



Application for Ethical review of a Unit

Reference Number (School use only)

This application form is to be used by coordinators of units in which students will be required to undertake collection of information, data or samples, be involved in human experimentation in practical classes, or be involved in the design and testing of non-medical devices as part of the teaching or assessment of a unit. In the case of human experimentation, a diagnostic or therapeutic procedure that is an accepted part of treatment and is recognised as current clinical practice by the appropriate professional body or can be characterised as being of a non-intrusive nature used as a pedagogical tool is allowed, but requires ethics clearance.

Read the Guideline: Application for Unit Clearance guideline found at <http://www.nd.edu.au/research/hrec/policies.shtml>

TEACHING MUST NOT COMMENCE UNTIL WRITTEN APPROVAL HAS BEEN PROVIDED BY THE SCHOOL RESEARCH COMMITTEE.

UNIT CODE AND TITLE :

PERIOD OF DATA COLLECTION/ EXPERIMENTATION

SCHOOL/CENTRE

UNIT COORDINATOR DETAILS [UNDA staff member that takes overall responsibility for the unit]

Name			
UNDA Address			
UNDA Email		Phone	

UNIT SUMMARY

Provide a brief summary of the unit outlining the broad aims.

1. STUDY DESIGN DETAILS

1.1 DATA COLLECTION DETAILS

(a) What data collection technique(s) will be used? [Type an X to all that apply]

Questionnaire

Individual Interview

Focus group Interview

Observation

Collection of samples

Audio- or video-taping interviewees or events (with consent)

Other (please give details below)

(b) Provide an explanation of the data collection/experimentation/activity addressing:

- **Design/approach of the activity**
- **Objectives of the activity**
- **What the participants will be asked to do**
- **Importance or relevance of the activity**

1.2 PARTICIPANT PRIVACY

What type of data will be collected?

Identified

Potentially identifiable

De-identified (anonymous)

[Provide further information below if necessary]

1.3 RESEARCH LOCATION

Will the activities be undertaken on-site at The University of Notre Dame Australia?

YES NO *(If NO, give details of off-campus location below)*

2. PARTICIPANTS

2.1 PROVIDE NUMBER, AGE RANGE AND SOURCE OF PARTICIPANTS

2.2 PROVIDE DETAILS OF THE METHOD OF RECRUITMENT

2.3 DEPENDENT RELATIONSHIPS

[The issue of research involving persons in dependent or unequal relationships (e.g. student/lecturer) is discussed in Section 7 of the *National Statement* (2007). Such a relationship may compromise a participant's ability to give consent which is free from any form of pressure (real or implied).]

If there is a dependent relationship, please explain below and outline the steps to be taken by the coordinator to ensure that participation is completely voluntary and not influenced by the relationship in any way.

3. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

[Refer to Chapter 2.2 of the *National Statement* regarding general requirements for consent. Information to participants must be provided at their level of comprehension regarding purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. Information should be written in a Plain Language Statement. Each participant's consent must be clearly established.]

3.1 PROVIDING INFORMATION FOR PARTICIPANTS

(a) Will you be providing participants with information in a written Plain Language Statement?

YES

NO

(If NO, provide details of the protocol you will use to explain the research project to participants and invite their participation?)

3.2 PLAIN LANGUAGE STATEMENT

NOT APPLICABLE

(UNDA plain language statement templates can be found at <http://www.nd.edu.au/research/hrec/apply.shtml>)

CONFIRM THAT THE PLAIN LANGUAGE STATEMENT WILL:

1. be printed on University of Notre Dame Australia letterhead
2. provide details of the purpose of the activity
3. provide details of what involvement in the activity will require (e.g. involvement in interviews, completion of questionnaire, audio/video-taping of events, and estimated time commitment)
4. provide details of any risks involved and the procedures in place to minimise these.
5. advise that the project has received approval by the School Research Committee
6. include a clear statement involvement in the project will not affect ongoing assessment/grades/ management or treatment of health (if relevant)
7. state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied
8. provide advice that if participants have any concerns about the conduct of this project that they can contact the Ethics Officer of The University of Notre Dame Australia, ph: (08) 9433 0964; fax (08) 9433 0544, research@nd.edu.au

PLEASE ATTACH A COPY OF THE PLAIN LANGUAGE STATEMENT TO YOUR APPLICATION

3.3 OBTAINING CONSENT

How will each participant's consent be established?

By signing and returning a Consent Form

By returning an anonymous survey

Via a verbal agreement

Other *[Briefly describe below]:*

3.4 CONSENT FORM

NOT APPLICABLE

(Consent form templates can be found at <http://www.nd.edu.au/research/hrec/apply.shtml>)

CONFIRM THAT THE CONSENT FORM WILL:

1. be printed on University of Notre Dame Australia letterhead
2. include the title of the unit and unit coordinator
3. state that the activity is for teaching purposes
4. state that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied
5. outline particular requirements of participants including, for example, whether interviews are to be audio and/or video-taped

PLEASE ATTACH A COPY OF THE CONSENT FORM TO YOUR APPLICATION

5 DATA STORAGE, SECURITY AND DISPOSAL

[Refer to Chapter 2 of the Australian Code for the Responsible Conduct of Research and University policy 'Code of Practice for name identified data' <http://www.nd.edu.au/research/hrec/policies.shtml>]

5.1 DATA STORAGE

Will data storage comply with the University policy?

YES

NO

[If No, please explain below]

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5.2 DATA SECURITY

(a) Will only the lecturer be responsible for security of data collected?

YES

NO

[If No, please provide further details below. You may also use this space to explain any differences between arrangements in the field, and on return to campus.]

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(b) What will happen to the data collected at the conclusion of the unit?

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7. DECLARATION BY RESEARCHER

If approval is granted, the activities will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

As unit coordinator, I agree:

- To only start the activity after obtaining final approval from the School Research Committee (SRC);
- To accept the responsibility to monitor the conduct of data collection for assessment or teaching requirements of a unit to ensure that it remains within the scope of the Unit Clearance and complies with University policy, the National Statement (2007), and other relevant legislative and/or regulatory requirements.
- To provide additional information as requested by the SRC;
- To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- To notify the SRC in writing immediately if any change to the activity is proposed and await approval before proceeding with the proposed change;
- To notify the SRC in writing immediately if any adverse event occurs after the approval of the SRC has been obtained;
- To only use data and any tissue samples collected for the study for which approval has been given;
- To store data, information and samples securely and to maintain the confidentiality of data, information and/or samples collected from or about participants;

I have read the NHMRC *National Statement on Ethical Conduct in Human Research* (2007) and agree to comply with its provisions.

Unit Coordinator's Name	Signature	Date

8. CHECKLIST AND OTHER ATTACHMENTS

8.1 CHECKLIST

Attach Unit Clearance checklist.

8.2 OTHER ATTACHMENTS

Please check that the following documents are attached to your application.

Document	Draft Only	Final Version	N/A
Questionnaire or survey			
Interview Questions			
Experimentation/Activity protocol			
Recruitment advertisement or letter			
Plain Language Statement (PLS) (<i>section 3.2</i>)			
Consent Form (<i>section 3.4</i>)			

9. DECLARATION BY SCHOOL RESEARCH COMMITTEE [SRC]

DATE APPLICATION WAS RECEIVED	
DATE SRC REVIEW COMPLETED	
PERIOD OF APPROVAL	
DATE UNIT COORDINATOR NOTIFIED	

I have read the application for a Unit Clearance. I confirm that the Unit Coordinator will accept the responsibility to monitor the conduct of data collection for assessment or teaching requirements of a unit to ensure that it remains within the scope of the Unit Clearance and complies with University policy, the National Statement, and other relevant legislative and/or regulatory requirements.

Comments/Provisos:

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Name of SRC Chair	Signature	Date

Note: If the SRC Chair is also the Unit Co-ordinator for this unit, the declaration must be signed by another authorised member of the SRC.

Once approved, the School Research Committee must forward a copy of the application to the Ethics Officer.