsor is a collaborative or cooperative research group, Public Health Organisations should negotiate the payment of the costs for the legal advice with the sponsor, acknowledging that not all collaborative or cooperative research groups will be in a position to meet these costs.

Where the Public Health Organisation seeks legal advice, it has the absolute discretion, subject to Department of Health policies, to nominate its own legal advisors notwithstanding that the cost of such legal advice is to be met by the commercial sponsor.

## Annex 1: Eastern Border States schedule 4/7 pre-approval submission

Sponsor: [name]  
 Contact: [name, title, and contact details of person to whom general correspondence should be addressed]  
 Legal Rep.: [acting on behalf of the sponsor - if different from above – name, title and contact details of person to whom queries should be sent]  
 Submitted: [dd/mm/year – to be marked by the Sponsor]  
 Received: [dd/mm/year – to be marked by an EBS representative]

Select the standard Clinical Trial Research Agreement (CTRA) to which the proposed clauses apply:

- Standard Medicines Australia CTRA for Commercially Sponsored Trials
- Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor
- Standard Medical Technology Association of Australia CTRA
- Standard Collaborative or Cooperative Research Groups CTRA

	Sponsors' proposed clause	Referred Clause in Standard Agreement	Sponsors' Justification	EBS Comment
<b>Sponsor Name</b>	<p><i>Please insert the proposed clause.</i></p> <p><i>If the proposed clause is an amendment of an existing clause in the CTRA, please use track changes (i.e. strikethrough for deletions and/or underling and bold for new additional words or sentences) to allow for easy comparisons</i></p>	<p><i>Please insert in full the respective CTRA clause that the proposed clause is to replace or amend</i></p>	<p><i>Please provide justification for the proposed change in relation to:</i></p> <ul style="list-style-type: none"> <li>• <i>Why the need for a new clause</i></li> <li>• <i>What deficiencies the new clause addresses</i></li> <li>• <i>How the new clause enhances the CTRA overall</i></li> <li>• <i>How the amended clause differ, in intent, from the existing clause in the CTRA</i></li> <li>• <i>Whether the clause is a restatement of GCP requirements, and if so why it is necessary to be included.</i></li> </ul> <p><i>Please attach a separate page if required</i></p>	