Research Clinical Trials Policy

Section 1 - Background and Purpose

(1) La Trobe University (the 'University') is committed to supporting clinical trials.

(2) The Clinical Trials Policy ('Policy') establishes a framework to ensure that clinical trials are carried out at the highest scientific and ethical standards to ensure data quality and safety of research participants.

(3) The Policy works in conjunction with the University Research Governance Policy to ensure legislative and regulatory requirements, policy mandates, principles and best practice standards for research are met.

(4) The purpose of the Policy is to:

a. provide a framework and procedures to ensure the highest standards of clinical practice, ethics and safety in the governance of clinical trials; and
b. enable effective and quality clinical trial research partnerships with commercial/industry partners, the health sector, not-for-profit organisations and other organisations collaborating with La Trobe researchers.

Section 2 - Scope

(5) For the purposes of this policy, a clinical trial is defined as 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 and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care etc.. (World Health Organization)

(6) This Policy applies to clinical trials, as:

a. All campuses; and
b. Staff and Students of the University who engage in the conduct of a clinical trial within their University roles and sponsored by one of the following types of legal entities:
    i. Commercial/Industry Partners
    ii. The University
    iii. By another organisation (e.g., another University, non-for-profit and other organisations collaborating with La Trobe Researchers.)
c. Clinical trials where the University is a site of a clinical trial, regardless of whether the University is the Sponsor.

Section 3 - Policy Statement

(7) The University encourages and supports clinical trial-related activities.

(8) The Policy is based on the Principles of Research Governance as specified in the Research Governance Policy.

Section 4 - Procedures

Part A - General Principles

(9) All clinical trials must be conducted in compliance with:

a. all relevant laws;
b. University policies and procedures; and
c. any guidelines and codes required by legal agreement, contract or by a regulatory authority.

(10) La Trobe staff and students must inform the University Research Office about any clinical trial they are involved in on La Trobe premises or conducted at other sites (e.g., hospitals, other universities, research institutes, or sites within the community). The process is outlined on the clinical trials website.

Part B - Initial Assessment

(11) Prior to the University and/or its staff and students initiating, or agreeing to participate in, clinical trial-related activities, the following must be considered:

a. who the Sponsor of the Clinical Trial will be (in most cases this will be the institution administering the funds);
b. possible benefits to the University;
c. possible benefits to participants and the community;
d. agreement of supporting departments, collaborating organisations and the University asset managers and, if applicable, site-specific assessment conducted in accordance with the procedures associated with this Policy;
e. Study documentation covering the following study feasibility points:
    i. the appropriate management of work health and safety responsibilities;
    ii. the proposed contractual and legal arrangements;
    iii. insurance and indemnity responsibilities;
    iv. the Sponsor’s requirements;
    v. ethical and regulatory requirements;
    vi. financial requirements;
    vii. sourcing of any materials or equipment to be used in the trial;
    viii. proposed locations of trial sites;
    ix. required training for staff and students involved in the trial;
    x. any involvement of international trial sites and/or partners.

(12) La Trobe Co-ordinating/Site Investigators where appropriate, will seek advice from the Research Office as early as possible in the development process about the project.

(13) Additional consultation regarding the roles and responsibilities may be required between the researchers, the Research Office, the sponsor company and/or funding body. The Research Office can help facilitate any consultation as required.

(14) Where the University considers taking on the roles and obligations of Sponsor, each situation will be assessed on its individual merits in consultation with the Research Office.

(15) If La Trobe is acting as the Sponsor and is collaborating with a Foreign Organisation to conduct a clinical trial in another country, an equivalent to a Clinical Trials Research Agreement must be signed prior to site activation in the

Foreign Country.

Part C - Equipment and Materials

(16) Researchers must source all equipment and materials through safe and ethical channels.

(17) Where appropriate, the Principal Investigator must ensure all contracts and warranties are in place before the use of any research equipment or materials.

(18) All staff and students should be adequately trained and/or certified to use any research equipment and materials.

Part D - Training and Credentialing

(19) The University will:

a. provide ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles;
b. provide TransCelerate R2 (E6) accredited Good Clinical Practice(GCP) Training to all staff and students involved in clinical trials. Access to training is outlined on the clinical trials webpage;
c. ensure supervisors of research trainees have the appropriate skills, qualifications and resources.

(20) The Sponsor will:

a. ensure all researchers involved in the conduct of clinical trials have appropriate skills, qualifications, experience and resources; and
b. ensure all researchers involved in the conduct of clinical trials have current GCP training certification.

Part E - Project Design

(21) Projects should be designed in line with the NHMRC National Statement on Ethical Conduct in Human Research 2007 and for drug and device trials should also be designed in accordance with the Therapeutic Goods Administration Guideline on Good Clinical Practice. Where there is conflicting advice, the National Statement should take precedence over the TGA notes on Good Clinical Practice.

Part F - Project Authorisation

(22) Project authorisation includes the relevant checkpoints and approvals from Parts G-M below.

Part G - Insurance and Indemnity

(23) The Sponsor is responsible for arranging Clinical Trials Insurance, and the site is responsible for other matters of Indemnity. The minimum amount and responsibilities are outlined on the clinical trials website.

Part H - Intellectual Property and Research Data Management

(24) Researchers must be aware of their responsibilities and obligations associated with intellectual property (IP), including ownership, copyright and patents as outlined in any legal agreements and Research Data Management Plans. Any IP should be informed by the University's Intellectual Property Policy, which is designed to ensure commercially valuable intellectual property is protected to the benefit of relevant parties and society.

(25) Research data should be managed according to the research data management plan that has been approved as part of the lead HREC ethics approval. Where possible data management should comply with the

University's Research Data Management Policy.

(26) Researchers must manage all aspects of data capture, storage, retention and sharing before, during and after research is completed.

Part I - Legal and Contract Administration

(27) All research requires a written agreement between the University and each participating clinical trial site. This is required even if there is no funding provided for or required by the project. The research agreements depend on sponsor type and are outlined on the clinical trials website.

(28) Where an existing approved Partnership Agreement exists, that agreement shall be used. Where there is no such agreement in place with that partner, collaborator or site, the University supports the use of the Medicines Australia approved Collaborative Research Group (CRG) Clinical Trial Research Agreement (CTRA) template or Medical Technology Association of Australia (MTAA) agreements.

(29) All CTRAs/MTAAs must be discussed with the Research Office prior to execution.

(30) All CTRAs and other research agreements should comply with the Research Contracts and Grants Policy.

(31) These can only be signed by an authorised signing authority such as the Executive Director, Research Office. Refer to Delegations and Authorisations Policy. However, the Site Principal Investigator must sign the Principal Investigator section of the CTRA or MTAA.

Part J - Finances

(32) Researchers must ensure they have adequate funding to cover costs associated with the clinical trial.

(33) Multiple funding sources may be required to adequately fund the clinical trial.

Part K - Risk Management

(34) Research must not commence without the relevant approvals or acknowledgements in place. The types of approvals and processes are outlined on the clinical trials website.

(35) When La Trobe is engaged in a clinical trial and the requirements of this Policy cannot be met by a collaborating institution and/or clinical trial site, the Research Office (on behalf of the researchers) will engage with the University's Risk Management Office to seek advice on risk and liability.

(36) All staff and students on a project must declare any real or perceived conflicts of interest in compliance with the University's Conflict of Interest Policy.

(37) Any research involving the manufacture of therapeutic products used in clinical trials must be manufactured in accordance with the Good Manufacturing Practice principles and procedures to ensure that therapeutic goods are of high quality.

Part L - Ethics and Governance Review

(38) All clinical trials must have ethics approval prior to project commencement. Whether they are submitted to the La Trobe University Human Research Ethics Committee (HREC) or to an external HREC depends on the circumstances of the trial as outlined on the clinical trials website. The lead HREC is the allocated HREC which provides ethical approval for the project. The lead HREC is identified based on the following information:

a. where the study is conducted
b. single or multisite
c. the Coordinating Investigator and Site Principal Investigator requirements (for multisite projects)

(39) For externally approved clinical trials (that is, approved by a non-La Trobe University HREC), researchers must provide a completed and externally approved form via the process outlined on the website.

(40) Management of post-approval requirements such as modifications to an approved project, annual and final reports and safety reporting should be done in accordance with the sponsorship type and lead HREC requirements. Advice on these requirements is outlined on the clinical trials website.

Part M - Registration and Notification

(41) The Co-ordinating Principal Investigator must register any clinical trial when the University is the sponsor on a primary registry in the World Health Organisation (WHO) Registry Network. The University recommends the Australian New Zealand Clinical Trials Registry.

(42) Trials using experimental or off-label drugs and/or medical devices must complete a Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) form. The process is outlined on the clinical trials website.

Part N - Project Delivery

(43) Project delivery includes the relevant checkpoints and approvals from Parts O-Q below.

Part O - Monitoring

(44) Safety of research participants, staff and students should be prioritised over all other aspects of the research. Therefore, during the conduct of a clinical trial, staff on the project must notify the Research Office (and any external HREC if they are the approver) as soon as they become aware of any of the following:

a. reportable event arising where the University is the Sponsor and/or Lead HREC (i.e. the HREC who has jurisdiction to give ethical approval for a clinical trial) and/or the event occurred on La Trobe premises. Reporting requirements and timeframes are outlined on the clinical trials website.
b. change in the information provided in the risk 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 this Policy or pertaining to the ethical acceptability, participant safety or integrity issues in relation to the clinical trial.

(45) The Research Office will:

a. establish and maintain a confidential University record of clinical trial activities notified to it; and
b. where required, provide the Risk Management Office with any information that may impact on the acceptable risk and/or insurance requirements.
c. when the University is acting as the Sponsor it may from time to time conduct monitoring per the University's monitoring policy.

Part P - Complaints Handling

(46) Complaints about the conduct of clinical trials by University staff, students, and/or clinical trials sponsored by the University should be made per the University's complaints process outlined on the clinical trials website.

(47) Allegations involving possible breaches of the Australian Code for the Responsible Conduct of Research (2018) are to be made and managed per the process outlined in the University's Research Misconduct Procedure.

Part Q - Reporting

(48) Reporting of safety events, changes to the project, annual monitoring reports, and any other reports as required from time to time should be done so in line with the Sponsor and Lead HREC requirements as outlined on the clinical trials website.

Part R - Project Closure

(49) The Research Office should be notified when a clinical trial is closed per the processes outlined on the clinical trials website.

Part S - Roles and Responsibilities

(50) The University is responsible to:

a. make appropriate training available to researchers on the requirements of this Policy and legislative, regulatory and other requirements applicable to clinical trials;
b. obtain and maintain appropriate insurance cover for clinical trial activities conducted by it or on its behalf; and
c. manage formal research collaboration partnerships the University enters.

(51) The Executive Director, Research Office is responsible for the administration and implementation of this Policy or any processes associated with it.

(52) The Research Office is responsible to:

a. develop, negotiate, co-ordinate and support the documentation and contracts relating to clinical trials;
b. coordinate the risk assessment process;
c. provide or coordinate research support services for researchers involved in clinical trials; and
d. in consultation with the Co-ordinating Investigators, determine whether, and on what terms, the University will participate in clinical trials; and
e. manage Ethics Committees and ethical review processes for clinical trials as outlined on the clinical trials website.

(53) Co-ordinating Investigators are responsible to:

a. conduct the clinical trial;
b. ensure compliance with the approved protocol;
c. take appropriate steps to ensure compliance with all legislative, regulatory, policy and other requirements applicable to any clinical trial, including any requirements of the reviewing Human Research Ethics Committee;
d. monitor the conduct of University researchers and others undertaking activities within the clinical trial, ensuring they are aware of their responsibilities;
e. register the clinical trials and maintain evidence of registration consistent with this Policy and any associated procedures;
f. provide information to the Research Office and other groups specified in this Policy or the processes associated with this Policy where required; and
g. carry out safety monitoring and reporting as required.

(54) All staff and students involved in clinical trials are responsible to:

a. keep appropriate records where required;
b. identify and inform the co-ordinating investigator of existing and emerging risks relating to clinical trial activities;
c. undertake TransCelerate R2 (E6) accredited Good Clinical Practice training (which is valid for 3 years) before being involved in the clinical trial; and
d. undertake activities in accordance with this procedure.

Section 5 - Definitions

(55) Definitions in the procedure are intended for use within the University Policy and Research Governance Framework. They are not necessarily defined the same way as definitions of the same terms in external documents, even if these documents are referred to in this Policy.

a. Affiliate: means 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.
b. 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 health outcomes (this definition is from the World Health Organisation).
c. Research Office: The University Office that supports all researchers with contracts, grants, research partnerships, ethics and research performance data. It includes the following teams:
    i. Ethics, Biosafety and Integrity (includes Research Governance)
    ii. Consulting and Contracts
    iii. Grants
    iv. Research Performance
    v. Research Impact
d. Co-ordinating investigator: means the investigator responsible for co-ordination of all other investigators in a clinical trial conducted at multiple sites. For single site clinical trials, the terms principal investigator and co-ordinating investigator are synonymous. For clinical trials where the University is both the sponsor and a trial site, the co-ordinating investigator may be the principal investigator at the University site.
e. Clinical Trial Notification (CTN) scheme: means the scheme operated by the Therapeutic Goods Administration (TGA) that permits therapeutic goods to be used for experimental purposes if the relevant clinical trial is notified to the TGA.
f. Clinical Trial Exemption (CTX) scheme: means the scheme operated by the Therapeutic Goods Administration (TGA) that permits therapeutic goods to be used for experimental purposes if the relevant clinical trial is approved by the TGA.
g. Good Clinical Practice: means the international standard for conducting clinical research. Generally referred to as GCP, it is a process incorporating established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human beings. All researchers involved in clinical trial research must be GCP trained.
h. Good Manufacturing Practice: means a system for ensuring that investigational products are consistently produced and controlled according to quality standards. See the Australian Government Therapeutic Goods Administration Good Manufacturing Practice Overview.
i. 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.

j. National Health and Medical Research Council (NHMRC): refers to Australia's peak funding body for medical research.

k. Policy: means this entire document.

l. Protocol: means a document describing 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.

m. Research: has the definition given in the Australian Code for the Responsible Conduct of Research. The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

n. Researcher: has the meaning given in the Australian Code for the Responsible Conduct of Research (2018) that is, person (or persons) who conducts, or assists with the conduct of, research.

o. Research Governance: means broadly the framework of principles, roles and responsibilities at the University that ensure the quality, safety and integrity of research and compliance with all obligations and commitments. See the Research Governance Policy for more detail.

p. Serious Adverse Event: has the meaning given in the NHMRC's Safely Monitoring and Reporting Clinical Trials Involving Therapeutic Goods 2016 (or any replacement for it). The defintion in 2016 version is 'Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect'.

q. Site: means the physical 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.

r. Site Principal Investigator: means for multi-site clinical trials the person listed as the Site Principal Investigator takes responsibility of the project only at that site.

s. 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: an Australian resident or an incorporated body conducting business in Australia with a representative residing in Australia.

t. Staff: means all employees of the University or affiliated enterprises with which the University has a formal agreement and includes casual employees, clinical staff and unpaid members of the University such as Honorary and Adjunct appointments, all of which are registered on the HR system.

u. Student: a student enrolled at the University and who is named as a student investigator on the ethics approval.

v. Therapeutic goods: has the meaning given in the Therapeutic Goods Act 1989 and includes medicines, medical devices, biologicals and goods declared to be therapeutic goods under that legislation

w. Therapeutic Goods Administration: means the agency in the Commonwealth Department of Health, commonly referred to as the TGA, with responsibility for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia.

Status and Details

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