

**CHECKLIST TO COMPARE NEAF with MATER APPLICATION**

If any of the following information is missing from your NEAF application please complete an addendum to submit to the HREC.

**Applications must be written in lay terms, using simple and non-technical language.**

**1. PURPOSE OF THE STUDY**

Have you stated, in plain language, what the research in this proposal is intended to accomplish. Have you indicated the **hypothesis** to be tested?

**2. BACKGROUND**

Have you briefly stated the background of the study? Have you included a critical evaluation of existing knowledge, and specifically identified the gaps that the project is intended to fill.

**3. CHARACTERISTICS OF THE SUBJECT POPULATION**

Have you indicated which group(s) of patients will be involved in the project?

a. **AGE RANGE.**

b. **NUMBER OF PARTICIPANTS IN TOTAL**

c. **NUMBER OF MATER PARTICIPANTS**

d. **SEX.**

e. **INCLUSION CRITERIA.**

f. **EXCLUSION CRITERIA.** *Where minority groups or NESB persons are excluded, have you provided justification?*

**g. JUSTIFICATION OF VULNERABLE PARTICIPANTS.** Have vulnerable participants been included (collectivities, children, pregnant women, foetuses, prisoners, the mentally ill)? If so, have you provided justification of the need to use these participants in the research? *For research involving Aboriginal and Torres Strait Islander participants have you addressed the NHMRC "Values & Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. Have you liaises with Mater (or community) Aboriginal and Torres Strait Islander Liaison Officers before submitting your application.*

**4. METHOD OF PARTICIPANT SELECTION**

Have you described the way in which potential participants will be identified and recruited? Have you attached a copy of any planned **advertisements**?

**5. STUDY SITE**

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Have you stated the location(s) where the study will be conducted? Please list all Australian sites and advise if the study has been approved and is in progress. For multi-centre projects, have you: Provided evidence of ethics approval from the other institution(s) involved.

If this study is to be conducted at more than one QH site have you considered using the Mutual Acceptance Model? Please refer to: <http://www.health.qld.gov.au/ethics/mam4mcr.asp>

If you wish to conduct research at the Brisbane Private Hospital have you liaised with that site in preparing your application?

### **6. METHODS AND PROCEDURES APPLIED TO HUMAN PARTICIPANTS**

Have you described the study design and all procedures (sequentially) to be applied to participants, also including?

- a. Attached a full copy of the protocol.
- b. Attached copies of the questionnaire(s) to be administered, where appropriate.
- c. Considered including a flow chart if this is a complicated study.
- d. If you have made reference to the main protocol in your application have you referred to the chapter, page and paragraph?
- e. If the design is complicated and at times easier to refer to the main protocol have you justified why you do not wish to describe the study in your own words?

### **7. SAMPLE SIZE AND DATA ANALYSIS**

- a. **SAMPLE SIZE** Have you explained the way in which the sample size was calculated, and provided justification of the sample size in terms of its statistical validity?
- b. **DATA ANALYSIS** Have you provided details of the data analysis techniques to be employed?
- c. **PRIMARY & SECONDARY OUTCOMES** Have you provided details on how outcomes are being measured?

### **8. POTENTIAL RISKS**

- a. **RISK CLASSIFICATION.**
- b. **POTENTIAL RISKS.**

### **9. PROTECTION AGAINST RISKS**

- a. Have you considered if a radiation safety report is to be provided to the HREC? Does your research proposal involving irradiation of human participants? (ACHS Equip Guide Criterion 5.1.8). ACHS

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advises this is in relation to treatment of participants not diagnostic procedures. Has this been completed?

- b. Have you described the procedures utilised to minimise and/or manage the potential risks identified in Q 8 & 9.

**10. POTENTIAL BENEFITS OF THE STUDY**

Have you described the potential benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society?



**11. THERAPEUTIC ALTERNATIVES**

- a. **THERAPEUTIC ALTERNATIVES.** Have you described the therapeutic alternatives available to the participant in the non-research context?
- b. **RISK/BENEFIT RELATIONSHIP.** Have you described the risk/benefit relationship of the therapeutic alternatives compared with the research?  
Or, if the therapeutic alternatives in the non-research context do not exist, indicated this and provided justification.

**12. RESOURCE IMPLICATIONS**

Have you provided an estimate of the additional services that will be required to accommodate the research, over and above those normally provided as part of patient care.

- a. **PROPOSED BUDGET** Have you attached a copy of the budget for the project, which provides a breakdown of the way in which funds will be spent according to the following categories: personnel, infrastructure, equipment, maintenance costs, travel, and accommodation?
- b. **PHARMACY/PATHOLOGY SERVICES/RADIOLOGY**
- c. **RESOURCE IMPLICATIONS FOR THE HOSPITAL/NURSING SERVICES**
- d. **BUDGET APPROVAL.**
- e. **Full/Partial Industry Sponsorship – have you provided the Research Ethics Coordinator with invoicing details including Company name and address, and name of Clinical Research Associate.**

**13. INDEMNIFICATION**

Have you provided evidence of indemnification for research participants for any adverse events that arise out of or in connection with participation in the study? If no special indemnity arrangements have been made for research participants, have you indicated this and provided justification? Please be aware, research without indemnity may require approval by the Hospital Insurers before commencement of your study. Rogencamp & Co Lawyers for the Mater Health Services will review all CTNs, Clinical Trial Agreements & Indemnity Agreements and provide advice on non-indemnified research. Please ensure you have liaised directly with Mr Justin Sharp or provide originals to the Research Ethics Coordinator and include photocopies with your application. If you have submitted legal documents with your application they will be forwarded on your behalf to Rogencamp & Co. Any changes required in these documents may be actioned during the process of review and approval.

- Indemnity – (wording on Indemnity agreement - **Mater Misericordiae Health Services Brisbane Limited ACN 096 708 922 for and on behalf of the eq. Mater Adult Hospital**).

**14. FINANCIAL OBLIGATIONS/COMPENSATION OF PARTICIPANTS**

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- a. Have you outlined the financial obligations that the participant will incur as a result of participating in the study, where applicable? Are the costs to the participant over and above what would normally be incurred by standard treatment, e.g., additional diagnostic/follow-up tests, longer hospitalisation?
- b. Described any economic incentives or other rewards for participation, and prerequisite condition(s) that must be fulfilled by participants in order to receive either full or partial compensation. If participants will not receive compensation for participation, have you indicated this?

**15. CONFIDENTIALITY**

- a. Have you described if the research involve the collection or disclosure of personal information, eg from medical records, which may involve a breach of confidentiality? (Confidentiality will not be breached if the data to be collected does not include information that would identify individuals, or if the consent of individuals to the release of the information will be obtained.)
- b. Described the specific steps to be taken to protect confidentiality of data. If data with participant identifiers will be released, specified the person(s) or agency to whom this information will be released.

**16. INFORMATION PURPOSELY WITHHELD**

- a. **INFORMATION WITHHELD.** Stated any information purposely withheld from the participant and justified this non-disclosure. If no information is to be withheld, indicated this.
- b. **DEBRIEFING.** Described the way in which post-study feedback will be given to participants.

**17. INFORMED CONSENT**

Explained the way in which consent/assent will be obtained including:

- a. Who will solicit informed consent from the participant, and when will consent be sought?
- b. If you are not seeking Informed Consent have you addressed the requirements in the National Statement on Ethical Conduct in Research Involving Humans, Privacy Act and Section 95A of the Privacy Act? (<http://www.health.gov.au/nhmrc/publications/pdf/e43.pdf>)
- c. Will the project be explained verbally to the participant, in addition to the provision of a written Patient Information Sheet?
- d. How long will the participant be given to consider whether they wish to participate, before being required to indicate their decision?
- e. How will the timing of and setting for the process of informed consent be conducive to rational and thoughtful decision-making by the participant in order to ensure it is without coercion or undue influence?

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- f. How will it be determined that the participant understood the information presented?
- g. Will the participants be mentally and physically competent to give informed consent? If not, describe the degree of impairment relative to their ability to consent to participate in research.
- h. If children (under 18) will be participants, how will their assent be obtained?  
Attach copies of all consent/assent forms and Patient Information Sheets. Please ensure that the format, content and readability level is in compliance with the *Consent Guidelines*.

**18. INFORMATION FOR STAFF**

Has a Staff Information Sheet been completed to be included in the charts of all patients involved in the research project?

- a. Have you explained how staff will be involved in administering the protocol and be informed/trained?
- b. Have you attached a copy of the Staff Information Sheet, which will be used to explain the project to staff?

**19. OTHER ETHICAL IMPLICATIONS**

Outlined any additional issues/concerns, which may be relevant to the Committee's deliberations.

- a. In accordance with 12.5 of the National Statement informed the HREC of any business or other similar association which may exist between you and the supplier of a drug or surgical or other device to be used in this trial. *Eg. Have you disclosed if you have shares in the sponsoring company?*

**20. NOMINATION OF SCIENTIFIC ASSESSORS**

All protocols submitted to the Mater Health Services Human Research Ethics Committee will be reviewed by the Scientific Sub Committee two weeks prior to the Research Ethics Meeting. Should further scientific clarification be required, have you nominated two assessors?

Name	Address	Ph:	Email

*Have you checked the willingness and availability of your nominated assessors in order to prevent delays in the approval of your application?*



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**NON-ASSESSORS** Investigators preferring that a particular assessor NOT be approached to review their protocol may indicate this and provide justification for this request. Has this been addressed?

### **ADDENDUM:**

#### **INTELLECTUAL PROPERTY:**

Will your research lead to intellectual property?    Yes        No   

If you have answered yes to this question or you are unsure, please refer to the MHS Policy on Intellectual Property. This is available through Docucube on the Intranet. Please refer to [MSH-CORP-P-2.07 INTELLECTUAL PROPERTY POLICY V1.0.pdf](#)

**PLEASE NOTE THAT YOU ARE REQUIRED TO SUBMIT THE ORIGINAL DOCUMENTS AND 20 COPIES OF THE APPLICATION**

**LATE REQUESTS FOR ETHICS APPROVAL WILL NOT BE ACCEPTED, BUT WILL BE REFERRED TO THE FOLLOWING MEETING.**

**APPLICATIONS WITHOUT COMPLETED SIGNATURES WILL NOT BE ACCEPTED, BUT WILL BE REFERRED TO THE FOLLOWING MEETING.**

**CLOSING TIME FOR SUBMISSION OF APPLICATIONS IS 16:00 (4PM)**