

Policy

Guideline

Guideline for the Use of Clinical Trial Agreements in Research

Objective file number: 2009-00540

Policy developed by: Health Reform Division

Next review due: 1 January 2014

Summary This Guideline outlines the requirements for the usage of Clinical Trial Agreements for clinical research trials being undertaken across the South Australian public health system.

Keywords Clinical trials, research governance, clinical research, research management.

Policy history Is this a new policy? **N**
Does this policy amend or update an existing policy? **Y**
Does this policy replace an existing policy? **N**
If so, which policies?

Applies to All SA Health Portfolio

Staff impact All Staff

PDS reference G0092

Version control and change history

Version	Date from	Date to	Amendment
1.0	01/06/2010	20/03/2012	Original version
1.1	21/03/2012	Current	Version 1.1



Government
of South Australia

SA Health

1. Introduction

SA Health is committed to supporting high quality health and medical research across the South Australian public health system. Clinical trials are an important area of research, and participation in these trials can support breakthrough medical and pharmaceutical innovations, provide participants with access to beneficial therapeutics they would not otherwise be entitled to, and strengthen research capacity in South Australia.

Clinical research trial agreements are legal agreements used to formalise the obligations and relationship between the clinical trial sponsor, investigator/s and institution where the trial is being carried out.

SA Health supports the use of four separate clinical trial agreements that have been developed for use across a range of clinical trials. This Guideline provides direction on their usage across the South Australian public health system.

2. Medicines Australia Clinical Trial Research Agreements

- Medicines Australia has developed a series of standardised clinical trial agreements to support the conduct of clinical research trials across Australia. These agreements outline the responsibilities and obligations of the clinical trial sponsor, the coordinating/principal investigator and the institution where the trial is being undertaken, with respect to the clinical trial being conducted.
- Each of these agreements addresses key requirements, including:
 - Financial considerations
 - Provision of Equipment and the Investigational Product
 - Intellectual property
 - Termination of the agreement
- The three Medicines Australia agreements supported by SA Health are:
 - Standard Clinical Research Trials Research Agreement for Commercially Sponsored Trials;
 - Standard Clinical Research Trials Research Agreement for Contract Research Organisations;
 - Standard Clinical Research Trials Research Agreement for Collaborative Research Group (CRG) Studies.
- The agreements are intended to be used in unmodified form by research sponsors and investigators, and can be accessed via the Medicines Australia website, <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>.
- Modifications or additions to the standard clauses in these agreements can be made by way of agreed Special Conditions which can be included in the schedules of the agreements (see Section 7 of the Commercially Sponsored and Contract Research Organisation agreements, and Section 4 of the CRG agreement). SA Health institutions should note that if the study sponsor proposes amendments to the standard clauses within the agreement, the institution should review these clauses and seek legal advice (where necessary) on the implications of these clauses prior to signing the agreement.

3. Clinical Oncology Society of Australia (COSA) Clinical Trial Agreement

- The COSA Clinical Trial Agreement has been developed specifically for use in oncology clinical trials involving Collaborative Research Groups (CRGs). These groups are investigator-led consortiums that undertake clinical trials independently of direct industry sponsorship.
- COSA is the peak national body that represents professionals in the field of cancer control across Australia (see <http://www.cosa.org.au>). Their Clinical Trial Agreement is comparable to the Medicines Australia agreement (Collaborative Research Group studies), and aims to provide a standard agreement to support investigator led oncology trials across Australia.
- This agreement sets out the responsibilities and obligations of the CRG with regard to the principal investigator and institution where the trial is being undertaken.
- The body of this agreement contains a standard set of clauses and is intended to be used in unmodified form, with scope to include special conditions (e.g. specific requirements of the local site/investigator) in Schedule 4 of the agreement.
- Should the CRG make additions to the standard agreement by way of Schedule 4 variations, the SA Health institution is recommended to seek advice on associated legal and risk management issues (where applicable).
- SA Health has reviewed and endorses the use of this agreement, and recommends its usage for applicable clinical trials being undertaken under the auspices of COSA at SA Health institutions and across the South Australian public health system.

4. General Comments

- SA Health endorses the use of these agreements for clinical research trials, and recommends their usage for applicable trials taking place at SA Health institutions and across the South Australian public health system.