

Human Research Ethics Committee

Application For Amendment to approved Research Involving Humans

OFFICE USE ONLY:

HREC Reference No.:

Date Received:

Amendment No: _____ Date: _____

1 CHIEF INVESTIGATOR *or* PROJECT SUPERVISOR (first named on the approval notification)

Name: <i>Title / first name / family name</i>	
Qualifications and position held:	
Organisation name and postal address:	
Telephone and Fax:	
Email address:	

2 TITLE OF PROJECT (as it appears on the approval notification)

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3 APPROVAL DETAILS

UnitingCare Health HREC Reference No.

4 STUDENT RESEARCH

Is the research the project of a student of a tertiary institution in Queensland? Yes No

If YES: Name of Student

Name of Supervisor

5 PROJECT STATUS

Has the project commenced? Yes No

If YES, when did the project commence? (dd/mm/yy):

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6 DETAILS OF PROPOSED AMENDMENT NO. _____

Provide details of the proposed amendment(s) to the research protocol. Where appropriate, present in terms of **from** the existing protocol **to** the new protocol. *Attach the original of any documents that are new or revised as a result of the amendment, eg advertisements, participant information sheets, surveys, clinical protocols. For revised documents, please highlight changes or show tracked changes. Identify documents with version # and date.*

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7 JUSTIFICATION FOR VARIATION Why is the amendment necessary?

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8 RESEARCH PARTICIPANTS

Does the amendment involve recruiting new participant groups, or changing the way in which participants are to be recruited? Yes No

If YES, provide full details using the following headings:

What is the participant group?

What is the number of participants involved and what is the justification for choosing this number?

From where will the participants be recruited? (Identify any hospitals organisations that are to be involved.)

How and by whom will participants be approached to receive the invitation to participate?

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

9 ETHICAL CONSIDERATIONS

What ethical considerations, if any, are raised by the proposed variation? (*Refer to the National Statement on Ethical Conduct in Research Involving Humans, section 1 and other sections relevant to the project.*)

10 DECLARATION

In signing this application, I declare that:

- 1 The research protocol conforms to the *National Statement on Ethical Conduct in Research Involving Humans, 1999*, which I have read.
- 2 The documents that are new or revised as a result of the variation are attached, eg advertisements, participant information sheets, consent forms, surveys, clinical protocols.
- 3 The variation will not be implemented prior to receiving approval from the ethics committee.

I make this application on the basis that the information it contains is confidential and will be used by UnitingCare Health 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.

SIGNATURE:	
Chief/Qualified Investigator	Date:
Name:	