



MACQUARIE
University

INVESTIGATOR INITIATED CLINICAL TRIALS (IICT) WHERE MACQUARIE UNIVERSITY IS A SPONSOR

INSTITUTIONAL FRAMEWORK AND GUIDELINES



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MACQUARIE UNIVERSITY IS A SPONSOR

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Introduction

A University working group was established in late 2019 to develop a framework and guidelines at institutional and local level (e.g. MQ Health) for management of Investigator Initiated Clinical Trials (IICTs) where Macquarie University (MQ) is a sponsor. The working group had monthly meetings to discuss progress and to review draft documents.

Membership includes:

- Prof Roger Chung (*Deputy Dean Research and Innovation (FMHHS)*),
- Dr Kandy White (*Director Research Ethics and Integrity*),
- Dr Yordanka Krastev (*Clinical Research Manager, FMHHS*),
- Ms Nicola Chapman (*Head of Clinical Operations, Clinical Trials Unit, FMHHS*),
- Prof Howard Gurney (*Director, Clinical Trials Unit, FMHHS*),
- Ms Jennifer Rowland (*Human Ethics Lead*),
- Ms Amy Bruce (*Clinical Quality Manager, Clinical Trails Unit, FMHHS*).

The focus of the framework is to offer a risk mitigation strategy when MQ is a sponsor of IICTs and to address governance aspects of University sponsorship at several levels.

Investigator Initiated Clinical Trials

DEFINITIONS

Clinical trial as per the *ICG GCP* definition is: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are considered synonymous.

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Characteristics of Investigator Initiated Clinical Trials

- An investigator initiates and organises the trial and may be defined as the sponsor of the trial and will be responsible for the sponsor's functions; or
- The investigator's institution (e.g. hospital, research institute or university) is defined as the sponsor with the same functions.
- The clinical trial addresses relevant clinical questions and not industry needs.
- The Principal Investigator or the Hospital/Institution is the primary author and custodian of the clinical trial protocol.
- A pharmaceutical/device company is NOT acting as the sponsor for the purposes of the Clinical Trial Notification (CTN) application.
- Another party (usually a pharmaceutical or medical device company) provides the medicinal product or device used in the clinical trial but has no other involvement in the conduct of the trial.

(References: [Australian Clinical Trials Sponsorship](#) webpage and [Melbourne Health - SOP No.011](#))

Regulation of clinical trials

Clinical trial research is regulated primarily by the Commonwealth's Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC). Further information about clinical trials regulations can be found at:

- www.australianclinicaltrials.gov.au/
- www.tga.gov.au/clinical-trials
- medicinesaustralia.com.au/policy/clinical-trials/
- www.clinicaltrials.gov/ct2/home
- <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

Clinical Trial Registration

Researchers are required to register clinical trials in a publicly accessible register as trial registration promotes transparency, identifies gaps, and prevents unnecessary duplication of research.

Clinical trials should be registered prior to the enrolment of the first participant. The [Australian New Zealand Clinical Trials Registry \(ANZCTR\)](#) is an online registry of clinical trials being undertaken in Australia, New Zealand and elsewhere. The ANZCTR recommends commencing the registration process at least 3 weeks prior to the anticipated recruitment start date. If you are unsure if registration is required, please contact the ANZCTR info@actr.org.au.

Prospective trial registration is an ethical obligation and is increasingly required by medical journal editors as a precondition of publication. (Ref: [International Committee of Medical Journal Editors \(ICMJE\) - Policy on Trial Registration](#))

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World Health Organisation Registry Network provides prospective trial registries with a forum to exchange information and work together to establish best practice for clinical trial registration. <http://www.who.int/ictcp/network/primary/en/>

Responsibilities of Macquarie University as a Sponsor

Sponsor definition: All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity (an overseas company cannot be the sponsor of a trial in Australia). Sponsors of trials may include individuals, companies, institutions, or organisations. The trial sponsor is responsible for the initiation, management, and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct.

Sponsor responsibilities: In accordance with [Guideline for Good Clinical Practice \(GCP\); Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice ICH E6\(R2\)](#), the sponsor of a clinical trial has the following responsibilities:

1. Quality Management throughout all stages of the trial process (*Section 5.1*).
 - Key elements: Critical Process and Data Identification, Risk Identification, Risk Evaluation, Risk Control, Risk Communication, Risk Review, Risk Reporting (*Sections 5.0.1 - 5.0.7*).
2. Implementing and Maintaining Quality Assurance and Quality Control (This includes written SOPs and relevant agreements with all involved parties).
3. Oversight of any Contract Research Organisation (CRO) – (Note: any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor).
4. Designation of appropriate Medical Expertise (appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems).
5. The use of qualified individuals in the trial design:
 - a. Biostatisticians
 - b. Clinical pharmacologists
 - c. Clinical physicians
6. Use these qualified individuals to supervise Trial Management, Data Handling, and Record Keeping, e.g. Establishment of a fully regulated DSMB as per the NHMRC guidance on [Data Safety Monitoring Boards \(DSMBs\)](#).
7. Retaining qualified and adequately resourced Investigator's (refer to Section 4 Investigator's responsibilities).
8. Define, establish, and allocate trial related responsibilities.
9. Provide insurance to compensate subjects and indemnify investigators.
10. Financing – agreement between the sponsor and investigator.
11. Notification/Submission to Regulatory authorities i.e. CTN or Clinical Trial Approval (CTA) through TGA Business portal.

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12. Confirmation of Review by HREC.
13. Information on Investigational Product(s) i.e. Investigators Brochures.
14. Manufacturing, Packaging, Labelling, and Coding Investigational Product(s) meets regulations.
15. Supplying and Handling Investigational Product(s).
16. Record Access for review and/or auditing purposes.
17. Safety Reporting (*Refer to section 5.16 and [Safety monitoring and reporting in clinical trials involving therapeutic goods](#) guideline, NHMRC 2018*).
18. Adverse Drug Reaction Reporting (Refer to section 5.17).
19. Monitoring - sponsor to determine the extent and nature of monitoring, e.g. on-site monitoring (by monitor), centralised monitoring or a combination of both (Section 5.18.3-4).
20. Self-Auditing procedures (Section 5.19).
21. Strategies for noncompliance with protocol, SOPs, GCP or other regulatory requirements (Section 5.20).
22. Protocols for Premature Termination or Suspension of a Trial.
23. Preparation and Generation of Clinical Trial/Study Reports.
24. Responsibilities associated with Multicentre Trials.

Principal Investigator Responsibilities

According to Section 4 of the [ICH E6\(R2\) GCP guidelines](#), the Principal investigator is responsible for:

1. Investigator's Qualifications and Agreements
2. Adequate Resources
3. Medical Care of Trial Subjects
4. Communication with HREC
5. Compliance with Protocol
6. Investigational Product(s)
7. Randomization Procedures and Unblinding
8. Informed Consent of Trial Subjects
9. Records and Reports
10. Progress Reports
11. Safety Reporting
12. Premature Termination or Suspension of a Trial
13. Final Report(s) by Investigator

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Key University Units/ Functions

Institutional Human Research Ethics Committee

The National Statement requires that all clinical trials must be reviewed by a HREC. All clinical trials undertaken at Macquarie University must be approved by the Macquarie University HREC (Medical Sciences). The HREC reviews the scientific and ethical aspects of clinical trials. Applications to MQ HREC must be submitted online via the [FoRA - Human Research Management System](#), supported by clinical trial protocol and an up to date Investigator's Brochure (IB) (*where applicable*).

All applications must be submitted via [FoRA](#).

For more information about this system, how to submit new applications and the management of existing applications, please refer to the [Human Research Ethics Management support](#) page.

For further information, contact the Ethics Secretariat: ethics.secretariat@mq.edu.au.

Risk and Insurance

The University's insurance program involves the proactive management and mitigation of known insurable risk events and the purchase of insurance policies. The critical point is what the Macquarie University involvement in the research is, rather than the person who is conducting the research. The Medical area of coverage includes the following types of insurances:

- Professional indemnity – medical and allied health professionals;
- Medical malpractice; and
- Clinical trials.

Current clinical trial insurance is a “no fault” insurance with a broad coverage of human research. All clinical research involving human participants (not only clinical trials) is covered under the policy. This includes projects using patient health data and observational studies.

The insurances vary depending on the University involvement in the research.

- For Macquarie University sponsored research, the clinical trial will be insured after obtaining ethics approval from Macquarie University HREC, final governance approval has been granted and providing clarity regarding the nature of the trial and participant's profiles.
- For Commercially sponsored studies– the sponsor must hold appropriate clinical trial insurance policy coverage. NSW Health has published a Policy Directive which requires commercial sponsored trials to maintain a limit of liability of no less than \$20 million for any one occurrence in the aggregate and maximum \$25,000 retention.

If you have any insurance related questions for investigator initiated clinical trial and other clinical research study, you should contact the [MQ Health Clinical Research Manager](#) in the first instance.

Alternatively, you can email the MQ insurance directly at insurance@mq.edu.au.

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Research Services - Contracts team

Any research-related contracts and agreements with external organisations must be submitted to the University's Research Policy and Contracts Team (RPCT) to ensure they are acceptable to both you and the University. Where appropriate, contract negotiation and/or drafting may be referred to the Office of General Counsel (OGC) by RPCT. Part of the role of RPCT is to ensure contracts comply with the University's Code for the Responsible Conduct of Research and other University policies.

NB: Only the Deputy Vice-Chancellor (Research) or his delegate is authorised to sign research contracts or agreements on behalf of Macquarie University.

A RESEARCH CONTRACT:

- Describes the expectation and requirements of each party
- Ensures those involved know what is expected from them
- Is a written 'expression' of what has been discussed and agreed
- Protects interests of researchers
- Protects the University's interest
- Protects collaborator/funder requirements

Detailed information about the process, the timeframes for funded and non-funded research agreements and key contacts can be found on the [RPCT webpage](#).

If you have any questions related to research agreements/contracts, please contact the Research Policy and Contracts Team at researchcontracts@mq.edu.au.

Macquarie University Governance

MQ Institutional Governance

1. Under the University Delegation of Authority, the Deputy Vice-Chancellor Research (DVCR) is the person responsible for sign off for MQ sponsorship of IICTs.
2. Determination of MQ becoming a sponsor of an IICT based on following:
 - *Chief investigator affiliation* – should be Macquarie University staff or honorary appointment for insurance and liability purposes.
 - *Risk assessment* – determination based on risk matrix
 - *Funding source* – e.g. NHMRC grant, self-funded by investigator funds, industry grant or Collaborative research group funding (excluding pharmaceutical companies), philanthropic funding.
 - *Study site/s* - Single site or multisite study.
 - *If the clinical trial is to be conducted overseas Macquarie University cannot be a sponsor.*
 - *Indemnity and insurance aspects* – Depending on the nature of the clinical trial, the following insurance policies may respond - Clinical trial insurance, professional

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indemnity, public liability, medical malpractice insurance, student personal accident or workers compensation.

3. Delegation of responsibilities to Local governance (MQ Health or Clinical Trials Unit (CTU)).

Local Governance (MQ Health level)

MQ Health clinical research governance (CRG)

As of March 2018, all research to be conducted at MQ Health premises and involving MQ Health patients or staff is required to have clinical research governance authorisation before commencement.

Focus of CRG process at MQ Health:

- Assess the feasibility of the proposed clinical research project (including clinical trials);
- Consider the resource implications for MQ Health.
- Identify and manage any unusual insurance or other risk(s).
- Ensure relevant sign-offs are in place to meet institutional obligations.

Broader scope of the MQ Health CRG

- To capture all clinical research (including clinical trials) conducted at MQ Health.
- To help identify any issues with the project early.
- To ensure that necessary governance considerations are applied to proposed research.
- To provide a structure and make it easier for investigators to conduct research.

In addition, to ensure:

- The research team has the capacity, capability and financial resources (e.g. funding, approval to use hospital and other resources, relevant expertise and sufficient participant pool) to carry out the proposed clinical research.
- The proposed clinical research is in line with the MQ Health strategic priorities.
- The MQ Health Executive team is aware of and supports the proposed clinical research.
- Relevant approvals are in place before research begins.
- Researchers are well supported to conduct high-quality research at MQ Health.

The MQ Health Clinical Research Executive (CRE) assesses the feasibility and quality of proposed clinical research projects and their alignment with the MQ Health strategic priorities. The expertise of the CRE includes the following areas: academic, clinical, clinical trials, research practice and management.

Note: For IICTs a scientific review is conducted in parallel with the CRG review. Central point of contact for governance queries and general advice and guidance on undertaking clinical research and IICTs is the [MQ Health Clinical Research Manager](#). Details

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of the IICT application process can be found on the [Governance for Macquarie sponsored Investigator Initiated Clinical Trials \(IICTs\)](#) webpage.

Local Governance - (FMHHS Clinical Trials Unit)

- Development and maintenance of Standard Operating Procedures (SOPs).
- Implement and Maintain Quality Assurance and Quality Control systems.
- Facilitate GCP training for investigators.
- On behalf of the investigator/institution maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial.
- Coordinate most of the investigator initiated clinical trials.

Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) submission to the Therapeutic Goods Administration (TGA)

Clinical Trial Notification (CTN) scheme is a **notification** process. The clinical trial sponsor must notify TGA of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. This must take place before starting to use the goods. The notification form (eCTN) must be submitted online and accompanied by the [relevant fee](#).

[eCTN](#) submission to the TGA is required if:

- A product for the trial is not entered on [the Australian Register of Therapeutic Goods](#) (ARTG), including any new formulation of an existing product or any new route of administration; or
- The proposed use of a registered or listed product is outside the conditions of its marketing approval.

[eCTN](#) submission if Macquarie University is the sponsor:

- The eCTN submission for Macquarie University is done by the [MQ Health Clinical Research Manager](#).
- Macquarie University has an institutional account with TGA and an authorised person to be the institutional administrator.
- You need to liaise with the [MQ Health Clinical Research Manager](#) and supply the full project details, including all site details before the eCTN application can be lodged at the TGA portal.
- Please note that HREC approval is required before CTN submission.
- Credit card payment of the CTN fee is preferable.

For further information, contact the [MQ Health Clinical Research Manager](#).

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Clinical Trial Approval (CTA) (*formally Clinical Trial Exemption (CTX) scheme*) is an **approval** process. The sponsor submits an application to TGA seeking approval to supply 'unapproved' therapeutic goods in a clinical trial. The application must be accompanied by the [relevant fee](#).

- TGA evaluates summary information about the product including relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial.
- The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.
- CTA applications are submitted using paper-based forms. There are two forms that must be completed by the sponsor and submitted to [TGA](#) via post.

More information about CTN and CTA schemes is available on the [TGA website](#).

Safety Reporting

Safety reporting of significant safety Issues (SSIs) outside of HREC and TGA reporting. Information about MQ safety reporting requirements can be found on the Clinical Research Governance [clinical trial-initiation, management, monitoring and reporting](#) webpage.

References

1. [Australian code for the responsible conduct of research](#) (2018)
2. [National statement on ethical conduct in human research 2007](#) (updated 2018)
3. [Australian clinical trial handbook](#)
4. [Therapeutic Goods Administration clinical trial notification/clinical trial approval schemes](#)
5. [Guideline for Good Clinical Practice \(GCP\); Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice ICH E6\(R2\)](#)
6. [Data Safety Monitoring Boards \(DSMB\) NHMRC, 2018](#)
7. [Safety monitoring and reporting in clinical trials involving therapeutic goods, NHMRC, 2016](#)
8. [Risk-based management and monitoring of clinical trials involving therapeutic goods 2018](#)
9. [Competencies for Australian academic clinical trialists, NHMRC, 2018](#)
10. [ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice](#)



Macquarie University is a vibrant hub of intellectual thinkers, all working towards a brighter future for our communities and our planet.

A PLACE OF INSPIRATION

Macquarie is uniquely located in the heart of Australia's largest high-tech precinct, a thriving locale which is predicted to double in size in the next 20 years to become the fourth largest CBD in Australia.

Our campus spans 126 hectares, with open green space that gives our community the freedom to think and grow. We are home to fantastic facilities with excellent transport links to the city and suburbs, supported by an on-campus train station.

RENOWNED FOR EXCELLENCE

We are ranked among the top two per cent of universities in the world, and with a 5-star QS rating, we are renowned for producing graduates that are among the most sought-after professionals in the world.

A PROUD TRADITION OF DISCOVERY

Our enviable research efforts are brought to life by renowned researchers whose audacious solutions to issues of global significance are benefiting the world we live in.

BUILDING SUCCESSFUL GRADUATES

Our pioneering approach to teaching and learning is built around a connected learning community: our students are considered partners and co-creators in their learning experience.

FIND OUT MORE

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