INVESTIGATOR INITIATED CLINICAL TRIAL (IICT) PI ESSENTIALS GUIDE

Stage	Steps/Document's required
Development of clinical trial protocol and supplementary documents	• Protocol - complete the MQ recommended SPIRIT statement for investigator initiated clinical trials. • Seek biostatistical advise or peer-review from an expert in the field. • Ensure current CVs of the **Principal Investigator and research team** demonstrating affiliation with the trial site (MQ) and training and experience to conduct the clinical trial. • Ensure current Good Clinical Practice (GCP) certificates for **the PI and the research team.** • Itemised study budget /funding information *(if applicable*). • Investigator brochure (*if relevant*).
Submission for MQ Health Clinical Research governance (CRG) and scientific review	• Download and complete the Clinical Research Governance IICT application form. • Download and complete the MQ IICT PI agreement where MQ is a sponsor or a site. • Submit the CRG IICT application form, the clinical trial protocol, MQ IICT PI agreement, all CVs, and GCP certificates for the PI and the research team, along with any other supporting documentation relevant to the project in one project submission to: clinical.research@mqhealth.org.au for parallel governance and internal scientific review. **Note:** Scientific review of the IICT where MQ is a site - External review is accepted. External review documentation must be submitted for CRE review in the project submission. • A CRG endorsement-subject to conditions letter will be provided. The endorsement letter **must** be uploaded into the ethics application.
Submission of ethics application for HREC review	MQ Human Research Ethics applications are submitted via the online Human Research Ethics System - FoRA. Support and guidance: ethics.secretariat@mq.edu.au • Log into FoRA using your One ID and password. • Complete the ethics application form titled HREA, upload full protocol and all supporting documents. Ensure you upload the CRG endorsement - subject to conditions letter under the Upload section. • Ethics submissions should be sent via the **'more than low risk'** pathway to HREC (*Medical Sciences*). For HREC submission deadline and meeting dates, please visit HREC important dates.
Research contract/s	• Macquarie University accepts standard Medicines Australia Clinical trial research agreements (CTRA). • Any other templates for research-related contracts and agreements with external organisations must be discussed and submitted to the University's Research Policy and Contracts Team (RPCT) to ensure they are acceptable to both the PI and the University. • If you are using an unregistered product, you will need an agreement or letter of intent from the manufacturer to supply the product to Macquarie.
Final MQ Health authorisation and confirmation of MQ sponsorship	The PI must provide evidence of final approvals to clinical.research@mqhealth.org.au • Copy of final Macquarie University HREC approval. • Executed Clinical Trial Research Agreement (CTRA), (*or other research contract/agreement*). • Agreements with service providers and/or MUH (*if applicable*). *NOTE:* If the project is run by the MQ Clinical Trials Unit, a submission of the Evidence of Final Approvals - CTU clinical trials form should be sufficient. **MQ sponsorship or MQ as a site** The Clinical Research team will initiate the request for DVCR approval for Macquarie University sponsorship. The Clinical Research team will initiate the request for DVCR approval for Macquarie University sponsorship. Once approved by the DVCR, the Clinical Research team will initiate the

	request for DVCR approval for Macquarie University sponsorship. Once approved by the DVCR, the Clinical Research team will issue the final MQ Health authorisation for Macquarie University sponsorship letter.
Study Registration	**eCTN submission to TGA where Macquarie is a sponsor** • HREC approval is required before CTN submission. • The eCTN submission for Macquarie University is submitted by the Clinical Research Manager: clinical.research@mqhealth.org.au or +61-2-9850-2834. • If the project is managed by the Clinical Trials Unit, the CTU team will assist in this process. **Clinical Trial Registration** Please register your clinical trial in a publicly accessible registry before recruitment of the first participant. E.g., Australian and New Zealand Clinical Trials Registry (ANZCTR).
Reporting	• Regular reporting annually to the HREC (Medical Sciences) via FoRA. (*Annually as part of HREC standard reporting*). • Regular reporting to Clinical Research Executive ***(If specified in the final governance authorisation letter)*** • Serious Adverse Events, SUSARs and USMs reports to MQ Clinical Trials Safety Officer **within 24 hours** at ResearchSafetyReporting@mq.edu.au using the safety report form**.**
Project closure	• Final reports submitted to the HREC via FoRA. • Email the Clinical Research Governance Team clinical.research@mqhealth.org.au once the final report has been approved to notify the study has closed.

For further information about the process, please visit the IICT webpage.