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Supporting Process:

Research and Research Training Processes

Clinical Trials Policy (MPF1352)

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1. Objective

1.1. The objectives of this policy are to enable and support the conduct of Clinical Trials in light of the significant community benefit of this activity by:

- a) setting out the framework under which Clinical Trials are governed, monitored and facilitated by the University, to support regulatory and ethical compliance and identification and management of institutional risk; and
- b) defining the roles, responsibilities and authorities in relation to the University's oversight, conduct and management of Clinical Trial Activities.

2. Scope

2.1. This policy applies to all Clinical Trial Activities.

2.2. This policy does not apply to any University Personnel involved in a Clinical Trial when that involvement is entirely independent of their University affiliation.

3. Authority

3.1. This policy is made under the [University of Melbourne Act 2009 \(Vic\)](#) and the Council Regulation and supports compliance with current versions of the:

- a) *Therapeutic Goods Act 1989* (Cth)
- b) *Therapeutic Goods Regulations 1990* (Cth)
- c) *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth)
- d) National Statement on Ethical Conduct in Human Research (2007 and all updates), and
- e) AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
- f) Australian Code for the Responsible Conduct of Research
- 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.

4. Policy

4.1. The University recognises that its participation in Clinical Trial Activities offers significant benefit to the community through informing improved health outcomes for individuals, optimising management of limited health resources and the training of high calibre clinical researchers.

4.2. The University is committed to ensuring that its Clinical Trial Activities are conducted with appropriate institutional oversight and in a manner that yields valuable outcomes through robust trial design that supports research integrity and compliance.

4.3. University Research Personnel must:

a) ensure that Clinical Trial Activities are designed and conducted in a manner that:

- i. supports compliance with all applicable laws, University policies and processes, guidelines, codes of conduct and contractual requirements, including those set out in [Schedule 1](#) , relevant to the particular Clinical Trial Activity; and
- ii. yields high calibre research outcomes;

b) ensure that Clinical Trial Activities are appropriately managed at a project level to minimise risks and support compliance;

c) effectively and transparently manage actual, perceived or potential conflicts of interest in relation to Clinical Trial Activities in accordance with the Managing Conflicts of Interest Policy ([MPF1366](#)); and

d) provide relevant information to the University to facilitate institutional oversight and decision-making.

4.4. University involvement in a Clinical Trial Activity may only proceed if:

a) the benefits of the Clinical Trial Activity outweigh the risks (including, without limitation, medico-legal risks, financial risks and reputational risks);

b) compliance requirements can be appropriately discharged by the University or delegated to an external party;

c) the University holds appropriate insurance in respect of the Clinical Trial Activity;

d) the Clinical Trial Activity is appropriately funded;

e) applicable HREC approvals are in place;

f) in the cases of:

- i. the University acting as Sponsor of a Clinical Trial;
- ii. the University acting as a proposed Trial Site; or
- iii. Clinical Trial Activity deemed to be of elevated risk,

the Clinical Trials Review Committee has reviewed the activity and it has been approved by the Deputy Vice-Chancellor (Research)(or nominee).

5. Procedural principles

Sponsorship

5.1. All Clinical Trial Activities must have a Sponsor.

5.2. The University may act as Sponsor of a Clinical Trial subject to:

a) the approval of the Deputy Vice-Chancellor (Research) (or nominee) taking into account the matters set out at section 4.4(a)-(e);

b) consultation with the Clinical Trials Review Committee (**CTRC**); and

c) this policy.

5.3. The University will not normally act as Sponsor in relation to sites outside of Australia. In such cases, in addition to the requirements of sections 5.1 and 5.5 (as the case may be), the Sponsor must normally be based in the jurisdiction in which the Clinical Trial Activity occurs unless otherwise approved by the Deputy Vice-Chancellor (Research) (or nominee).

5.4. The University will not act as Sponsor for Industry Initiated Clinical Trial Activities.

5.5. The University may act as Sponsor of an Investigator Initiated Clinical Trial where it is satisfied that:

- a) clinical risk is reasonable, relative to standard of care and clinical skill and oversight;
- b) all Sponsor Responsibilities can be discharged, whether directly by the University, or by delegation to other parties under legally-binding arrangements, including independent monitoring arrangements commensurate to the risk, size and complexity of the Clinical Trial and there is an appropriate mechanism for evaluating all available safety information; and
- c) all details of the HREC approval have been notified by the relevant University Research Personnel to the University's Office of Research, Ethics and Integrity.

Acting as a Trial Site

5.6. All Clinical Trial Activity for which the University is a proposed Trial Site will be:

- a) assessed by the University's site principal investigator in accordance with University procedures 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) referred to the Clinical Trials Review Committee (see 4.4).

Trials of Elevated Risk

5.7. All Clinical Trial Activity assessed as being of elevated risk in accordance with University procedures, including trials for which the safety of the investigational product, intervention or device is unknown, will be referred to the Clinical Trials Review Committee.

Clinical Trials Review Committee

5.8. The Deputy Vice-Chancellor (Research) will establish, and appoint members to, a Clinical Trials Review Committee (**CTRC**).

5.9. The functions of the CTRC are to:

- a) provide recommendations and advice to the Deputy Vice-Chancellor (Research) in relation to the University:
 - i. acting as Sponsor;
 - ii. acting as a Trial Site; and
 - iii. participating in a Clinical Trial Activity of elevated risk;
- b) receive reports from the University's Office of Research, Ethics and Integrity relating to Clinical Trial Activities, including: Suspected Unexpected Serious Adverse Reactions (SUSAR), Unanticipated Serious Adverse Device Effects (USADE), Significant Safety Issues (SSI) and Urgent Safety Measures (USM);
- c) establish sub-committees to oversee complex or large-scale Clinical Trial Activities; and
- d) such other functions as the Deputy Vice-Chancellor (Research) determines are necessary or convenient to assist the University to discharge its oversight of, and decision-making in respect of, Clinical Trial Activities.

5.10. The composition of the CTRC will include:

- a) a Chancellery representative (Chair);
- b) subject-matter experts;
- c) the University's Office of Research, Ethics and Integrity representative; and
- d) a Legal and Risk representative.

5.11. The CTRC will meet as such times (whether in person or otherwise), and adopt such processes, as are determined by the Chair.

5.12. The CTRC Chair may, at the Chair's discretion, invite persons other than CTRC members to attend a meeting of the CTRC to provide expert input into matters before the CTRC.

5.13. The University's Office of Research, Ethics and Integrity will provide secretariat support to the CTRC.

University Research Personnel responsibilities, including registration and notification

5.14. The University Research Personnel responsible for the University's involvement in a Clinical Trial must:

- a) register the ethics approval of the Clinical Trial Activity with the University's Office of Research Ethics and Integrity, irrespective of whether the Reviewing HREC is the University's HREC;
- b) if acting as Chief Investigator on any Clinical Trial for which the University is the Sponsor, discharge or delegate all Sponsor responsibilities and register the Clinical Trial on a primary registry in the World Health Organisation (WHO) Registry Network (such as the Australian New Zealand Clinical Trials Registry);
- c) if acting as Chief Investigator of a CTN or CTA Trial and the University has agreed to act as Sponsor under this policy, ensure that a CTN or CTA is arranged through the University's Office of Research, Ethics and Integrity;
- d) notify the University's Insurance Office of the Clinical Trial and provide such information as may be required by the Insurance Office to arrange or confirm appropriate cover;
- e) notify the University's Office of Research, Ethics and Integrity immediately after becoming aware of any:
 - i. SUSAR, USADE, SSI and USMs;
 - ii. material change to the information provided to the CTRC and relevant delegate for the purposes of assessing and approving the Clinical Trial, including any information that would alter the University's risk assessment;
 - iii. information which may prejudice the University's reputation;
 - iv. breach or potential breach of any applicable laws, University policies and processes, guidelines, codes of conduct and contractual requirements relevant to the Clinical Trial; and
- f) ensure that the appointment of a Sponsor is evidenced in writing; and
- g) do such other things as may be prescribed by processes made under this policy.

Management and Training

5.15. All University involvement in Clinical Trial Activity must be:

- a) notified to Research Innovation and Commercialisation; and
- b) documented and retained in accordance with the University's Contracts Policy ([MPF1247](#)), Records Management Policy ([MPF1106](#)), Management of Research Data and Records Policy ([MPF1242](#)) and related processes

by the Chief Investigator.

5.16. All University Research Personnel directly involved in the conduct, oversight, or management of Clinical Trials must undertake TransCelerate accredited Good Clinical Practice training, and all University Research Personnel who supervise clinical researchers must ensure that this occurs in accordance with all applicable polices, codes, regulations.

6. Roles and responsibilities

Role/Decision/Action	Responsibility	Conditions and limitations
Approval for the University to act as Sponsor of a Clinical Trial.	DVC(R) or nominee	A checklist of criteria for University sponsorship is attached, Schedule 2 .
Provision of advice in relation to Clinical Trial decision-making at the request of DVC(R)	Clinical Trials Review Committee	
Institutional level governance	Chancellery	

Support for institutional-level governance, compliance and operations, including centrally administering CTNs, CTAs and Clinical Trial registries	Office of Research, Ethics and Integrity	
Administration of this policy and any procedures under it	Office of Research, Ethics and Integrity	...
Day-to-day management and monitoring of the Clinical Trial, project-level governance and compliance with all HREC, legal, regulatory and University policy requirements, providing information to the University's Office of Research, Ethics and Integrity to support this policy.	University CI and/or PI, under the oversight of the relevant Department, School and Faculty	...
Long-term archiving of original Clinical Trial documentation	University CI and/or PI, under the oversight of the relevant Department, School and Faculty	
Expert advice on design, project-level governance and compliance	Methods and Implementation Support for Clinical and Health research Hub (MISCH), MDHS.	
Clinical Trial contracts	Legal Services, RIC; CI	
Clinical Trial Insurance	Insurance Office, Legal & Risk.	

7. Definitions

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 on biomedical or health-related outcomes (*adapted from the World Health Organisation definition*). The assignments are determined by the study's protocol. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, imaging or diagnostic procedures, devices, behavioural treatments, process-of-care changes, preventive care.

Clinical Trial Activities means any Clinical Trial related activities conducted by University Research Personnel and/or using University resources and may include, without limitation:

- (a) developing or advising in relation to a Protocol;
- (b) analysis of data arising from a Clinical Trial;
- (c) acting as Sponsor;
- (d) recruitment of participants;
- (e) carrying out a Protocol;
- (f) acting as a Trial Site.

Chief Investigator means the University's lead Investigator for a Clinical Trial.

CTN means Clinical Trial Notification under the Therapeutic Goods Act.

CTN Trial means a Clinical Trial that requires Clinical Trial Notification under the Therapeutic Goods Act.

CTA means Clinical Trial Approval scheme under the Therapeutic Goods Act.

CTA Trial means a Clinical Trial that requires Clinical Trial Approval to supply unapproved therapeutic goods in Australia under the Therapeutic Goods Act.

Clinical Trials Review Committee or CTRC means the committee established under 5.10.

Discharge means to do all that is required to perform a duty or fulfil a responsibility.

DVC(R) means Deputy Vice-Chancellor (Research).

HREC means Human Research Ethics Committee.

ICH Guideline for Good Clinical Practice means the current version of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice as adopted by the TGA with annotations.

Industry Initiated Clinical Trial means a Clinical Trial initiated and managed by industry.

Investigator Initiated Clinical Trial means a Clinical Trial initiated and managed by a non-industry researcher, institution or collaborative group.

ISO 14155 means the current version of the Clinical investigation of medical devices for human subjects - Good clinical practice

NHMRC means National Health and Medical Research Council

Non-CTN or CTA Trial means a Clinical Trial that does not require CTN or CTA under the Therapeutic Goods Act.

Protocol means the document which describes the objectives, design, methodology, statistical considerations and organisation of the Clinical Trial, as such document may be amended from time to time and most recently approved by the responsible HREC.

RIC means Research Innovation and Commercialisation.

SUSAR means Serious Unexpected Serious Adverse Reaction and is an adverse reaction that is both serious and unexpected.

SSI means significant safety issue and is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Sponsor means:

(a) in the case of a CTN or CTA Trial, the incorporated body appointed as Sponsor for the purposes of Therapeutic Goods Act compliance; and

(b) in the case of a Non-CTN or CTA Trial, the individual, company, institution, or organisation which is accountable to the approving HREC for the conduct of the trial.

Sponsor Responsibilities means all responsibilities ascribed to a Sponsor by law, regulation, code or policy, including, as applicable, under the *ICH Guideline for Good Clinical Practice* and the *Therapeutic Goods Act*.

TGA means Therapeutic Goods Administration.

Trial Site means a location where a Clinical Trial will be conducted, including where the intervention will be implemented or administered to study participants.

USADE means unanticipated serious adverse device effect and is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report

University Research Personnel means staff, students, honoraries and visitors conducting research in their University capacity.

USM means urgent safety measure and is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

POLICY APPROVER

Deputy Vice-Chancellor (Research)

POLICY STEWARD

Pro Vice-Chancellor (Research Infrastructure)

REVIEW

This policy is to be reviewed by 31 March 2024.

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	Deputy Vice-Chancellor (Research)	31 March 2021	31 March 2021	New policy.
2	Pro Vice-Chancellor (Research Collaboration & Partnerships)	31 May 2021	1 June 2021	Section 5.16 updated.
3	Deputy Vice-Chancellor (Research)	25 October 2023	1 November 2023	Amendment to 4.3(c) to link Managing Conflicts of Interest Policy (MPF1366), and changed policy steward from Pro Vice-Chancellor (Research Collaboration & Partnerships) to Pro Vice-Chancellor (Research Infrastructure).
4	Policy Officer	1 November 2023	1 November 2023	Amended display issue with policy steward title.