



INVESTIGATOR INITIATED CLINICAL TRIALS - PRINCIPAL INVESTIGATOR AGREEMENT

Please indicate if Macquarie University is a sponsor or a site

SPONSOR SITE

1 Principal Investigator's Qualifications and Agreements

- 1.1. The Principal Investigator (PI) assumes responsibility for the proper conduct of the trial.
- 1.2. The PI will be familiar with the appropriate use of the investigational product(s).
- 1.3. The PI is aware of and will comply with the TGA annotated International Conference on Harmonisation (ICH), Good Clinical Practice (GCP) guidelines, The Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research and Macquarie University policies and guidelines.
- 1.4. The PI will maintain a list of all appropriately qualified persons to whom he or she has delegated significant trial-related duties.
- 1.5. The PI will permit monitoring and auditing by Macquarie University.
- 1.6. The PI must disclose and manage actual, potential, or perceived conflicts of interest.

2 Adequate Resources

- 2.1. The PI will be able to demonstrate potential for recruiting the required number of suitable subjects within the agreed recruitment period.
- 2.2. The PI will have enough time to properly conduct and complete the trial to GCP requirements within the agreed trial period.
- 2.3. The PI will have available an adequate number of qualified staff and facilities for the foreseen duration of the trial to conduct the trial properly and safely.
- 2.4. The PI will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
- 2.5. The PI is responsible for supervising any individual or party to whom he/she delegates trial-related duties and functions conducted at the trial site.

3 Medical Care of Trial Subjects

- 3.1. A qualified physician, who is a PI or a sub-investigator for the trial, will be responsible for all trial-related medical decisions.
- 3.2. The PI will ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial.

4 Ethics and Governance Approval

- 4.1. The PI/institution will have favorable written and dated approval from the Human Research Ethics Committee (HREC) and MQ Health final governance authorisation BEFORE any subjects are recruited at Macquarie University.
- 4.2. The PI should ensure, prior to the commencement of the project, that study records will be made available for any monitoring/ auditing process that is due during the conduct of the trial.

5 Compliance with Protocol

- 5.1. The PI must comply with the approved protocol.
- 5.2. The PI will document and explain any deviation from the approved protocol or noncompliance with GCP.
- 5.3. The PI may implement a deviation from the protocol to eliminate an immediate hazard(s) to trial subjects without prior HREC approval.

6 Investigational Product(s)

- 6.1. Responsibility for investigational product(s) accountability, storage, dispensing and appropriate destruction at the trial site rests with the PI.

- 6.2. The PI ensures the investigational product(s) is/are used according to the protocol and patients are trained and checked regularly that they are taking the investigational product(s) correctly.

7 Informed Consent of Trial Subjects

- 7.1. In obtaining and documenting informed consent, the PI will comply with and will adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki and to the Australian National Statement on Ethical Conduct in Human Research.

8 Records

- 8.1. The PI will ensure attributable, accurate, contemporaneous, complete, legible, and timely collected trial related data.
- 8.2. Data reported in the trial database will be consistent with the source documents or the discrepancies will be explained.
- 8.3. The PI will ensure a site file of essential documents (as specified in section 8 of ICH-GCP) is maintained and is archived for at least 15 years after the study is complete.

9 Progress Reports

- 9.1. The PI will promptly provide written reports to MQ Health Clinical Research Executive and the HREC on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects. This includes reporting any serious breaches of GCP or the protocol within 72 hours of becoming aware of the breach.
- 9.2. The PI will submit written summaries of the trial status including a clear summary of its safety profile to the HREC annually or more frequently if requested.

10 Safety Reporting

- 10.1. The PI will report immediately (**within 24 hours**) to Macquarie University Clinical Trials Safety Officer via email: researchsafetyreporting@mq.edu.au the following:
- all serious adverse events (SAEs),
 - any birth defect arising from any pregnancy of a participant (or partner) and
 - all urgent safety measure instigated by the site.
- 10.2. Report to Macquarie University Clinical Trials Safety Officer via email: researchsafetyreporting@mq.edu.au and the HREC **within 72 hours** of becoming aware of the event:
- All significant safety issues,
 - Suspected Unexpected Serious Adverse Reactions (SUSARS) arising from the local site.
- 10.3. Report as specified in the protocol to the Macquarie University Clinical Trials Safety Officer via email: researchsafetyreporting@mq.edu.au any other safety critical events relevant to the participants on the clinical trial.

11 Final Report by Investigator

- 11.1. Upon completion of the clinical trial, the PI will provide MQ Health Clinical Research Executive and the HREC with a summary of the trial outcomes.

I acknowledge this Agreement and understand the obligations it imposes.

Principal Investigator name (*printed*): _____

Signed: _____

Date: _____