**mental health commission Clinical trials Assessment Form**

*Complete this form only if your research project is a clinical trial.*

**1. Clinical Trial Phase (nominate one only)**

|  |  |
| --- | --- |
| Phase 0 clinical trial  | [ ]  |
| Phase I clinical trial  | [ ]  |
| Phase II clinical trial  | [ ]  |
| Phase III clinical trial  | [ ]  |
| Phase IV/post marketing surveillance | [ ]  |

**2. Clinical Trial Scheme**

2.1. Is this research conducted under the Clinical Trial Notification (CTN) scheme?

 Yes [ ]  No [ ]

2.2. Is this research conducted under the Clinical Trial Notification Exemption (CTX) scheme?

 Yes [ ]  No [ ]

If Yes to 2.1 or 2.2, attach the relevant TGA Form (signed by the Principal Investigator and HREC Chair/delegate).

**3. Clinical Trials Registry**

*Section 19 of the Declaration of Helsinki (2008) states: “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject”. In addition, the InternationalCommittee of Medical Journal Editors (ICMJE) has made an essential criterion for publication of a trial in one oftheir journals that the details of a trial should be publiclyavailable in a clinical trials registry.*

3.1. Is the clinical trial registered on a publicly accessible clinical trials registry database?

 Yes [ ]  No [ ]

3.1.1. If Yes, tick the relevant box:

|  |  |
| --- | --- |
| Australian New Zealand Clinical Trials Registry <http://www.anzctr.org.au/Default.aspx>  | [ ]  |
| Clinicaltrials.gov[www.clinicaltrials.gov](http://www.clinicaltrials.gov)  | [ ]  |
| Other (specify):  | [ ]  |

3.1.1.2. Trial Registry reference number:

If the Trial Registry reference number is unavailable at the time of submission forward the number to the RGO before recruitment of the first participant.

3.1.2. If not registered, explain why the project is not registered on a publicly accessible clinical trials registry database.

*Registration details (including registry number) must be submitted to the RGO before recruitment of the first participant.*

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4. Commercial Nature of Clinical Trial

4.1. Is the clinical trial/investigation commercial? Please tick one box:

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| --- | --- |
| Yes, commercial (**Complete 4.1.1.**) | [ ]  |
| No, non-commercial (**Complete 4.1.2**) | [ ]  |

4.1.1. Commercial trials

If the project is a commercial clinical trial/investigation is indemnity being provided by an external entity? Yes [ ]  No [ ]

4.1.1.1. If Yes, Is the draft Medicines Australia (MA)/Medical Technology Association of Australia (MTAA) Standard Indemnity Form(s) attached? Yes [ ]  No [ ]

4.1.1.1.1. If No, explain why the MA/MTAA Standard Indemnity Form(s) is not attached.

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4.1.1.2. If indemnity is being provided by an external commercial entity is there evidence of adequate and current insurance cover attached? Yes [ ]  No [ ]

4.1.1.2.1. If No, explain why insurance cover documentation is not attached.

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4.1.2. Non-commercial trials

*In most investigator initiated, collaborative or non-commercially funded clinical trials the indemnity clauses will be mutual i.e. each party will be responsible for their own liabilities. Occasionally external entities will have to produce evidence of insurance to ensure they can cover these liabilities. If in doubt contact the relevant RGO*.

Does the non-commercial trial involve an external entity? Yes [ ]  No [ ]

4.1.2.1.If the project is a non-commercial clinical trial involving the MHC and an external entity, will both parties be responsible for their own liabilities? Yes [ ]  No [ ]

4.1.2.1.1. Yes, is evidence of adequate and current insurance cover required? Yes [ ]  No [ ]

4.1.2.1.1.1. If Yes, is the insurance document attached? Yes [ ]  No [ ]

4.1.2.1.1.2. If No, explain why insurance cover documentation is not attached.

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**ATTACH THIS CLINICAL TRIALS ASSESSMENT FORM TO YOUR COMPLETED SITE SPECIFIC ASSESSMENT AND SUBMIT TO THE MHC RESEARCH GOVERNANCE OFFICER AT** **MHC.RGO@MHC.WA.GOV.AU****.**