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| UnitingCare Health<br>**Human Research Ethics Committee**<br>**Initial Application for**<br>**Ethics Approval for Research Involving Humans** | *OFFICE USE ONLY:*<br>Register No:<br>Date Received: |

**NOTE:** This form is to be used for applications to Uniting*Care* Health Human Research Ethics Committee (HREC). Do not use this form to renew an existing approval or to apply for approval of additions or variations/amendments to an approved project – refer to *Application for Amendment* form.

To tick the hospitals at which you wish to conduct this research, double-click on the appropriate box, click on Checked, then OK.:

☐ The Wesley Hospital, Brisbane
☐ St Andrew's War Memorial Hospital, Brisbane
☐ Sunshine Coast Private Hospital
☐ St Stephen's Hospital, Maryborough

## 1 SHORT TITLE OF PROJECT

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## 2 APPROVAL FROM ANOTHER ETHICS COMMITTEE

Has this project been submitted (or will be submitted) to another Ethics Committee for approval? Yes ☐ No ☐

If *YES:* Name the committee(s), and give the status of each application. *(Attach copies of correspondence)*

| *Name of Ethics Committee and Institution* | *Application Reference No* | *Approved / Pending/ Rejected / To be submitted* |
|---|---|---|
| | | |

## 3 CHIEF INVESTIGATOR *or* PROJECT SUPERVISOR *(Note: only **one** person to be named)*

| | |
|---|---|
| Name: *Title / first name / family name* | |
| Qualifications and position held: | |
| Organisational unit and mailing address: | |
| Telephone and Fax: | |
| Email address: | |
| Is the Chief Investigator an accredited practitioner at a Uniting Church hospital? | *(hospital name)* |

## 4 CO-INVESTIGATORS *and/or* STUDENT RESEARCHER

| | |
|---|---|
| Name: *Title / first name / family name* | |
| Qualifications and position(s) held: | |
| Organisational unit and mailing address: | |
| Telephone and Fax: | |
| Email address: | |
| Is this Co-Investigator an accredited practitioner at a Uniting Church hospital? | *(hospital name)* |

| | |
|---|---|
| Name: *Title / first name / family name* | |
| Qualifications and position(s) held: | |
| Organisational unit and mailing address: | |
| Telephone and Fax: | |
| Email address: | |
| Is this Co-Investigator an accredited practitioner at a Uniting Church hospital? | *(hospital name)* |

*Copy table and repeat for each additional co-investigator.*

## 5 STUDENT RESEARCH

Is the research the project of a student of a university or other tertiary educational institution in Queensland? Yes ☐ No ☐

If *YES:*

| | | | |
|---|---|---|---|
| Name of student: | | Student No: | |
| Course of study: | | | |
| Principal supervisor: | | | |

## 6 ESTIMATED DURATION OF PROJECT (dd/mm/yy)

This is the period during which you anticipate contact with participants, their personal records, or human tissue samples.

From: To:

## 7 FUNDING

Is the project the subject of an application for funding to an internal or external grants body, drug company, etc? Yes ☐ No ☐

If *YES*

(a) List the funding sources and give the status of each application.

| *Funding Body* | *Approved/Pending/Rejected/To be submitted* |
|---|---|
| | |

(b) What is the exact project title on the funding application(s)?

(c) Is there any affiliation or financial interest between the sponsor/funding body and the researcher(s) or supervisor associated with this research?

If *Yes:* Please declare:

(d) Are there any conditions placed on this research by the funding body? Yes ☐ No ☐

If *Yes*: Please provide details.

## 8 PRIVACY LEGISLATION

Does the project involve access to personal information held by a Commonwealth department or agency, or a private sector organisation? Yes ☐ No ☐

If *YES*, will the access to personal information be **without** the consent of the individual(s) to whom the information relates? Yes ☐ No ☐

If *YES to both of the above*, specify the type of data to be accessed/collected, the departments/agencies holding the information, and the number of records involved.

## 9 AIMS AND VALUE OF PROJECT

Using plain English, provide a concise and simple description of your proposed research that sets out the background, precise aims/hypotheses/research questions, why you consider the research is worth doing, and what its potential merit and significance might be. Include references from your literature review to support the description.

## 10 REPLICATION STUDIES

Has the same or a similar study been conducted in Australia or overseas? Yes ☐ No ☐

If *YES:* Provide a brief statement giving your reasons and justification for wishing to replicate the work, with a brief but representative, literature review.

## 11 SPECIFIC TYPES OF RESEARCH

Does the proposed research involve any of the following? Yes ☐ No ☐

If *YES:* Refer to the relevant section of the *National Statement on Ethical Conduct in Research Involving Humans* (designated NS…) and provide a statement detailing how your research protocol conforms to the requirements of the Statement.

| | | |
|---|---|---|
| Children or young people under 18 years of age? (NS 4) | Yes ☐ | No ☐ |
| People with intellectual or mental impairment, temporary or permanent? (NS5) | Yes ☐ | No ☐ |
| People highly dependent on medical care, eg emergency care, intensive care, neonatal intensive care, terminally ill, or unconscious? (NS6) | Yes ☐ | No ☐ |
| Aboriginal and Torres Strait Islander individuals, communities, or groups? (Guidelines and NS9) ATSIC cultural sensitivities should be respected. | Yes ☐ | No ☐ |
| If Yes , confirm that the requirements of National Statement Chapter 4.7 would be observed. | Yes ☐ | |
| Other specific cultural, ethnic or indigenous groups? (NS8 –' Collectivities') | Yes ☐ | No ☐ |
| Assisted reproductive technology? (NS 11) | Yes ☐ | No ☐ |
| Epidemiology research? (NS 14) | Yes ☐ | No ☐ |
| Use of human tissue samples? (NS 15) | Yes ☐ | No ☐ |
| Human genetic research? (NS 16) | Yes ☐ | No ☐ |
| Deception of participants, concealment or covert observation? (NS 17) | Yes ☐ | No ☐ |

## 12 CLINICAL TRIALS

Does the project involve the use of drugs, alternative or complementary therapies, therapeutic devices, or departure from standard treatment/care? Yes ☐ No ☐

If *YES*, complete and attach **APPENDIX A.**

## 13 SAFETY IMPLICATIONS

Does the proposed research involve work on, use of, or exposure to any of the following?

| | | |
|---|---|---|
| Genetically modified organisms | Yes ☐ | No ☐ |
| Biologically hazardous materials | Yes ☐ | No ☐ |
| Chemically hazardous materials | Yes ☐ | No ☐ |
| Carcinogens | Yes ☐ | No ☐ |
| Teratogens | Yes ☐ | No ☐ |
| Radioisotopes | Yes ☐ | No ☐ |
| Ionising radiation | Yes ☐ | No ☐ |

| | | |
|---|---|---|
| Non-ionising radiation | Yes ☐ | No ☐ |
| Any other potential safety hazard for either participants or researchers? | Yes ☐ | No ☐ |

## 14 RESEARCH PLAN AND PROCEDURES

Provide a plain English description of the proposed research plan and procedures, **using the following headings** (*for more information, refer to Guidelines)*:

**What is the research design/method?**

**Where will the project be conducted?**
*(Identify any hospitals, organisations, etc, that are to be involved.)*

**Will the study involve staff or other resources on the part of Uniting*Care* Health facilities/services?**

**What is the participant group(s) and why has it been selected?**

**How many participants will be recruited and what is the rationale for that number?**

**How, by whom, and where, will potential participants be selected and approached to receive the invitation to participate?** *(Attach copies of letters, advertisements, posters or other recruitment material to be used.)*

**How much time will potential participants have to consider the invitation to participate?**

**What is required of participants?**
*(Attach a copy of any surveys, interview schedules, data sheets, etc to be used.)*

**Where will research activities involving participants be conducted?**

**Relevant experience of researchers.**

## 15 ANALYSIS

Explain how the information you receive will be analysed/interpreted and reported. What specific approaches or techniques (statistical or qualitative) will be employed?

## 16 PROPOSED REVIEW OF PROGRESS, PARTICIPANT CARE, STUDY CONCLUSION PROCEDURES

Describe the mechanisms that will be put in place to deal with the following:

**Review of progress of the project.**

**Duty of care to participants and research staff.**

**Procedures for reporting adverse events.**

**Premature cessation of project.**

**Feedback of results to participants and publication of the results, if this planned.**

**Post trial follow-up.**

## 17 SUMMARY OF ETHICAL CONSIDERATIONS

Address the ethical considerations of your research to satisfy the Committee that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and that cultural heritage, both individual and collective, will be respected in the course of your research. Your response should address the following issues:

*(for more detail, refer to NS 1 and the Application Guidelines)*

**How will voluntary participation be ensured?**

**Is active consent being sought from all participants for all aspects of the research involving them? If No, why not?**

**Are any participants in a dependent relationship with the researcher, the institution or the funding body (for example the researcher's clinical patients/clients or students; employees of the institution; recipients of services provided by the funding body)?** **Yes** ☐ **No** ☐

**If YES: What steps will be taken to ensure that participants are free to participate or refuse to participate in the research?**

**Is it anticipated that all participants will have the capacity to consent to their participation in the research?** Yes ☐ No☐

**If NO: Please explain why (e.g. children, incompetent participants, etc.) and explain how proxy or substitute consent will be obtained from the person with legal authority to consent on behalf of the participant.**

**How will participants' privacy be protected during the recruitment process, or access to tissue samples, or access to records?**

**Will any part of the research activities be placed on an audiotape, film, photograph, video-tape, cd, dvd, memory stick or other media?** Yes ☐ No ☐

**If YES:To what purpose will the audiotape, film, photograph, video-tape, cd, dvd, memory stick or other media be used?**
**For what audience(s) will the audiotape, film, photograph, video-tape, cd, dvd, memory stick or other media be exhibited?**

**What are the benefits and risks to participants and how will risks be minimised?**

**How does the project address the participants' freedom to discontinue participation? Will there be any adverse effects on participants if they withdraw their consent and will they be able to withdraw data concerning themselves if they withdraw their consent?**

**Are there any potential conflicts of interest for the researchers?**

**Will the research involve payments/rewards/inducements to participants?**

**How will confidentiality/anonymity of information received be ensured?**

**Any other ethical issues specific to your research?**

## 18 STORAGE, ACCESS AND DISPOSAL OF DATA

Describe what research data will be stored, where, for what period of time, the measures that will be put in place to ensure security of the data, who will have access to the data, and the method and timing of disposal of the data.

## 19 DECLARATION BY APPLICANTS

1 In signing this application, I declare that the research protocol conforms to the *National Statement on Ethical Conduct in Research Involving Humans, 2007*, which I have read.

2. Where I am the project supervisor for the research described herein that will be conducted by a student of a university or other tertiary institution in Queensland, I declare that I have provided guidance to the student in the design, methodology and consideration of ethical issues of the proposed research.

3 I make this application on the basis that the information it contains is confidential and will be used by Uniting Health*Care* for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

**All investigators named at Q3 and Q4 are to sign this declaration.**

| | *Name* | *Signature* | *Date* |
|---|---|---|---|
| Chief investigator/ project supervisor | | | |
| Investigator 2 | | | |
| Investigator 3 | | | |
| Investigator 4 | | | |
| Investigator 5 | | | |
| Investigator 6 | | | |

| UnitingCare Health<br>**Human Research Ethics Committee**<br>**Initial Application for Ethics Approval for Research Involving Humans** | **APPENDIX A**<br>**CLINICAL TRIALS** |
|---|---|

NOTE: To be completed by applicants where the proposed research is a clinical trial of: drugs; natural, herbal, homeopathic or complementary therapies; therapeutic devices; innovative therapy/ intervention or a departure from standard treatment/care.

Applicants must demonstrate that the proposed research complies with Sections 12 and 13 of the *National Statement on Ethical Conduct in Research Involving Humans, 2007*, available at http://www.health.gov.au/nhmrc/issues/researchethics.htm and the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*, available at http://www.health.gov.au:80/tga/docs/html/ich13595.htm

**1 CHIEF INVESTIGATOR *or* PROJECT SUPERVISOR**
*(The person identified at Question 3 on the 'Initial Application for Ethics Approval for Research Involving Humans')*

| Name: Title / first name / family name | |
|---|---|

**2 SHORT TITLE OF PROJECT** *(as per Question 1 of the Initial Application)*

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*FOR TRIALS OF INNOVATIVE THERAPY/INTERVENTION, OR DEPARTURES FROM STANDARD TREATMENT/CARE, GO TO Question 6.*

**3 List any drugs, natural/complementary therapies, or therapeutic devices to be tested, and give details of their Australian marketing approval status, including approved indications, dosage and modes of administration.**

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**4 If the drugs, natural/complementary therapies, or therapeutic devices are approved for use in Australia, will they be used in accordance with their approval?**

Yes ☐ No ☐

**If NO: Explain how the proposed use is outside the conditions of approval and provide justification for the proposed use**.

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**5 Will the trial be registered with the Therapeutic Goods Administration (TGA) under its:**

Clinical Trial Notification (CTN) Scheme? Yes ☐ No ☐

If *YES, complete as far as possible, and attach the CTN application form – section 5 of the form will be completed when the ethics committee approves your protocol.*

Clinical Trial Exemption (CTX/CTE) Scheme? Yes ☐ No ☐

*GO TO Question 7*

**6 For trials of innovative therapy/intervention, or departures from standard treatment/care, provide details of the therapy or intervention to be tested, and provide justification for its use.**

**7 TRIAL SPONSOR**

***Is the trial sponsored, eg by a drug company or device manufacturer?*** Yes ☐ No ☐

**If YES, who is the sponsor? Important: please provide name, address of sponsor and contact person.**

**Will the Medicines Australia *Compensation Guidelines for Injury* apply?** (see http://www.apma.com.au/headers/publications.html. Yes ☐ No ☐

*Attach two originals of a document indemnifying Uniting Church in Australia Property Trust (Q)*
*The document should comply with the Medicines Australia* **Form of Indemnity for Clinical Trials** (see http://www.apma.com.au/headers/publications.html).

**8 Provide details of the trial budget relating to payments to medical staff involved in recruiting participants, and payments to researchers, institutions or organisations involved in the research. If there is any business or similar association between the researcher and the supplier of a drug or surgical or other therapeutic device to be used in the trial, this should be described.**

**9 TRIAL SITES**

**List all sites where the trial will be conducted, including international sites.**

**10 DOCUMENTS TO BE ATTACHED:**

- **Full Clinical Protocol** – ten copies
- For non-registered drugs or devices, the **Investigator Drug Brochure or equivalent documentation for devices** – one copy
- For registered drugs or devices, the latest version of the **Product Information** – ten copies
- **Form of Indemnification for Clinical Trials**, where relevant – two originals signed by the sponsor