

Completed applications, including one original and two copies should be submitted to:

The Secretary, Human Research Ethics Committee
Office of Research & Development, Curtin University of Technology
GPO Box U1987, PERTH WA 6845

“Instructions for Applicants” are on the last page, however please note specifically that:

- Some projects, particularly undergraduate projects, may qualify for submission of an alternative application form titled *Application for Approval of Research with Minimal Risk (Ethical Requirements)* (Form C) – see Application for details.
- Applications for an extension of ethics approval can be made using a Form B.

SECTION 1

Project title

A phenomenological exploration of the factors that influence pain relief choices for childbirth

Principal investigator

Jjjj Kkkk

Student ID
(if applicable)

22223333

School/area/organisation

School of Physiotherapy

Mailing Address (if not C/- School)

C/o School of Physiotherapy

Contact phone number(s)

EMAIL

Co-investigator(s)

Project supervisor

Dr Staff Member

Project or application Type

1. **STUDENT please specify**

(i) Doctoral (eg, PhD)

(ii) Master's by Research

(iii) Master's by Coursework

(iv) Honours or undergraduate

If (i) or (ii) above,

Have you submitted an application for Candidacy?

YES

NO

2. **STAFF**

3. **EXTERNAL**

CHECKLIST *If you answer YES to any of the questions below, you will be required to submit an application for ethics approval. Even if all questions are answered NO, your school or division may still require that an ethics application be submitted.*

Does your research involve -

(please circle)

1	Any novel procedure in the therapy or management of patients in a clinical setting?	YES <input type="radio"/> NO <input checked="" type="radio"/>
2	Any form of physically invasive procedure on patients such as blood collection, exercise regimens or physical examination, and which is not part of their clinical management?	YES <input type="radio"/> NO <input checked="" type="radio"/>
3	Any form of physically invasive procedure on volunteer participants such as body fluid collection (eg blood, urine, semen), exercise regimens or physical examination?	YES <input type="radio"/> NO <input checked="" type="radio"/>
4	The administration of any form of drug, medicine (other than in the course of standard medical procedure) or placebo?	YES <input type="radio"/> NO <input checked="" type="radio"/>
5	Physical pain, beyond mild discomfort?	YES <input type="radio"/> NO <input checked="" type="radio"/>
6	Obtaining and storage of blood, body fluid or tissue samples from the participants?	YES <input type="radio"/> NO <input checked="" type="radio"/>
7	The participation of minors (under 18 years), other than in the observation of normal school activity?	YES <input type="radio"/> NO <input checked="" type="radio"/>
8	Participants who are in a dependent situation, such as students or residents of an institution (such as a hospital, nursing home or prison or patients highly dependent on medical care), other than those who are being observed in their normal environment where such observation is considered innocuous?	YES <input type="radio"/> NO <input checked="" type="radio"/>
9	Participants who may be unable to give or incapable of giving informed consent?	YES <input type="radio"/> NO <input checked="" type="radio"/>
10	The participation of Aboriginal or Torres Strait Islanders, or other peoples from identifiable cultural, ethnic or minority groups?	YES <input type="radio"/> NO <input checked="" type="radio"/>
11	Acquisition of data about organisations or individuals through any form of database and in which those organisations or individuals are directly or indirectly identifiable?	YES <input type="radio"/> NO <input checked="" type="radio"/>
12	Use of questionnaire or interviews which may be linked either directly (eg through recording of names) or indirectly (eg through a cross-linked code) to the individual?	YES <input type="radio"/> NO <input checked="" type="radio"/>
13	Use of questionnaire, interview, or procedure irrespective of the recording of the individual's identity, which might be reasonably expected to cause discomfort, embarrassment, or psychological or spiritual harm to the participants?	YES <input type="radio"/> NO <input checked="" type="radio"/>
14	Processes that potentially exclude and/or disadvantage a person or group, such as the collection of information which may expose the person/group to discrimination or misrepresentation?	YES <input type="radio"/> NO <input checked="" type="radio"/>
15	Collection or disclosure of personal information by a Commonwealth, State or Territory agency that might involve a breach of an Information Privacy Principle (as defined by the Commonwealth Privacy Act 1988 and the Australian Standard)?	YES <input type="radio"/> NO <input checked="" type="radio"/>
16	Collection or disclosure of personal information by a private sector organisation [that might involve a breach of a National Privacy Principle (as defined by the Commonwealth Privacy Act 1988)]?	YES <input type="radio"/> NO <input checked="" type="radio"/>
17	Payments or inducements, other than reasonable recompense, to participants for their participation?	YES <input type="radio"/> NO <input checked="" type="radio"/>
18	Deception of the participants including concealment and covert observation?	YES <input type="radio"/> NO <input checked="" type="radio"/>
19	Disclosure of the response outside the research which could place the participants at risk of criminal prosecution or civil liability or be damaging to their financial standing, employability, professional or personal relationships?	YES <input type="radio"/> NO <input checked="" type="radio"/>
20	Any other ethical issue of the study which has not been addressed in this Checklist?	YES <input type="radio"/> NO <input checked="" type="radio"/>

Supervisor Signature: Staff Member

Date: _____

- (xi) Provide a brief description of the participants/collectivities involved. How will participants be recruited?
Researchers who would like permission to have access to the personal details of staff or students of Curtin for the purposes of directly inviting them to participate in a research study (e.g. contact details) will require both the approval of (i) the Human Research Ethics Committee and (ii) the General Manager, Student and Staff Services, in that order.

Participants will be recruited from the Curtin University staff and student population through notices, electronic bulletins and word of mouth. A total of 10 -12 women who have given birth to 2 or more children in the past 10 years will be sought. Women who did not have any choice regarding their use or type of analgesic (ie emergency caesarean section) will be excluded from the study.

- (xii) Will personal (identified) data be obtained from a Commonwealth Agency? If YES, please specify, e.g. Department of Foreign Affairs.
 (see Section 1.1 of the *Guidelines under Section 95 of the Privacy Act 1988*, “The use of the Guidelines”)?

YES NO

- (xiii) Will **health** information data be collected from an **organisation in the private sector** (i.e. not from a Commonwealth or State government agency)? e.g. use of patient information from a private hospital. If YES, please specify the organisation and type of data, and answer questions (a) – (d) below.
 (see *Guidelines under Section 95A of the Privacy Act 1988*, page 5; pages 11-17 and pages 35 – 44 the ‘National Privacy Principles (NPPs)’)

YES NO
 (if No, go to Section 2
 “Protocol” below)

Organisation from which health information data will be collected: _____

The number or records involved: _____

Description of data to be collected:

N/A

- a. Does the data include information that identifies the individual(s) involved?
if yes, go to (b) YES NO
- b. Could the research be conducted using de-identified information?
if no, go to (c) YES NO
- c. Is the use or disclosure a directly related secondary purpose within the reasonable expectations of the individual?
if no, go to (d) YES NO
- d. Is it proposed to undertake the research, with the consent of the individual(s) involved?
 If no, then Section 95A Guidelines will be applied. Refer to Guidelines A.1 to A.3 YES NO

SECTION 2 – PROTOCOL

The main concern of the Human Research Ethics Committee in evaluating proposals is to establish conformity with the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*. Researchers must comply with the provisions of the National Statement. Chapters 1 *Principles of Ethical Conduct* and 18 *Privacy of Information* are essential reading for all applicants prior to completion of the following questions. **All questions must be answered.** Applicants are required to provide a brief summary **in the spaces provided**. This will assist in expediting the review process. Non-compliance with this request will result in the application being returned to the applicant.

- 1. Briefly describe (in point form and in less than 100 words) your proposed procedure including: recruitment of subjects, experimental design and/or procedure and analysis of data.** *An essential condition of the ethical acceptability of research is the determination that the scientific quality of a proposal are such that the objectives of the proposal can reasonably be expected to be achieved.*

- Women who have given birth to 2 or more children in the past 10 years will be recruited from the Curtin University population for this phenomenological study
- Those who agree to participate will attend a semi-structured interview of approximately 20 minutes duration at a convenient time with two of the investigators.
- The investigators will ask the participant to describe the factors which influenced their selection of pain relief for their first and subsequent births.
- The interview will be audiotaped. After completion of the interview, the recording will be typed up in preparation for analysis.
- The transcripts will be analysed for recurring patterns and themes which may identify the factors most likely to influence a woman's choices regarding pain relief.

- 2. Provide detail that demonstrates the research is being conducted or supervised only by persons or teams with experience, qualifications and technical competence appropriate to the research.**

The study has been designed by third year undergraduate physiotherapy students. Assistance has been provided by the Unit Co-ordinator, a qualified physiotherapist who has twenty years of experience in conducting clinical research.

Analysis will be performed by the students with assistance from the Unit Co ordinator.

- 3. Provide sufficient procedural/experimental detail to enable the Committee to judge whether any risks to which the participants may be exposed are warranted by the possible benefits/outcomes of the study. How will the researcher deal with situations in which participants are identified to be at risk?**

Your answer must demonstrate that the welfare, rights, beliefs, perceptions, customs and cultural heritage of the participants are observed; the risks of harm or discomfort to participants is minimised; and that respect for the dignity and well being of the participants takes precedence over the expected benefits

As the names of the participants will not be recorded, there is minimal risk that the study will constitute an invasion of privacy. The audio tape will be wiped as soon as the analysis has been completed to further protect anonymity.. We do not believe that the questions to be asked are potentially embarrassing or likely to cause mental anguish or discomfort however participants will be reminded during the interview that they can choose not to answer questions and that their choices will be respected
The findings of the survey will be made available to respondents, on request. It is hoped that the findings will help the health care profession to gain a better understanding of the decision making processes of women preparing for child birth.

4. Describe how participants will consent to participate in the study, and how they are informed of their rights.

Attach copies of the Participant Information Sheet and Consent Form intended for use. Approval cannot be granted until these documents have been submitted. *Your answer should demonstrate that the provisions of Section 1.7-1.12 of the National Statement have been satisfied.*

Subjects will consent to this study by following the usual processes. Potential subjects who express an interest in participation will be sent a subject information sheet which will outline the rights and expectations of the participants. One of the investigators will then contact them, by phone or e-mail, and set up an agreeable time for the interview. At this point, the investigator will endeavour to answer any questions the potential subject has.

On arrival at the interview location, the participant will again have the process explained to them, be informed of their rights and be given an opportunity to clarify any uncertainties prior to signing the informed consent document.

5. Describe the extent to which issues of privacy are to be addressed in relation to the collection of data from individuals or groups, and the extent to which the collection intrudes upon the personal affairs of the individual or group. Refer to the National Privacy Principles (see the NHMRC Guidelines under Section 95A of the Privacy Act 1988). Your response should specifically address:-

- a. Justification if identified or potentially identifiable information is to be used rather than de-identified information
- b. Justification if consent is not being sought to use personal information.
- c. The specific uses to which the personal information used during the study will be applied.
- d. The proposed method of publication of results of the research

- a. De-identified data will be used, hence no justification is required
- b. Consent will be gained prior to the interview.
- c. No specific personal information such as name, age, address or marital situation will be recorded. As such individuals will not be able to be identified.
- d. The results of this study will be presented at the Physiotherapy Undergraduate Research Symposium in Semester 2 and may be published in peer reviewed physiotherapy journals.

6. Provide details of the storage and security arrangements for personal information that will be collected within the study to ensure confidentiality.

Where personal information about research participants or a collectivity is collected, stored, accessed, used, or disposed of, a researcher must strive to ensure that the privacy, confidentiality and cultural sensitivities of the participants and/or the collectivity are to be fulfilled.

Refer to the Joint NHMRC/AVCC Statement and Guidelines on Research Practice, Section 2 'Data Storage and Retention' Your response should address: -

- a. The estimated time of retention of the personal information
- b. The identity of the custodian(s) of the personal information used during the research
- c. Security standards to be applied to the personal information
- d. List of personnel with access to the personal information
- e. Standards that will be applied to protect personal information disclosed by a Commonwealth agency or private sector organisation (if applicable)
- f. The media or forms of the data that are to be stored. For example, electronic data on floppy disc, hard copies, cassette tapes, field samples, photographs, video tape, etc.

The data will be entered in to a database and stored on a zip disc or compact disc in a secured cabinet in the School of Physiotherapy for a period of 5 years.
Access to the data will be limited to the investigators and the supervisor.

7. **Provide a description of any survey instruments/questionnaires intended for use in the study, including questions/material intended for interviews/workshops and semi-structured interviews.** All such material must be submitted for approval. If the instrument has not been designed at the time of application, then a brief description of the anticipated nature of the questions must be provided. Instruments that are widely recognised as being standard in the field should be identified as such, or be available for viewing upon request.
Final approval will be dependent on the satisfactory submission of all instruments.

A copy of the semi-structured interview is attached.

8. **Attach a detailed description of the project using the headings below.**

- Aims/objectives of the study
- Background
- Significance/Justification of the study
- Methods (including - data to be collected and source of data; target population; study period; participant recruitment procedures, instruments)
- References

Do not attach copies of grant applications

Recommended length = maximum 10 pages (one and a half line spacing), excluding references. Research students may alternatively attach a copy of their candidacy research proposal. Pages must be numbered. Applicants are reminded to use non-specialist language.

SIGNATURES

Principal Investigator

Jfff Kkkk

Date

Project Supervisor

Staff Member

Date

Head of School (*only where investigator is a student*)

Head of School

Date