Clinical Trials Policy

Section 1 - Preamble

(1) This Policy is effective from 7 August 2024.

Section 2 - Purpose

(2) This Policy establishes the framework for the University's Clinical trial activities to ensure:

a. compliance with ethical, good clinical practice, safety and regulatory requirements in the governance of Clinical trials; and
b. effective risk management and quality assurance for Clinical trial activities.

Section 3 - Scope

(3) This Policy applies to the University's Clinical trials, which include:

a. Deakin staff and students who engage in Clinical trial activities within their University roles
b. Clinical trials for which the University is a Sponsor
c. Clinical trials for which the University is a Site for a Clinical trial, regardless of whether the University is the Sponsor.

(4) This Policy does not apply to staff and students when acting outside their employment, enrolment, or affiliation with the University. Where a Deakin staff member is also affiliated with another institute or organisation, the actual, perceived or potential conflicts of interest in relation to Clinical trial activities must be dealt with in accordance with the Declaration of Interests procedure.

(5) This Policy works in conjunction with the Research Conduct Policy.

Section 4 - Policy

(6) The University is committed to ensuring Deakin Clinical trials are conducted with appropriate institutional oversight and in an ethical manner that yields valuable outcomes and with robust trial designs to support research integrity and compliance.

(7) The Deputy Vice-Chancellor Research and Innovation has established the Clinical Trial Governance Committee to act as the delegate of the Approving authority in accordance with the Clinical Trials Governance Committee Terms of Reference.

(8) A Clinical trial for which the University is the intended Sponsor or Site may only proceed where the Clinical Trial Governance Committee has:

a. authorised the University trial Site
b. approved the University as Sponsor.

(9) Deakin staff and students engaged in Clinical trial activities must be aware of and comply with all relevant guidelines and legislation including the following:

a. Therapeutic Goods Act 1989
b. Therapeutic Goods Regulations 1990 (Cth)
c. Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
d. National Statement on Ethical Conduct in Human Research (current version)
e. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
f. Australian Code for the Responsible Conduct of Research, 2018
g. ICH Guideline for Good Clinical Practice, Annotated by the Therapeutic Goods Administration (TGA); and
h. ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice.

(10) Departures from the standards of conduct outlined in this Policy and the Australian Code for the Responsible Conduct of Research, 2018 may amount to a research code breach or serious research code breach and will be addressed in accordance with the Research Integrity Breaches Procedure.

Training and documentation

(11) Deakin staff and students directly involved in Clinical trial activities must complete TransCelerate accredited Good Clinical Practice training, prior to participating in clinical trial activities. Training must be renewed every three years.

(12) Principal Investigators are responsible for ensuring that Clinical trial team members complete requisite training prior to delegation of Clinical trial activities, and that this training is documented in a Training Log.

(13) All documentation relating to Clinical trial activities must be retained in accordance with the Research Data Management Procedure and Information and Records Management Policy.

Clinical trial risk assessment

(14) Principal Investigators are required to undertake a risk assessment in accordance with the Risk Management policy, utilising Deakin's risk framework and resources, prior to initiating, or agreeing to participate in, Clinical trial activities. The risk assessment must be reviewed throughout Clinical trial conduct, to protect Clinical trial participants and increase the likelihood of achieving the objectives of the Clinical trial.

(15) Deakin staff or students engaging or collaborating with an international partner on Clinical trial activities must do so in accordance with the International Relations Regulation Policy.

Sponsorship confirmation

(16) Deakin staff and students must ensure a sponsor is confirmed in writing for a Clinical trial prior to commencing the Clinical trial, which can either be:

a. Deakin University; or
b. An external organisation. This must be an Australian entity for Clinical trials involving Unapproved therapeutic goods in Australia.

(17) The University will only act as a Co-Sponsor for multinational trials where the external organisation sponsors the overseas sites and Deakin University sponsors the Australian sites.

(18) The University may act as a Sponsor of a Clinical trial if approved by the Clinical Trial Governance Committee and all the following criteria are met:

a. The lead Principal Investigator is a paid Deakin staff member
b. Investigators are qualified by education, training and experience and have adequate resources and facilities to conduct the Clinical trial
c. Clinical risk is reasonable, relative to standard of care and clinical skill and oversight
d. All Sponsor responsibilities can be discharged, whether directly by the University, or by delegation to other parties under legally-binding arrangements, including monitoring arrangements commensurate to the risk, size and complexity of the Clinical trial
e. There is an appropriate mechanism for evaluating all available safety information as per NHMRC guidelines
f. Trial design and conduct is consistent with ICH-GCP Good Clinical Practice.

(19) The University will not act as a Sponsor for:

a. Sites outside of Australia
b. Clinical trials that require submission to the TGA under the Clinical Trial Approval (CTA) scheme (which is reserved for “high-risk or novel treatments where there is no or limited knowledge of safety”).

Contracts and agreements

(20) All Clinical trials involving a third party must have written agreements in place prior to initiation of Clinical trial activities. These agreements must adhere to the Contracts policy and External Relationships and Partnerships policy and detail and define all roles and responsibilities including the name of the sponsor.

Insurance

(21) All University Clinical trials must have appropriate insurance in place prior to the commencement of, and at all times during the conduct of, the Clinical trial.

(22) Where the University is a Sponsor, the University will obtain and ensure there is maintenance of appropriate insurance for the sponsored Clinical trial.

(23) Where the University is the intended Sponsor or Site, the University’s participation in a Clinical trial can only proceed if the Principal Investigator has contacted the Deakin Insurance Manager at finance.insurance@deakin.edu.au and confirmed insurance coverage.

(24) External commercial Sponsors may have additional insurance requirements, which must be determined prior to contract negotiation.

Research ethics

(25) Principal Investigators are responsible for ensuring their Clinical trial adheres to the National Statement on Ethical Conduct in Human Research (current version) and the Human Research Ethics Procedure.

Site authorisation

Deakin acting as a Trial Site

(26) Clinical trials where the University is proposed to be acting as a Site must:

a. be assessed by Deakin’s site Principal Investigator to establish the suitability of the University’s capacity, capability, procedures and resources to conduct the Clinical trial at the proposed University site; and

b. be authorised to be conducted at the University as a Site by the Clinical Trial Governance Committee.

External organisation acting as a Trial Site

(27) Authorisation from the Approving authority at each site must be given prior to commencement of the Clinical trial at the site. The Principal Investigator at each site is responsible for submitting site governance documentation to the relevant research governance office where the Clinical trial will be conducted.

Additional requirements when using therapeutic goods

(28) Where any Clinical trial involves the manufacture of Therapeutic goods, such goods must be manufactured, handled and stored in accordance with Good Manufacturing Practice (GMP).

(29) Prior to the supply of the Therapeutic good in Australia, the Sponsor of a Clinical trial involving an Unapproved therapeutic good must notify the TGA through a Clinical Trial Notification (CTN) or obtain Clinical Trial Approval (CTA). Where the University is the Sponsor, Research Ethics and Integrity will submit the CTN to the TGA. The University will not sponsor Clinical trials required to submit through the CTA scheme.

(30) Principal Investigators are responsible for reporting any evidence of or known intentions of tampering with Therapeutic goods to Research Ethics and Integrity immediately.

Section 5 - Roles and Responsibilities

(31) Roles and responsibilities are as set out in the table below.

Responsible Party	Role
Deputy Vice-Chancellor Research and Innovation	Approving authority Establish Clinical Trial Governance Committee
Clinical Trial Governance Committee	Approving authority delegate Decision-making in relation to the University acting as a Sponsor or Site
Principal Investigator	Day-to-day management and monitoring of the Clinical Trial, supervision of Clinical trial team, project-level governance and compliance with all ethics, legal, regulatory and University policy requirements, providing information to Research Ethics and Integrity to support this Policy.
Research Ethics and Integrity	Support for institutional-level governance, compliance and operations, including centrally administering CTNs and reporting to regulatory bodies
Insurance Office	Confirm insurance coverage of Clinical trial activities where the University is a Sponsor or Site

Section 6 - Policies and Procedures

(32) The following policies and procedures document how to comply with this Policy:

a. Contracts policy
b. Declaration of Interest procedure
c. External Relationships and Partnerships policy
d. Human Research Ethics Procedure
e. Information and Records Management Policy
f. International Relations Regulation policy

g. Research Data Management Procedure
h. Research Conduct Policy
i. Research Integrity Breaches Procedure
j. Risk Management policy.

Section 7 - Definitions

(33) For the purpose of this Policy:

a. Approving authority: the body, organisation or institution that provides the final authorisation for the conduct of the Clinical trial at the Site following ethics approval. The granting of ethics approval does not oblige an Approving authority to grant authorisation at their site.
b. Clinical trial: any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include, but are not restricted to, drugs, cells or other biological products, surgical procedures, radiological procedures, devices, behavioural interventions, psychological interventions, process-of-care changes, preventive care, health-related educational interventions.
c. Clinical trial activities: any tasks related to the conduct, management or oversight of Clinical trials by Deakin staff or students or using the University's resources or infrastructure including but not limited to:
    i. Acting as Site
    ii. Acting as Sponsor
    iii. Trial design
    iv. Data analysis
    v. Consenting of participants
    vi. Supply of the investigational product(s) or device(s) or equipment.
    vii. Clinical trial activities does not include enrolling in or undertaking Clinical trial activities as a participant.
d. Principal Investigator: paid Deakin staff member responsible for the conduct of the Clinical trial at the trial site, with the responsibilities outlined in Section 4 of the TGA INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) or Section 10 of ISO 14155.
e. Site: the location where Clinical trial activities are conducted.
f. Sponsor: responsible for the initiation, management and financing of the Clinical trial and carries the medico-legal responsibility associated with its conduct. For Clinical trials conducted under the Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) scheme, the sponsor has additional responsibilities for managing the supply and administration of Therapeutic goods.
g. Therapeutic goods: as defined in the Therapeutic Goods Act 1989 (Cth).
h. Training log: a record of all training relating to a specific Clinical trial undertaken by a Clinical trial team member who has been delegated Clinical trial related duties, as described in the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.
i. Unapproved therapeutic goods: Therapeutic goods that have not been approved for use in Australia or those where their proposed use differs from the terms of the Australian Register of Therapeutic Goods entry.

Status and Details

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Expiry Date	To Be Advised
Responsible Executive	Matthew Clarke Deputy Vice-Chancellor Research and Innovation +61 3 924 43979
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