**CHECKLIST FOR HREC APPLICATIONS**

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| --- | --- |
| **For Macquarie University/Macquarie University Hospital Applications** | **For Macquarie University/ Macquarie University Hospital research projects where the protocol has already been reviewed by a NSW Health HREC (Prior Review applications)** |
| Human Research Ethics Application (HREA) or National Ethics Application Form (NEAF) | Macquarie University Hospital Prior Review Form |
| Recruitment documents including advertisements, emails etc. | HREA + Approval correspondence from approving HREC |
| Participant Information and Consent Form (PICF) on letterhead including version # and date | Macquarie University/Macquarie University Hospital PICF on Macquarie University letterhead with Macquarie University Ethics Committee details (incl. version # and date) |
| Short 1-Page Protocol Summary for Scientific Review | Any other information relevant to Macquarie University (advertising documents, recruitment emails etc.) |
| Any other information relevant to review |  |

**If the project is a clinical trial (for all projects whether or not prior reviewed):**

Each clinical trial to be conducted at Macquarie University/Macquarie University, and which is sponsored by a third-party, must be governed by a written agreement clarifying the obligations and responsibilities of the parties involved in the trial.

NB: By law all sponsored research must have an Australian Sponsor.

**For Commercially Sponsored Studies, Clinical Trial Research Agreement (CTRA):**

For Commercially sponsored studies where the company has accepted all the roles of the sponsor the “Clinical Trial Research Agreement - Medicines Australia Standard Form” should be used.

**Contract Research Organisation (CRO) CTRA:**

Where the Contract Research Organisation (CRO) has accepted all the roles of the Sponsor the “Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor” should be used.

**Collaborative Group Sponsored CTRA:**

In the case of a collaborative sponsored clinical trial, the “Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies” should be used.

**Phase IV CTRA:**

For post marketing surveillance Phase IV studies the “Clinical Trial Research Agreement- Phase 4 Clinical Trial (Medicines)” should be used.

These documents are available on the Medicines Australia (MA) website:

<http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>

For Clinical Trials using devices:

**Commercially Sponsored Device Trial Clinical Investigation Research Agreement**:

For Commercially sponsored device trials the “*The MTAA Standard Clinical Investigation Research Agreement*” should be used:

This document is available on the Medical Technology Association of Australia (MTAA) website: <http://www.mtaa.org.au/policy-initiatives/clinical-investigations>

**Investigator initiated trials:**

**Non-commercial clinical trials**

There are no template agreements for trials that are investigator initiated or collaborative studies and as such each agreement will require review by Macquarie University/ Macquarie University Hospital. In the first instance, contact the Director, Research Office at [ro@mq.edu.au](mailto:ro@mq.edu.au)

Indemnity Agreement from Sponsor which covers Macquarie University (using the Medicines Australia template)

<http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>

A current Insurance Certificate which covers private hospitals.

**NB**: All research projects hosted by Macquarie University/ Macquarie University Hospital involving Macquarie University/ Macquarie University Hospital or external staff must have appropriate insurance and indemnity prior to the project commencing.

Contact Details for sponsor including ABN for invoice. See the Macquarie University fee schedule at:

<http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/application_process>

Clinical Trial Protocol

Investigator’s Brochure

CTN/CTX Forms for projects conducted under the CTN/CTX Scheme

**For Clinical trials using devices:**

Technical Information (for devices etc)

For further information regarding MQ Health clinical research governance requirements, contact the Clinical Research Manager at [clinical.research@mqhealth.org.au](mailto:clinical.research@mqhealth.org.au). or on +61 02 9850 2834.