

APPLICATION FORM FOR ETHICS CLEARANCE

**FROM THE COLLEGE OF NURSING,
HUMAN RESEARCH ETHICS COMMITTEE**

It is a requirement of The College of Nursing and other research institutions that they make provision for the ethical review of research projects and other studies being conducted under the auspice of the College if they involve interventions with humans.

The interventions may range from studies involving The College of Nursing's archival material, to personal questionnaires/interviews involving students enrolled at the College. Investigators who are in doubt of the need to seek ethical clearance **must** seek advice from the Chair of The College of Nursing, Human Research Ethics Committee by contacting the Executive Assistant to the Executive Director, The College of Nursing, on hille@nursing.aust.edu.au.

Applicants must complete all sections of The College of Nursing, Human Research Ethics Committee's Application Form. Answers to questions must be typed and expressed in a manner that is meaningful to an informed layperson. Do not answer questions with 'see attached', enter the answer in the space provided.

Applications should be lodged AT LEAST TWO WEEKS prior to the Ethics Committee convening to enable proposals to be circulated to Committee members for review. Late applications will not be reviewed until a later meeting. For information regarding meeting dates, please contact the Executive Assistant to the Executive Director, The College of Nursing or view the College web site at www.nursing.aust.edu.

PREPARATION OF APPLICATIONS:

- Applications must be typed. Type font must be at least 11 point and Microsoft Word format.
- Do not break the format of the application.
- The original and seven (7) copies of The College of Nursing, Human Research Ethics Committee's application form should be submitted.
- Applicants should attach a summary of their proposed of not more than three (3) pages to the application form. This summary proposal should identify:
 - Background and purpose of the study;
 - Recruitment of Participant;
 - Method;
 - Analysis of the Data; and
 - Expected Outcomes of the Study.

APPLICATION CHECKLIST:

Before lodging your application, please check that:

- | | |
|---|--------|
| • All questions have been answered. | Yes/No |
| • All investigators exercising responsibility are identified. | Yes/No |
| • The chief investigator (or project supervisor in the case of student research) has been personally signed the declaration (Page). | Yes/No |
| • Applications and Summary Proposals are complete and the required number of copies is attached. | Yes/No |

N.B.: Applications must be submitted two weeks (14 days) prior to the committee convening.

Adapted from The University of Newcastle and Hunter Area Health Service

'Application for Ethics Clearance for Research Procedures Involving Humans, 1992 (modified July 1998)

ETHICS APPLICATION FORM FOR THE COLLEGE OF NURSING

ALL QUESTIONS MUST BE ANSWERED
PLEASE TYPE OR WRITE CLEARLY
DO NOT ALTER THE LAYOUT OR PAGINATION OF THE APPLICATION FORM

Acknowledgments

This form is based on Human Ethics Applications Form Version 3 (1 March 1998) University of Sydney and University of NSW prepared by: Mrs Gail Briody (University of Sydney), A/Professor David Cook (University of Sydney/Central Sydney Area Health Service), Professor Simon Gandevia (University of NSW), Dr Rob Loblay (University of Sydney/Australian Health Ethics Committee), Mr Ted McKeown (Hunter & Hunter), Ms Lesley Townsend (Central Sydney Area Health Service), Dr John Watson (University of Sydney), Mrs Margaret Wright (University of NSW).

SECTION 1: ADMINISTRATION & SUBMISSION TO OTHER INSTITUTIONAL ETHICS COMMITTEES (IECs)

1.1 (a) Full project title

(b) Short name by which the project will be known (if appropriate)

(c) Name of Chief Investigator

(d) Provide a brief lay description of the project (in less than 100 words).

1.2 Indicate the institution that you consider to be the primary site for this research project.

1.3 List the following details of the Chief Investigator/Supervisor, any Co-Investigator, Associate Investigator and Student. (If necessary, insert extra pages to follow this.)

Chief Investigator/Supervisor

Name:.....

Title:.....

Qualifications:.....

Positions held:.....

Full mailing address:.....

.....

Telephone number:

Fax number:

E-mail address:

Co-Investigator(s), Associate Investigator(s) or Student

Name:.....

Title:.....

Full mailing address:.....

.....

Telephone number:

Name:.....

Title:.....

Full mailing address:.....

.....

Telephone number:

Name:.....

Title:.....

Full mailing address:.....

.....

Telephone number:

Name:.....

Title:.....

Full mailing address:.....

.....

Telephone number:

1.4 (a) Indicate the proposed date of commencement of the project. Researchers are reminded that projects may not commence without the written approval of the Institutional Ethics Committee (IEC).

(b) Indicate the proposed duration of the project.

1.5 Indicate the location at which the research will be undertaken.

1.6 (a) Is this submission being made as part of an application for research funding? Yes No
If you answered YES, list the funding bodies to which you have submitted, or intend to submit, this project.

(b) If the title of the project submitted for funding is different from that listed under Question 1.1, state below.

1.7 Has this project been submitted to any other IEC(s)? Yes No
If you answered YES, give the name of the IEC(s), and indicate the status of the application at each (ie. submitted, approved, deferred or rejected).

Attach copies of the correspondence with each of the other IEC(s).

SECTION 2: NATURE OF RESEARCH INCLUDING RISKS

2.1 The nature of this project is most appropriately described as:

- (a) A clinical trial of drug(s) or device(s) Yes No
- (i) under the Clinical Trial Notification Scheme (CTN) Yes No
- (ii) under the Clinical Trial Exemption Scheme (CTX) Yes No
- (iii) using only approved drug(s)/device(s) in accordance with Therapeutic Goods Administration Approved Product Information Yes No
- (b) Human physiology research Yes No
- (c) Psychiatry/clinical psychology research Yes No
- (d) Behavioural research Yes No
- (e) Biomechanical research Yes No
- (f) Research using a questionnaire only Yes No
- (g) Research using qualitative methods Yes No
- (h) Other (indicate the nature of the research below) Yes No

- 2.2 (a) Does the protocol require any physically invasive or potentially harmful procedures (eg. drug administration, needle insertion)? Yes No

If you answered **YES**, please state the nature of the procedures, all the risks involved and, if possible, at what rate these risks are expected to occur. (All this information must be included in the Subject Information Statement.)

- (b) If you are doing research on patients, list the procedures/techniques that would not form part of routine clinical management.

- 2.3 Please list any drugs/devices to be used and their approval status both overseas and in Australia.

- 2.4 Is this research expected to benefit the participants directly or indirectly? Yes No

If you answered **YES**, please provide details.

2.5 Will the true purpose of the research be concealed from the participant(s)? Yes No
If you answered **YES**, please provide details of the concealment and any debriefing.

2.6 Is the research likely to induce any psychological or physical stress in the participant? Yes No
If you answered **YES**, please state what form this stress will take.

2.7 Could participation in the research adversely affect the participant(s)? Yes No
If you answered **YES**, what facilities/trained personnel are available to deal with such problems?

SECTION 3: INDEMNITY, COMPENSATION AND POSSIBLE CONFLICT OF INTEREST

- 3.1 (a) Will this research be undertaken on behalf of (or at the request of) a pharmaceutical company, or other commercial entity, or any other sponsor? Yes No

If you answered **YES**, will the sponsor provide support in money or kind?
Please provide details.

- (b) If you answered **YES** to (a), will that entity undertake in writing to abide by either the ABPI Clinical Trial Compensation Guidelines or the APMA Guidelines for Injury Resulting from Participation in an Industry–Sponsored Clinical Trial? Yes No N/A

- (c) If you answered **YES** to (a), will that entity undertake in writing to indemnify the institution, the IEC(s) and the researchers? Yes No N/A

- (d) If you answered **YES** to (a), (b) or (c), does the sponsor hold a current insurance policy to cover this project? Yes No N/A

If you answered **YES**, please provide a certificate of currency.
If you answered **NO**, please provide details

- 3.2 Do the researchers have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? Yes No

If you answered **YES**, please provide details.

- 3.3** Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this project? Yes No

If you answered **YES**, please provide details.

- 3.4** Are there any further ethical considerations that you wish to raise? Yes No
For example, have conditions been imposed upon the use, publication or ownership of the results?

If you answered **YES**, please detail what these considerations are.

4.3 If the subjects are to undergo a medical or other procedure are they:

– capable of understanding the general nature and effects of the proposed treatment? Yes No N/A

– capable of indicating whether they consent or do not consent to the proposed treatment? Yes No N/A

If you answered **NO** to either of the above, is the treatment a new treatment that has not yet gained the support of a substantial number of medical, nursing or allied health professionals specialising in the area of practice concerned? Yes No N/A

– Has the treatment been declared to be special treatment under the terms of the Guardianship Act 1987? (as amended). Yes No N/A

SECTION 5: RECRUITMENT OF SUBJECTS

5.1 (a) How many subjects will be recruited?

(b) How will the subjects be recruited?

5.2 (a) Does recruitment involve a direct personal approach from the researchers to the potential subjects? Yes No

If you answered **YES**, is there any pressure from researchers or others that might influence the potential subject to enrol? Yes No

If you answered **YES**, please explain.

(b) Does recruitment involve the circulation/publication of an advertisement, circular, letter, etc? Yes No

If you answered **YES**, provide a copy and indicate where and how often it will be published.

5.3 Will subjects receive any financial or other benefits as a result of participation? Yes No
If you answered **YES**, what are the amount/benefit and the justification for this?

5.4 Is the research targeting any particular ethnic or community group? Yes No
If you answered **YES**, which group is being targeted?

If you answered **YES**, has this been done in consultation with a representative of this group Yes No N/A

– If you have not consulted a representative of this group, please give reasons.

– If you have consulted a representative, whom have you consulted and how do they represent this group?

SECTION 6: PRIVACY AND PUBLICATION OF RESULTS

6.1 Is there a requirement for the researchers to obtain information of a personal nature about individuals without their consent :

- From Commonwealth departments or agencies? Yes No

- From other third parties, such as universities, hospitals, State Government agencies or employers? Yes No

If you answered **YES**, state what information will be sought and why written consent will not be obtained from the individual subjects.

6.2 Will any part of the experimental procedures be placed on audiotape, film/video, or other electronic medium? Yes No

If you answered **YES**, what is the medium and how it will be used?

6.3 Is there any possibility that information of a personal nature could be revealed to persons not directly connected with this project? Yes No

If you answered **YES**, please provide details.

6.4 (a) How will the results of the study be disseminated?

(b) How will the confidentiality of data collected/disseminated, including the identity of subjects, be ensured?

(c) What is the proposed storage of, and access to, files, audiotapes etc during the study?

(d) Specify how long the data files/audiotapes will be retained after the study and how they will be disposed of.

SECTION 7: SUBJECT INFORMATION AND CONSENT

7.1 Will a Subject Information Statement be provided? Yes No
If you answered **NO**, please give reasons.

7.2 Will written consent be obtained? Yes No
If you answered **NO**, please give reasons.

7.3 In the case of subjects for whom English is a second language, will arrangements be made to ensure comprehension of the Subject Information Statement and Consent Form? Yes No
If you answered **NO**, give reasons. If you answered **YES**, what arrangements have been made?

- 7.4 (a) Do the Subject Information Statement and Consent Form:
- Give the title of the project on every page? (Use a short title as appropriate) Yes No
 - are the page numbers expressed as page 1 of .., 2 of .., 3 of etc ? Yes No
 - include an assurance that participation is voluntary and subjects are permitted to withdraw from the project at any time without penalty or prejudice ? Yes No
 - give the name and telephone number of an appropriate investigator? Yes No
 - give a telephone number for an Executive Officer of the IEC, should a subject wish to make a complaint about the conduct of the research project ? Yes No

If you answered **NO** to any of the above, give reasons.

- (b) Are the first page of the Subject Information Statement and Consent Form printed on appropriate institutional letterhead? Yes No

SECTION 8: DESCRIPTION OF PROJECT

- 8.1 Describe the project in lay terms including the aims, hypotheses, potential significance and research plan (including inclusion/exclusion criteria, where relevant). You must satisfy the IEC that the study is valid and in accordance with accepted principles governing research involving humans. Where relevant, provide the projected number, sex and age range of subjects. The description must be no longer than 2 pages and must be in a font size of at least 10 points.

8.1 (continued)

DECLARATION OF RESEARCHERS

I/we apply for approval to conduct the research. If approval is granted, it will be undertaken in accordance with this application and other relevant laws, regulations and guidelines.

Signature of Chief Investigator or Supervisor

Name:.....(print)

Signature: Date

Signature of Associate Investigator(s) or Student(s)

Name:.....(print)

Signature: Date

Name:.....(print)

Signature: Date

Name:.....(print)

Signature: Date

Name:.....(print)

Signature: Date

After careful consideration and appropriate consultation, I am satisfied that the scientific merit of this work justifies its being performed and that the information that will be obtained justifies the inconvenience, discomfort and risks to subjects.

Signature of appropriate senior officer NOT ASSOCIATED with the research (eg. Head of School/ Department/ Unit/ Dean of Faculty).

Name:.....(print)

Title:.....(print)

Position:(print)

Signature: Date

CHECKLIST

The following documents are to be attached as indicated in the Guide to Applicants. Type N/A if not applicable.

Have you included the **original and 1 copy** of the following:

- Original application
- Consent Form(s)
- Subject Information Statement
- Recruitment advertisement/circular
- Evidence of permission to conduct research in locations not associated with the NSW College of Nursing
- Evidence of approval/rejection by other IEC(s), including comments and requested alterations to the protocol
- Copy of questionnaire(s), survey questions, interview topics to be covered etc.
- Statement from a medical/allied health practitioner accepting responsibility for any specific procedures to be carried out
- Relevant references or reference list
- One copy of the funding or grant application (if applicable)
- Any form requiring signature by the IEC (one copy)

When submitting an application to undertake a clinical trial of a drug or device, the following documents (**the original and 1 copy**) must be provided:

- Trial protocol
- Statement from the trial sponsor indicating compliance with the ABPI or APMA clinical trial compensation guidelines
- Statement from the trial sponsor indemnifying the relevant Area Health Service, University, the IECs and the investigators (as appropriate)
- Certificate of currency/sponsor's insurance

Procedures for The College of Nursing Human Research Ethics Committee in conjunction with the Privacy Act, 1988

Subsequent to advice from the Office of the Privacy Commissioner and Ms Josephine Holland of Blake Dawson and Waldron Solicitors, as well as careful perusal of the Privacy Act, 1988, The National Privacy Principles, and the Office of the Federal Privacy Commission's Information Sheet 9 – 2001 Handling Health Information for Research Management the following procedures have been identified to assist The College of Nursing Human Research Ethics Committee in their deliberations relating to the conduct of research involving students (or members) of The College of Nursing.

The sections of the documents as indicated in Appendix 1 are considered particularly pertinent to researchers wishing to conduct research using students (or members) of The College of Nursing, as well as to the The College of Nursing Human Research Ethics Committee who consider research proposals relating to this. These documents form the basis on which the following procedures relating to the use or disclosure of information gained by The College of Nursing from students enrolling in a course conducted by that College, or from members of the College, have been developed.

Sentinel Points:

- The information being used or disclosed must be directly related to the primary purpose for which it was collected;
- The individual providing the information could reasonably expect the organisation to use or disclose the information for that purpose. (Information Sheet 9 – 2001 Handling Health Information for Research and Management).

In relation to research involving students of The College of Nursing, researchers should provide evidence in their proposal that the above procedures have been considered and a rationale relating to their application to the research in question provided.

A further point for consideration by both The College of Nursing Human Research Ethics Committee and researchers in the context of attention to ethical issues in research relates to NPP 2.1(b) – Secondary use and disclosure with consent. Both parties should ensure their familiarity with, and attention to this section of the National Privacy Principles, and ensure that compliance has been met within the proposed research.

Procedures for NPP2 - Use and Disclosure

NPP 2.1(a) Primary and related purposes

Primary Purpose

Determining the primary purpose of collection should always be possible. Where an organisation collects personal information directly from the individual the context in which the individual gives the information to the organisation will help identify the primary purpose of collection. When an individual provides and an organisation collects personal information, they almost always do so for a particular purpose – for example, to buy or sell a particular product or receive a service. This is the primary purpose of collection even if the organisation has some additional purposes in mind.

How broadly an organisation can describe the primary purpose will need to be determined on a case-by-case basis and it will depend on the circumstances.

Where an organisation collects personal information indirectly a guide to its primary purpose of collection could be what the organisation does with the information soon after it first receives it.

Secondary Purpose

Related and directly related purposes within reasonable expectations

To be related the secondary purpose must be something that arises in the context of the primary purpose.

If personal information is sensitive information the use or disclosure must be directly related to the primary purpose of collection. This means that there must be a stronger connection between the use or disclosure and the primary purpose for collection.

Individual's reasonable expectations

The test for what the individual would 'reasonably expect' would be applied from the point of view of what an individual with no special knowledge of the industry or activity involved would expect.

The NPPs are not intended to prevent personal information about individuals acting in a business capacity from being exchanged in the normal course of a business. In these circumstances, ordinarily it is likely to be within individual's reasonable expects that information about them will be used and disclosed for generally accepted business purposes. For example, exchange of business cards and use of them for later business contacts would ordinarily be consistent with the NPP.

NPP 2.1(b) Secondary use and disclosure with consent

This allows an organisation to use or disclose personal information for a secondary purpose if it has the individual's consent. Consent to the use or disclosure can be express or implied. Implied consent arises where consent may reasonably be inferred in the circumstances from the conduct of the individual and the organisation. For example, it may be possible to infer consent from the individual's failure to opt out provided that the option to opt out was a clearly and prominently presented and easy to take up. If the organisation's use of disclosure has serious consequences for the individual, the organisation would have to be able to show that the individual could have been expected to understand what was going to happen to information about them and gave their consent. In such situations it would ordinarily be more appropriate for the organisation to seek express consent.

NB: The Tips for compliance related to this section.

Information Sheet 9 -2001 Handling Health Information for Research and Management

Using or disclosing health information

Using or disclosing health information for health service management activities.

While NPP 10 specifically addresses the collection of health information for the management, funding and monitoring of a health service, the use and disclosure principle, NPP2, does not. Identified information may be used or disclosed for managing, funding or monitoring a health service in limited circumstances. It may be used or disclosed for these purposes where:

- *the person has consented to the use or disclosure (NPP 2.1(b));*
- *the information is being used or disclosed for the same (primary) purpose for which the information was collected (NPP2.1);*
- *the information is being used or disclosed for a purpose directly related to the primary purpose for which the information was collected and the person would reasonably expect the organisation to use or disclose the information for that purpose (NPP 2.1(a); or,*
- *another exception to NPP 2 applies.*