Human Research Ethics Committee

Initial Application for
Ethical Review of Low Risk Research Involving Humans

About this Form:

This application form should be used by researchers seeking ethical approval for human research projects that meet the criteria of "low risk" research.

Please complete the "Checklist for Low Risk Research Projects" to assess whether the project satisfies the criteria for low risk research ethical review and submit with the completed "Initial Application for Ethics Review of Low Risk Research Involving Humans" form to the UnitingCare Health HREC for review and approval.

Information regarding Low Risk Research Ethical Review

The National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research 2007", herein called "The National Statement" recognises that human research involves a wide range of activities that have variable risks and potential benefits. The "National Statement" establishes different levels of ethical review, based on the degree of risk involved.

There are three levels of risk:

- Harm
- Discomfort
- Inconvenience

Researchers and Human Research Ethics Committees are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity.

Low Risk Research

The National Statement Section 2.1.6 describes research as "Low Risk" where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. However, for research involving certain groups, methodologies or procedures, only full Human R

Research Greater than Low Risk

Research involving more than low risk must complete either the UnitingCare Health HREC Initial Application for Ethics Approval for Research Involving Humans or National Ethics Application Form (NEAF) and submit for review and approval by the UnitingCare Health HREC.

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Checklist for Low Risk Research Projects

NHMRC "National Statement on Ethical Conduct in Human Research"
Sections 2.1.7, 5.1.18 -5.1.23

If the project includes any of the nine following types of research and/or participants, it will require full review by the HREC and **will not be eligible for low risk ethical review.**

1 Interventions and therapies, including clinical and non-clinical trials and innovations of new treatment modalities;
2 Human genetics;
3 Human stem cells;
4 Women who are pregnant and the human foetus;
5 People who are highly dependent on medical care who may be unable to give consent;
6 People with cognitive impairment;
7 People with an intellectual disability or a mental illness;
8 Research specifically targeting Aboriginal or Torres Strait Islanders;
9 People who may be involved in illegal activities.

If a project does **NOT** include any of the above, complete the detailed checklist below to ascertain whether the proposed research is eligible for consideration for low risk ethical review by the UnitingCare Health HREC.

1 Are any of the following topics covered in part or in whole?

- Research about parenting issues Yes ☐ No ☐
- Research investigating sensitive personal issues Yes ☐ No ☐
- Research investigating sensitive cultural issues Yes ☐ No ☐
- Explorations of grief, death or serious/traumatic loss Yes ☐ No ☐
- Mental Disorders e.g. depression, mood states, anxiety Yes ☐ No ☐
- Gambling Yes ☐ No ☐
- Eating disorders Yes ☐ No ☐
- Illicit drug use Yes ☐ No ☐
- Substance abuse (prescribed or over the counter) Yes ☐ No ☐
- Self report of criminal behaviour Yes ☐ No ☐
- Any psychological disorder Yes ☐ No ☐
- Suicide risks Yes ☐ No ☐
- Gender identity Yes ☐ No ☐
- Sexuality Yes ☐ No ☐
- Race or ethnic identity Yes ☐ No ☐
- Any disease or health problem Yes ☐ No ☐
- Fertility Yes ☐ No ☐
- Termination of pregnancy Yes ☐ No ☐

2 Are any of the following procedures to be employed?

- Use of personal data obtained from the Commonwealth or State Government Department/Agency with participant consent Yes ☐ No ☐
- Deception of participants Yes ☐ No ☐

- Concealing the purposes of the research Yes ☐ No ☐
- Covert observation (or minimal disclosure) Yes ☐ No ☐
- Audio or visual recording without consent Yes ☐ No ☐
- Recruitment of a third party or agency Yes ☐ No ☐
- Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching) Yes ☐ No ☐
- Psychological interventions or treatments Yes ☐ No ☐
- Involvement of any experimental manipulation or including the presentation of any stimulus other than question-asking Yes ☐ No ☐
- Invasive physical procedures Yes ☐ No ☐
- Infliction of pain Yes ☐ No ☐
- Administration of drugs Yes ☐ No ☐
- Administration of other substances or devices Yes ☐ No ☐
- Exposure to ionising radiation Yes ☐ No ☐
- Tissue sampling or blood for pathological or genetic testing Yes ☐ No ☐
- Collecting body fluids (e.g. saliva) Yes ☐ No ☐
- Use of medical records where participants can be identified or linked Yes ☐ No ☐

3 Other Risks

- Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots) Yes ☐ No ☐
- Are there any potential risks to non-participants in the research, such as, participants' family members and social community? (e.g. effects of biography on family and friends or infectious disease risk to the community) Yes ☐ No ☐

4 Select the categories that are targeted or likely to be included as participants in this research project.

- Suffers from a psychiatric/psychological/emotional impairment Yes ☐ No ☐
- Suffering a physical disability or medical condition Yes ☐ No ☐
- Participants are aged less than 18 years Yes ☐ No ☐
- Children and/or young people without parental or guardian consent Yes ☐ No ☐
- Resident of a custodial institution Yes ☐ No ☐
- Unable to give freely an informed consent due to difficulties in understanding information provided (e.g. language difficulties) Yes ☐ No ☐
- Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities Yes ☐ No ☐
- Participants specifically targeted belong to a cultural/minority group or any other collectivity Yes ☐ No ☐
- Those in a dependent relationship with the researcher (e.g. lecturer/student, doctor/patient, teacher/pupil & professional/client) Yes ☐ No ☐
- Participants are identifiable or re-identifiable Yes ☐ No ☐
- Participants are identifiable in the final report when specific consent for release has not been given Yes ☐ No ☐
- Research findings are expected to be published in a peer reviewed Journal Yes ☐ No ☐

If **'No'** has been answered to all the above questions, the project is eligible for low risk ethics review.

A **'yes'** answer to any item in the checklist 1-4 indicates that the project would normally **not be eligible** for low risk review. However, a **'yes'** answer does not necessarily automatically preclude the research from being reviewed through a low risk ethics review process. A project may still be deemed low risk if the following considerations are reasonably justified with the provision of detailed information to the following:

- The likelihood and severity of the risks (any risk greater than discomfort, even if unlikely, is not low risk):

- Indication of those participants and/or others the risks may effect:

- Indication of ways to minimise the risk:

- The potential benefits of the research:

- Indication of those that the benefits are likely to accrue:

If any of the checklist 1-4 has been answered **'yes'** it is advisable to consult with the UnitingCare Health HREC, **prior to** completing the "Initial Application for Ethics Review of Low Risk Research Involving Humans".

Human Research Ethics Committee

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NOTE: This form is to be used for applications to UnitingCare Health Human Research Ethics Committee.

Please tick the hospitals at which you wish to conduct this research:

- ☐ 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

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 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.

9 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.

10 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 UnitingCare 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.

11 ANALYSIS

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

12 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.

Post trial follow-up.

13 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?

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

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?

14 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.

15 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 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.

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			

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