

CLINICAL TRIALS POLICY 2016

The Deputy Vice-Chancellor (Research), as delegate of the Senate of the University of Sydney, adopts the following policy.

Dated: 28 October 2016

Last amended: 13 June 2017 (administrative amendments)

Signature:

Name: Professor Duncan Ivison, Deputy Vice-Chancellor (Research)

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1 Name of policy

This is the Clinical Trials Policy 2016.

2 Commencement

This policy commences on 1 January 2017.

3 Policy is binding

Except to the extent that a contrary intention is expressed, this policy binds the University, staff, students and affiliates.

4 Statement of intent

This policy:

- (a) sets out the principles underpinning the University's approach to clinical trials;
- (b) states the University's commitment to the responsible conduct of clinical trials; and
- (c) provides for appropriate and effective governance of clinical trials, including the identification and management of risk.

5 Application

- (1) This policy applies when, or if it is proposed that:
 - (a) the University is the sponsor of a clinical trial;
 - (b) the University is a site of a clinical trial; or
 - (c) staff, students or affiliates of the University engage in the conduct of a clinical trial within their University roles.
- (2) This policy does not apply to staff, students or affiliates when acting outside their employment, enrolment or affiliation with the University.

Note: An example would be when carrying out a clinical trial through employment or affiliation with a hospital or medical research institute.

6 Definitions

- (1) Definitions in this policy are intended for use within the University policy and operational framework. They are not necessarily the same as definitions of the same terms contained in external documents, whether or not referred to in this policy.
- (2) In this policy:

affiliate has the meaning given in the [Code of Conduct – Staff and Affiliates](#), which at the date of this policy is:

clinical title holders; adjunct, conjoint and honorary appointees; consultants and contractors to the University; holders of offices in University entities, members of Boards of University Foundations, members of University Committees; and any other persons appointed or engaged by the University to perform duties or functions on its behalf.

clinical trial	<p>means 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.</p> <p>Clinical trial interventions include, but are not limited to:</p> <ul style="list-style-type: none">• experimental drugs• cells and other biological products• vaccines• medical devices• surgical and other medical treatments and procedures• psychotherapeutic and behavioural therapies• health-related service changes• health-related preventive care strategies• health-related educational interventions. <p>Note: Researchers requiring assistance in identifying whether their project is a clinical trial should contact the Clinical Trials Office.</p>
Clinical Trials Advisory Committee	<p>means the committee established in clause 11 of this policy.</p>
Clinical Trials Office	<p>means the group within the Research Portfolio responsible for overseeing the University's participation in clinical trials. The Clinical Trials Office's role in oversight precludes it from carrying out or funding clinical trials itself, and from negotiating contractual arrangements with third parties for specific clinical trials.</p>
co-ordinating investigator (CI)	<p>means the investigator responsible for co-ordination of all other investigators in a clinical trial conducted at multiple sites. For single centre clinical trials, the terms principal investigator and co-ordinating investigator are synonymous. For clinical trials where the University is both the sponsor and a site, the co-ordinating investigator may be the principal investigator at the University site.</p>
CTN scheme	<p>means the Clinical Trial Notification scheme established consistently with the Therapeutic Goods Act 1989 (Cth) and operated by the TGA. This scheme permits therapeutic goods to be used for experimental purposes if the relevant clinical trial is notified to the TGA.</p>
CTX scheme	<p>means the Clinical Trial Exemption scheme established consistently with the Therapeutic Goods Act 1989 (Cth) and operated by the TGA. This scheme permits therapeutic goods to be used for experimental purposes if the relevant clinical trial is approved by the TGA.</p>
delegate	<p>means an employee, member or committee of Senate or any other person or entity to whom or which a delegation has been made by Senate.</p> <p>Note: See University of Sydney (Delegations of Authority – Administrative Functions) Rule 2010.</p>

GCP	means Good Clinical research Practice, which is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects.
GMP	means Good Manufacturing Practice, which is a system for ensuring that investigational products are consistently produced and controlled according to quality standards.
investigational product	means any medicine, device or other product or intervention being investigated, tested or used as a placebo or reference in a clinical trial.
principal investigator (PI)	means the investigator responsible for the conduct of a clinical trial at a particular site.
protocol	means a document that describes the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of a clinical trial. The sponsor of a clinical trial is responsible for the protocol.
research	has the meaning given in the Research Code of Conduct 2013 , which at the date of this policy is: investigation undertaken to gain or advance knowledge, understanding and insight. It does not include routine testing and routine analysis of materials, components or processes or the development of teaching materials or similar work.
researcher	has the meaning given in the Research Code of Conduct 2013 , which at the date of this policy is: any staff member, student or affiliate engaged in research.
serious adverse event	has the meaning given in the TGA's Access to Unapproved Therapeutic Goods – Clinical Trial in Australia (October 2004) (or any replacement for it).
site	means the location where a clinical trial is conducted. When a clinical trial is conducted at more than one site, using the same protocol, it is referred to as a multi-site or multi-centre trial.
sponsor	means the person, body, organisation or institution which takes overall responsibility for the conduct of a clinical trial, including responsibility for the protocol. The sponsor usually initiates, organises and supports the conduct of the clinical trial, including where another party funds the clinical trial or provides the product used in the clinical trial. The sponsor of a clinical trial conducted in Australia must be: <ul style="list-style-type: none">• an Australian resident; or• an incorporated body conducting business in Australia with a representative residing in Australia.
staff	means any employee of the University.

- student** has the meaning given in the [Code of Conduct for Students](#), which at the date of this policy is:
- all students of the University of Sydney, including but not limited to fee paying students, HECS students, PELS students, audit students, Centre for Continuing Education students, Centre for English Teaching students, exchange students, Study Abroad students, Summer School students and Winter School students.
- therapeutic goods** has the meaning given in the [Therapeutic Goods Act 1989 \(Cth\)](#) and includes medicines, medical devices, biologicals and goods declared to be therapeutic goods under that legislation.
- TGA** means the Therapeutic Goods Administration, in the Commonwealth Department of Health. The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia.

7 General principles

- (1) The University encourages and supports clinical trial-related activities.
- (2) All clinical trials are a form of human research. They must therefore comply with all relevant laws, University policies and procedures, and any guidelines and codes that the University is required to follow under law, by contract or by a regulatory authority, that are applicable to:
 - (a) human research; and
 - (b) the nature of the particular clinical trial,which may include, but are not limited to, those listed in Schedule 1.

8 Approval

- (1) The prior approval of the relevant delegate must be obtained before the University will participate, in any capacity, in a clinical trial.
- (2) Approval must be obtained consistently with the procedures associated with this policy.
- (3) In determining whether to approve the University's participation in a clinical trial, the relevant delegate must consider:
 - (a) the roles the University will take;
 - (b) the possible benefits to the University and the community of participation;
 - (c) the outcome of risk assessment and, if applicable, site-specific assessment conducted in accordance with the procedures associated with this policy;
 - (d) the appropriate management of work health and safety responsibilities;

Note: All parties involved in the clinical trial will have responsibilities for work health and safety and possibly overlapping duties. See [Work Health and Safety Policy 2016](#).
 - (e) the proposed contractual arrangements; and
 - (f) the research strategy of the University.

- (4) The University will not normally accept the **role of sponsor** of a clinical trial that:
- (a) evaluates the effects of an investigational product which is under development by a for-profit organisation;
 - (b) involves either:
 - (i) administering to humans a medicine or biological investigational product at a dose or ascending doses, or through a method of administration, not previously lawfully administered in humans in Australia; or
 - (ii) using a medical device, other than software, that has not previously been lawfully used in or on humans in Australia;
- or
- (c) is to be submitted to the TGA for review under the CTX scheme.

Note: Clause 8(4) is not intended to limit the University's engagement in these clinical trials in other capacities, for example as a site of a clinical trial sponsored by a pharmaceutical company.

- (5) The University will not normally accept **the role of sponsor** of a clinical trial in a foreign country. If the University is coordinating a clinical trial with sites outside Australia then, except in exceptional circumstances, the University must engage a person, body, organisation or institution to take on the obligations of sponsor in each of those foreign countries in accordance with local regulations.
- (6) CIs or PIs should first:
- (a) consult the Clinical Trials Advisory Committee; and
 - (b) seek approval from the relevant delegate,
- before submitting grant applications or investing time or resources planning for the University to act as the sponsor of a clinical trial in the circumstances described in clause 8(4) or 0.

9 Risk and site-specific assessment

- (1) Before seeking approval of a clinical trial, the CI or PI responsible for that clinical trial on behalf of the University must submit it for risk assessment in accordance with the procedures associated with this policy.
- (2) The University's CI or PI must disclose in writing in their submission for risk assessment:
- (a) any relevant conflicts of interests held by any researcher involved in that clinical trial; and
- Note:** The University's approach to conflicts of interests is set out in clause 8 of the [External Interests Policy 2010](#).
- (b) details of any funding or other support received or to be received from a granting body, company or other organisation (including investigational product or other resources) for the conduct of the clinical trial.
- (3) Risk assessment must be conducted by the Clinical Trials Office consistently with the procedures associated with this policy.
- (4) If a proposed clinical trial is assessed as "high risk" the responsible CI or PI should consult the Clinical Trials Advisory Committee for advice before the proposal is provided to the relevant delegate for consideration.

Note: See clause 11.

- (5) Before seeking approval of a clinical trial for which the University is a proposed site, the University's CI or PI must also submit it for site-specific assessment of the University's capacity to conduct the clinical trial at the proposed site, in accordance with the procedures associated with this policy.
- (6) Site-specific assessment must be conducted by the Clinical Trials Office consistently with the procedures associated with this policy.

10 Registration and notification

- (1) The University's CI or PI must notify the Clinical Trials Office of any clinical trial to which this policy applies.
- (2) The University's CI or PI must register any clinical trial for which the University is the sponsor on a primary registry in the World Health Organisation (WHO) Registry Network (such as the Australian New Zealand Clinical Trials Registry).

Note: The Australian New Zealand Clinical Trials Registry, www.anzctr.org.au, accepts trials for registration from all countries and from the full spectrum of clinical areas, including trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.

- (3) During the conduct of a clinical trial, the University's CI or PI must notify the Clinical Trials Office as soon as they become aware of any:
 - (a) serious adverse event which is an unexpected outcome of the clinical trial;
 - (b) change in the information provided in the risk assessment or site-specific assessment process for that clinical trial;
 - (c) breach or potential breach of any law, regulation or external guideline or code applicable to the clinical trial; or
 - (d) other matters required by the procedures associated with this policy.
- (4) The Clinical Trials Office will:
 - (a) establish and maintain a University record of clinical trial activities notified to it; and
Note: See [University Recordkeeping Policy](#) and [Recordkeeping Manual](#).
 - (b) provide the Office of General Counsel with information required by the University's insurers.

11 Clinical Trials Advisory Committee

- (1) There will be a Clinical Trials Advisory Committee that will be responsible for:
 - (a) providing advice to University CIs and PIs on risk reduction for proposed clinical trials which have been:
 - (i) assessed as "high risk"; or
 - (ii) otherwise referred to it by the Clinical Trials Office or the relevant delegate; and
 - (b) where possible, assisting the relevant CI or PI to develop a plan to mitigate risks or overcome difficulties presented by the clinical trial.
- (2) The Clinical Trials Advisory Committee will be chaired by a person appointed by the relevant delegate for approving clinical trials. The chairperson must be from a health related field with relevant experience in clinical trial activities.

- (3) The Clinical Trials Advisory Committee will meet as required, at the request of the relevant delegate or the chair of the Clinical Trials Advisory Committee.
- (4) Members of the Clinical Trials Advisory Committee will be:
 - (a) the chairperson;
 - (b) up to two (2) nominees of each of the Deans of Medicine, Nursing, Health Sciences and Science;
 - (c) up to two (2) nominees of the Deputy Vice-Chancellor (Research) with expertise in clinical trial activities; and
 - (d) up to three (3) additional persons appointed by the relevant delegate.

12 Roles and responsibilities

- (1) The **University** is responsible for:
 - (a) making appropriate training available to researchers on the requirements of this policy and legislative, regulatory and other requirements applicable to clinical trials; and
 - (b) obtaining and maintaining appropriate insurance cover for clinical trial activities conducted by it or on its behalf.
- (2) The **relevant delegate** is responsible for deciding whether, and on what terms, the University will participate in clinical trials.
- (3) The **Director, Research Integrity and Ethics Administration** is responsible for the administration of this policy any procedures associated with it.
- (4) The **Research Portfolio** is responsible for:
 - (a) developing, negotiating, co-ordinating and supporting the documentation by the Office of General Counsel of contracts relating to clinical trials;
 - (b) coordinating the risk assessment and site-specific assessment processes; and
 - (c) providing or coordinating research support services for researchers involved in clinical trials.
- (5) The **Clinical Trials Advisory Committee** has the roles and responsibilities set out in clause 11(1).
- (6) **University CIs and PIs** are responsible for:
 - (a) overseeing the conduct of the clinical trial;
 - (b) ensuring compliance with the applicable protocol;
 - (c) taking appropriate steps to ensure compliance with all legislative, regulatory, policy and other requirements applicable to a particular clinical trial, including any requirements of the reviewing Human Research Ethics Committee;
 - (d) monitoring the conduct of researchers and others undertaking activities within the clinical trial;
 - (e) registering the clinical trials and providing evidence of registration consistently with this policy and any associated procedures; and
 - (f) providing information to the Clinical Trials Office and other groups specified in this policy or the procedures associated with this policy where required.
- (7) All **staff, students and affiliates** involved in clinical trials on behalf of the University are responsible for:



- (a) keeping appropriate records where required;

Note: See [Research Code of Conduct 2013](#); [Research Data Management Policy 2014](#); [University Recordkeeping Policy](#); [Recordkeeping Manual](#).

- (b) identifying, and informing the University's CI or PI of, existing and emerging risks relating to clinical trial activities;
- (c) undertaking appropriate GCP training; and
- (d) undertaking activities in accordance with the protocol.

SCHEDULE 1

RELEVANT LAWS, POLICIES, PROCEDURES, GUIDELINES AND CODES

These include but are not limited to:

- (a) requirements imposed by the reviewing Human Research Ethics Committee, including requirements for informed consent and adverse event reporting;
- (b) the [Australian Code for the Responsible Conduct of Research \(2007\)](#) (or any replacement for it);
- (c) the [National Statement on Ethical Conduct in Human Research 2007 \(updated May 2015\)](#) (or any replacement for it) and all other NHMRC publications or guidelines relevant to the conduct of clinical trials;
- (d) the University's [Research Code of Conduct 2013](#);
- (e) the University's [Privacy Policy 2013](#), [Privacy Management Plan](#), and any additional statutory privacy requirements applicable to a particular clinical trial;
- (f) the [Therapeutic Goods Act 1989 \(Cth\)](#) (including CTN or CTX schemes where applicable), and any regulations, Therapeutic Goods Determinations, Therapeutic Goods Orders and other legislative instruments made under it;
- (g) the TGA's [Access to Unapproved Therapeutic Goods – Clinical Trial in Australia \(October 2004\)](#) (or any replacement for it) and all other TGA publications or guidelines relevant to the conduct of a particular clinical trial;
- (h) GMP requirements in relation to investigational products, such as:
 - (i) compliance with the TGA [Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to GMP for Medical Products](#); and
 - (ii) TGA conformity assessment requirements for medical devices;
- (i) GCP requirements for the conduct of clinical trials of therapeutic goods, such as:
 - (i) for medicines, the TGA [Note for Guidance on Good Clinical Practice \(CPMP/ICH135/95\) – Annotated with TGA Comments](#); and
 - (ii) for medical devices, ISO 14155:2011 [Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice](#); and
- (j) GCP principles for clinical trials not involving therapeutic goods, set out in the [World Health Organisation Handbook for Good Clinical Research Practice](#).

NOTES

Clinical Trials Policy 2016

Date adopted: 28 October 2016

Date commenced: 1 January 2017

Date amended: 13 January 2017 (administrative amendments)

Administrator: Director, Research Integrity and Ethics Administration

Review date:

Rescinded documents:

Related documents: *Privacy Act 1988 (Cth)*
Therapeutic Goods Act 1989 (Cth)

Privacy and Personal Information Protection Act 1998 (NSW)
Health Records and Information Privacy Act 2002 (NSW)
Human Tissue Act 1983 (NSW)

University of Sydney (Delegations of Authority – Administrative Functions) Rule 2016

Code of Conduct – Staff and Affiliates
Code of Conduct for Students
External Interests Policy 2010
Privacy Policy 2013
Research Code of Conduct 2013
Research Data Management Policy 2014
University Recordkeeping Policy
Work Health and Safety Policy 2016

Privacy Management Plan
Recordkeeping Manual

Australian Code for the Responsible Conduct of Research (2007)
National Statement on Ethical Conduct in Human Research (2007) updated March 2014

Australian Regulatory Guidelines for Medical Devices (May 2011)

Access to Unapproved Therapeutic Goods: Clinical Trials in Australia (October 2004)

Australian Clinical Trial Handbook (March 2006)

Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice

ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA comments (July 2000)

*Pharmaceutical Inspection Convention and Pharmaceutical
Inspection Co-operation Scheme (PIC/S) Guide to GMP for
Medicinal Products*

*World Health Organisation Handbook for Good Clinical Research
Practice*

AMENDMENT HISTORY

Provision	Amendment	Commencing
6; related documents	Updated references to <i>University of Sydney (Delegations of Authority – Administrative Functions) Rule 2016</i>	13 June 2017