



THE UNIVERSITY OF  
**NOTRE DAME**  
A U S T R A L I A

# INFORMATION BOOKLET: LEVELS OF ETHICS CLEARANCE - ACADEMIC STAFF AND RESEARCH STUDENTS

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<b>Purpose:</b>	The University has established these research ethics guidelines which specify what forms of research require ethics clearance, the level of ethics clearance required, and how clearance is to be obtained.
<b>Responsible Executive:</b>	Executive Director, Academic Services
<b>Responsible Office:</b>	Research Management Office
<b>Contact Officer:</b>	Manager
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## INTRODUCTION

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If your research impacts upon humans (including the collection of data, the testing of responses to conditions constructed by researchers, therapeutic and non-therapeutic research, clinical and non-clinical research and the like ) then it must conform to the [National Statement on Ethical Conduct in Research Involving Humans](#).

In the interests of the protection of the welfare and rights of participants in research, the University has established a set of research ethics guidelines. These guidelines specify what forms of research require ethics clearance, the level of ethics clearance required, and how clearance is to be obtained

Ethics clearance protocols are designed to protect participants, the researcher, the University and the community in general. Research involving human participants should also meet appropriate professional and cultural standards. In every piece of research involving human interventions there must be a balance between the cost of the human interventions to those participating in them (e.g. in terms of discomfort, personal risk, loss of privacy or other sort of harm) and the value to be achieved by carrying out the research. The University's Human Research Ethics Committee [HREC] has a primary responsibility to ensure that:

- participants in research have their integrity and autonomy as persons respected and protected
- harm or risks of harm to participants from research interventions are both minimised and outweighed by the benefits to themselves or others
- harm or risk to researchers are both minimised and outweighed by the benefits to themselves or others.

The *Statement* permits the HREC to establish procedures for expedited review in limited circumstances (NS2.27-2.29). The justification for expedited review is that the research involves minimal risk to participants, not that speedy approval is needed. Remember that whilst an application may be permitted expedited review only the HREC is able to give ethics approval.

## WHO HAS TO APPLY FOR ETHICS CLEARANCE?

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Any research involving contact with human subjects requires ethics approval. This includes but is not limited to

- clinical research
- action research projects
- research involving data collection by interviews, questionnaires, focus groups, observation
- use of human tissue

All academic staff and students conducting teaching activities involving human subjects or completing a thesis or dissertation are required to submit an application for unit or ethics clearance to either the School Research Committee or the HREC. It is the responsibility of the supervisor to assist students to complete their application for ethics clearance.

## DOES ALL RESEARCH REQUIRE ETHICS CLEARANCE?

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All research involving humans is normally considered to require ethics clearance at one of three levels. There are three kinds of impact which a research procedure may have on those participating: physical harm, psycho-social harm, and the risk of either (as opposed to its actuality).

- Physical Harm  
It is often the case that one must do some harm in order to bring about a greater good (every piece of surgery is an example) – the focus is on the minimisation of the harm and the maximisation of the good. In particular it will consider whether changes in procedure might be required to bring about that objective.
- Psycho-Social Harm  
This means everything from the invasion of privacy and contributing to a detrimental social reputation to the creation of enduring psychological fears and confusions e.g. giving information which could cause embarrassment.

- Risk of Harm  
Often what will be involved is not actual harm of any sort to participants but the risk of some harm. When the risk cannot be reasonably eliminated it is essential that the participant be properly informed of the risks involved. In explaining these risks to participants it is essential for the researchers to place themselves in the participant's position.

Research which can impact upon humans, without their participation, may also require ethics clearance. Examples of research which can impact upon humans, without their actual participation include:

- research involving work with human remains, where the remains can be directly linked to living humans (either on a direct familial or significant cultural basis);
- work involving sites of significant community, cultural, historical or religious significance to a definable group of humans; and
- research where the findings have a direct and significant impact upon the personal or professional affairs of a definable group of humans.

If you require ethics approval from another organisation in addition to that of the University of Notre Dame Australia, you may submit your application in that organisation's format.

There are a number of circumstances which do not, as a matter of course, require ethics clearance. Normally, you do not require ethics clearance if your project is market research or involves statistical or archival data. However, the subsequent use of data from such a project for a broader purpose (such as for research publication) would mean that the project would require ethics clearance.

Examples of projects that do not normally require formal approval include:

- Research conducted by the University only for the purposes of assessing the effectiveness or adequacy of an internal instrument or process. For example, a survey of staff, conducted to evaluate employee satisfaction and concerns; a questionnaire which evaluated the degree to which a cohort of students were satisfied with a course or service.
- Information from a public database where aggregated data which cannot be associated with one individual or group of individuals is used.
- Observations of behaviour within a public gathering which cannot be associated with any particular individual or group of individuals.
- Information which is already in the public domain (eg autobiographies, diaries)

## **LEVELS OF ETHICS CLEARANCE**

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There are three levels of research projects requiring ethics clearance.

1. Unit-based research projects: Unit clearance
2. Low Risk Research Projects: Low Risk review
3. High Risk Research Projects: Full ethics clearance

## **UNIT-BASED RESEARCH PROJECTS: UNIT CLEARANCE**

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The criteria applied to determining if ethics clearance is required for activities conducted as part of the curriculum is 'if an activity would be subject to ethics review in any other context, it is subject to review if it occurs in a teaching and/or training context'. Thus, research projects which are designed as a learning exercise or form part of unit assessment may require ethics approval.

Students may 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.

The unit coordinators must obtain Unit Clearance where such activities are involved.

The Unit Clearance does not cover:

- data collected for the purpose of later publication;
- data that is recorded in such a manner that the human subjects can be identified directly or indirectly;
- data that, if disclosed, may place the subjects at risk of criminal or civil liability or be damaging to their financial standing or employability or reputation;
- data that deals with sensitive aspects of the subjects own behaviour (such as illegal conduct, drug use, sexual behaviour, use of alcohol or information about health status);
- data collected for a research contract;
- students undertaking a research project for the purposes of an Honours or higher degree.

In such cases, an application for low risk or full ethics clearance must be completed by the academic staff member or student. Unit coordinators should complete the Unit Clearance Checklist.

Unit-based activities must be submitted for ethics clearance, and must be conducted in accordance with the University's Research Code of Practice; however, they:

- do not require the completion of a full form (a Unit Ethics Clearance form must be submitted); and
- are considered by the School Research Committee.

## **LOW RISK ETHICS REVIEW**

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Low risk review may be obtained for non-invasive projects where generally there is no risk to participants or researchers above the everyday norm and to projects not relating to research requiring full ethics appraisal by the HREC. Research with potential for physical or psychological harm will not be considered for low risk review.

Examples of the types of research projects that may be subject to Low Risk review include:

- Involves the use of standard tests and questionnaires administered appropriately to normal subject populations, with data recorded in such a manner that participants are not and cannot be identified in any report or other published output
- Involves observation of public behaviour on unidentified participants, with data recorded in such a manner that the participants are not and cannot be identified in any report or other published output
- Involves personal interviews with participants with data recorded in such a manner that participants are not and cannot be identified in any report or other published output
- Is carried out in an educational setting using groups of participants (rather than individual participants), with data recorded in such a manner that the participants are not and cannot be identified in any report or other published output
- Research which can be characterised as evaluative or quality improvement activity;
- Surveys of a group of individuals;
- Analysis of records collected by an organisation which are not on the public record.
- Involves the use of secondary data sources or archival materials based on informed consent.

Low Risk projects must be submitted for clearance, and must be conducted in accordance with the University's Research Code of Practice; however, they:

- do not require the completion of a full form (an Expedited Review form must be submitted); and
- are considered by the School Research Committee.

The project cannot be commenced until such time as the researcher is notified their project has qualified as Low Risk. Clearances granted by low risk review are subject to confirmation by the HREC. The HREC may elect to review the panel's decision or request further information / amendments to the project.

When a researcher believes their project is within this level of clearance (rather than requiring Full ethics clearance), by completing a Low Risk Checklist a researcher will be able to determine whether or not their project is likely to qualify under this level of clearance.

Researchers who believe their project qualifies for low risk ethics clearance should submit the completed forms to the School Research Committee. Submitted forms for low risk review are considered by the School Research Committee. Within 2 – 3 weeks the researcher will be issued with a written notification of the SRC's decision. Possible outcomes include:

- confirmation that the project has been granted ethics clearance by low risk review, and notification that the project can be commenced;
- confirmation that the project has been granted conditional ethics clearance by low risk review, but further information must be submitted about the project (which may include minor modifications to the project)\*;
- advice that the project has been referred to the next meeting of the HREC for consideration; or
- advice that a full application must be submitted for consideration at the next meeting of the HREC.

All decisions of the School Research Committee are subject to endorsement at the next meeting of the HREC. However, in most cases the researcher will be authorised to commence their project on the basis of the School Research Committee's decision. If you do not qualify for Low Risk clearance, you will need to go through the Full ethics application process.

## **FULL ETHICS CLEARANCE BY THE UNIVERSITY'S HUMAN RESEARCH ETHICS COMMITTEE [HREC]**

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Full ethics clearance is required for high risk research. All projects which involve the participation of humans or impacts on humans and do not qualify for Low Risk clearance must be submitted for Full ethics clearance.

High risk proposals are defined as research involving:

- Previously collected confidential data
- Involves external funding (whether successfully obtained or not)
- Uses intrusive techniques (highly personal interviewing, physical contact, etc)
- Involves invasive physical procedures, physical intervention or removal or collection of body fluids or tissues (such as blood, saliva or urine samples, biopsies)
- Involves a clinical trial or any drug, therapeutic product or biomaterial
- May cause discomfort (physical, psychological or social) beyond normal levels of inconvenience
- Involves the administration of any substance (including food and/or drink, by ingestion or inhalation, etc)
- Uses therapeutic techniques
- Involves hazardous or potentially hazardous substances or conditions
- Involves circumstances where the purpose of the study is not fully disclosed (deception, covert observation, part disclosure of intentions)
- Examines potentially sensitive or contentious issues (personal, social, political, cultural, ethnic, professional, etc – depending on context and people involved)
- Involves research in which there are inherent ethical or legal (or prospective legal) problems
- Involves minors as participants (if a child is under 18 years of age, permission in writing is required from the parent or guardian of the child).
- Seeks disclosure of information which may be prejudicial to participants (that is, for example, including information which has the potential to be incriminating, or could lead to loss of status/position in a community, profession or place of employment, etc)
- Uses a highly vulnerable subject population (homeless youth, people with intellectual disabilities, refugees, detainees, very young children, patients highly dependent on care, etc)
- Involves participants who are in a dependent relationship (teacher/student, professional/client, administrator/student, doctor/patient, parent/child, warder/prisoner, etc)
- Involves minors as participants where there is individual or one-to-one interaction between investigator and subject (in some cases police clearance may be recommended or required)
- Involves research covered by Commonwealth Privacy Act, e.g., relating to Commonwealth Government agencies

To apply for Full ethics clearance, a researcher must complete and submit the Application for Full Approval of a Project Involving Human Participants. Applications for Full ethics clearance

- require the completion of a Full clearance form; and
- are considered by the HREC (which meets every 5 - 7 weeks).

Submitted forms are considered by the HREC. Possible outcomes include:

- confirmation that the project has been granted ethics clearance and notification that the project can be commenced;

- confirmation that the project has been granted conditional ethics clearance, but further information must be submitted about the project (which may include minor modifications to the project); or
- advice that the project has not been granted ethics clearance (although the researcher may be invited to resubmit once the application / project has been revised).

The project cannot be commenced until such time as the researcher is notified the project has been granted ethics clearance and may be commenced.

## **WHEN SHOULD I START THINKING ABOUT ETHICS CLEARANCE?**

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Obtaining ethics clearance is a time consuming process and allowance for this process needs to be built into research plans. It can take months, for example, if your proposal has to go to the HREC and the Committee asks for some amendments. If you think your proposed research will need ethics clearance, you should start the process by reading *The National Statement on Ethical Conduct in Research Involving Humans* and consider the implications for your research.

## **WHAT DOCUMENTATION IS REQUIRED?**

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Students applying for ethics clearance must complete the required documentation which includes: the relevant ethics application form, the relevant checklist, a draft research proposal, an information and consent letter for participants that must conform to the format identified in the document 'Guidelines for information and consent letter for participants', any interview questions or questionnaires and letters of approval from organisations/groups taking part in or facilitating the study.

Human research ethics approval is made on the basis of a number of conditions. It is important that you are familiar with, and abide by, these conditions.

1. Any serious or unexpected adverse effects on research participants must be reported immediately to the Office of the Provost.
2. Any unforeseen events which might affect the continued ethical acceptability of the research project must be reported immediately to the Office of the Provost.
3. The HREC must be notified of, and approve, any changes (e.g. to research design or methodology, research tools, research participants' recruitment method) to the original protocol.
4. The HREC must be notified of any changes in the membership of the research team.

## **POINTS TO NOTE**

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- If the information you wish to analyse in your research was gathered by another party, you may still require ethics clearance.
- If the information you wish to analyse in your research was gathered by you as a researcher for another purpose, its re-use for a different purpose is not covered by the previous approval and/or consent and requires further ethics approval.
- If you require assistance or agreement from another organisation to undertake your research, you will need to gain written organisational permission/approval to access staff members, clients or other information for research purposes. This approval is separate from the ethics approval process and is usually required from the Chief Executive Officer or another authorised person.
- Signed consent is not needed if the information collected consists of de-identified data.
- Be clear about the difference between confidential and anonymous. Confidential data is where the researcher does not reveal the identity of the informant when writing up the research. Anonymous or de-identified data is where any piece of information which could identify the informant has been removed (so that even the researcher cannot identify individuals) or it was not collected in the first place.
- You need to let participants know that even if they agree to participate, they remain free to withdraw at any time during the interview process and if they do withdraw, the information they have provided will be destroyed.

- If you tell participants that they will have the opportunity to review how their interview data has been used you need to explain how this will happen.
- You need to provide participants with names and contact details of people they can contact if they have concerns. The first point of contact should be the researcher, the second the supervisor and the third the Executive Officer of the HREC.
- Funds attracted from successful grants, which involve ethical issues, will not be release until ethics approval has been granted.
- In Australia there is a legal obligation for raw data arising from human research to be stored securely. The University requires that research data be retained for a period of seven years. If your data are not stored by your School, the School must be aware of the location.