**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

**[ ]**  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. or on +61 02 9850 2834.