

Clinical Trials Procedures

Section 1 - Purpose and Scope

(1) These Procedures give effect to the [Research Quality, Standards and Integrity Policy](#) and set out the University expectations of University clinical trial staff when participating in any clinical trial activity in their capacity as a University staff member or student.

(2) These Procedures supplement national and international guidelines and University Policy and Procedures that govern human research and apply to any clinical trial activity where the University is:

- a. the clinical trial Sponsor; or
- b. a participating clinical trial site; or
- c. performing a trial related function including trial management, analysis, and reporting activities.

Section 2 - Definitions

(3) The [Definitions \(Academic\) Policy](#) applies to these Procedures.

(4) For the purposes of these Procedures the following definitions also apply:

- a. Clinical trial means any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of those interventions on health-related outcomes.
- b. Clinical trial site means the location(s) where trial-related activities are conducted and / or coordinated under the Investigator's oversight.
- c. Co-ordinating Principal Investigator means the lead Researcher with over-arching responsibility for the clinical trial. This role is sometimes called Chief Investigator or, for single site trials, Principal Investigator.
- d. DVCR means Deputy Vice-Chancellor (Research).
- e. Good clinical practice (GCP) is a collective term covering internationally recognised standards for the design, conduct and reporting of clinical trials. Standards include:
 - i. [ICH E6 \(R3\) Guideline for Good Clinical Practice](#);
 - ii. [ISO 14155 Clinical Investigation of medical devices for human subjects – Good Clinical practice](#);
 - iii. [ICH E8 \(R1\), General considerations for clinical studies](#).
- f. Health related interventions means any intervention used to modify a biomedical or health related outcome, including but not limited to drugs, biologicals, herbal and natural supplements, surgical procedures, devices including certain medical types of medical software and “apps”, psychotherapeutic, educational and behavioural treatments, exercise programmes, dietary interventions and process of care changes.
- g. Health-related outcomes include any biomedical or health related measures obtained about the participants including but not limited to pharmacokinetic physiological, biological or psychological measures, changes to disease progression, quality of life changes, changes to health-related behaviours and safety outcomes including adverse events.
- h. HREC means Human Research Ethics Committee.

- i. Investigator means any researcher performing clinical trial activities.
- j. National Statement means the [Australian National Statement on Ethical Conduct in Human Research \(2025\)](#).
- k. NHMRC means the Australian National Health and Medical Research Council.
- l. Sponsor means an individual, company, institution or organisation that takes responsibility for the initiation, management and arrangement of the financing of a clinical trial. For University-sponsored investigator initiated trials, the Principal Investigator is delegated some of the sponsor roles as outlined in Schedule A Roles and Responsibilities.
- m. Staff means all persons who are academic or professional employees of the University, including full time, part time, fixed term and casual and all adjunct, visiting, emeritus and conjoint appointees who are engaged in supervisory and other research roles on behalf of the University.
- n. Student means any individual who is registered as a student at the University, irrespective of their current enrolment status in any course of study offered by or within the University.
- o. Therapeutic Goods means health related products used in humans for various reasons including managing illness or injuries, altering bodily processes, testing for various conditions and replacing or modifying body parts. Therapeutic goods include prescription medicines, medicines available over the counter in retail outlets (including pharmacies), complementary medicines such as vitamins, herbal and traditional medicines), medical devices, vaccines and other goods such as blood products and disinfectants.
- p. Trial Master File (TMF) is as defined by ICH GCP(R3) C.2 Management of Essential Records as a repository help by the sponsor and by the investigator/institution of the essential records pertaining to the clinical trial.
- q. University means Southern Cross University.

Section 3 - Roles and Responsibilities

(5) University clinical trials must be conducted to the highest standards of research and in compliance with:

- a. University policies and procedures;
- b. The relevant GCP guidelines;
- c. Applicable legislation; and
- d. All other guidelines and codes required by legal agreement, contract, or regulatory authority.

Investigators

(6) The Co-ordinating Principal Investigator is responsible for:

- a. Obtaining a Clinical Trial Sponsor;
- b. Conducting a primary risk assessment in accordance with these Procedures;
- c. Conducting initial enquiries to ensure the clinical trial is covered by adequate insurance;
- d. Applying for institutional approval;
- e. Obtaining HREC approval;
- f. Monitoring clinical trial conduct;
- g. Ensuring contracts are executed for clinical trials involving external partners and funders; and
- h. Subject to the Delegations Rule, registering the clinical trial on:
 - i. a WHO-compliant publicly assessable clinical trials registry, for example the Australian New Zealand Clinical Trials Registry ([ANZCTR](#));
 - ii. the University's clinical trial register; and
 - iii. the Therapeutic Goods Administration, in cases where Clinical Trial Notification/Clinical Trial Approval schemes are applicable.

(7) All staff involved in clinical trials must complete the appropriate Good Clinical Practice (GCP) training. Certification must be renewed every three years or within twelve months of a major guideline update.

(8) Copies of GCP certification for staff working on a clinical trial must be kept in that clinical trial's master file (TMF) and be made available on request.

Sponsor

(9) All clinical trials that University Investigators contribute to in any capacity which take place at an Australian site must have an identified Australian Sponsor.

(10) The University may act as Sponsor for an Investigator-initiated clinical trial subject to written approval by the DVCR.

(11) To be eligible for University sponsorship a clinical trial must normally meet the following criteria:

- a. The proposed Principal Investigator is a University staff member;
- b. The University is the clinical trial's funding administrator;
- c. The University will retain the clinical trial's financial, academic and reputational benefits either wholly or partially;
- d. The clinical trial will qualify for coverage under the University's clinical trials insurance policy;
- e. The clinical trial's data will be collected, stored and managed in accordance with the University's [Research Data Management Procedures](#).

(12) The University will not normally act as Sponsor for clinical trials conducted at clinical trial sites outside of Australia. In such situations, Investigators should arrange for a local sponsor in that country.

Clinical Trials Oversight Group

(13) The DVCR will establish and appoint members to a Clinical Trials Oversight Group. The Group will provide recommendations and advice to the DVCR regarding trials referred to it for consideration. The composition and functions of the Clinical Trials Oversight Group will be documented by the Terms of Reference - Clinical Trials Oversight Group.

Section 4 - Risk Assessment

(14) A risk assessment must be performed for each University clinical trial as outlined in Schedule A.

(15) The risk assessment must be performed during the clinical trial's planning stage and be continually updated during the conduct of the clinical trial. The risk assessment must consider:

- a. Risks to participants;
- b. Risks to Investigators;
- c. Risks to the University; and
- d. Legislative and regulatory compliance risks.

(16) Individual risks will vary for each trial. At a minimum, Investigators and the University must consider:

- a. Whether the clinical trial has adequate funding;
- b. The appropriateness of the proposed clinical trial sponsor;
- c. Potential risks and benefits to the University;

- d. Whether the proposed clinical trial is aligned with University values and strategy;
- e. Whether the responsible Faculty, support departments, proposed collaborators and University asset managers have agreed to support the clinical trial;
- f. Workplace health & safety responsibilities;
- g. Contractual and legal arrangements and obligations; and
- h. Insurance and Indemnity responsibilities.

(17) The potential benefits of the clinical trial must outweigh the potential risks for any clinical trials conducted by University Investigators in any capacity.

Section 5 - Reporting

(18) The University has adopted a risk-based approach to Institutional monitoring and oversight of clinical trial activity and individual clinical trials, and as a first line, will make use of existing reporting systems including RISKWARE.

(19) Safety monitoring and reporting for clinical trials involving interventions other than therapeutic goods (for example, psychological, educational, behavioural, exercise) are to be aligned as far as possible with the requirements for therapeutic goods trials as set out in the relevant NHMRC Guidelines.

Section 6 - Associated Documents

(20) [Schedule A](#) of these Procedures supplements national and international regulations applicable to clinical trials and identifies roles and responsibilities for the conduct of University clinical trials.

(21) [Schedule B](#) of these Procedures provides a process flowchart for University clinical trial start-up and ongoing oversight.

(22) These Procedures should be read in conjunction with the following guidelines:

- a. [ICH E6 \(R3\) Guideline for Good Clinical Practice](#).
- b. [NHMRC Guideline: Risk-based management and monitoring of clinical trials involving therapeutic goods](#).
- c. NHMRC Guideline: Safety monitoring and reporting in clinical trials involving therapeutic goods.
- d. NHMRC Guideline: Reporting of Serious Breaches of Good clinical Practice (GCP) or the protocol for trials involving therapeutic goods.

(23) These Procedures should be read in conjunction with the following University documents:

- a. [Research Quality, Standards and Integrity Policy](#);
- b. [Research Data Management Procedures](#);
- c. [Research Collaboration Procedures](#);
- d. [Delegations Rule](#);
- e. [HRP06: Scheduled Substances](#).

(24) Other useful information is available from the Australian Government's Australian clinical trial handbook.

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