



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

POLICY: ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS

Purpose:	This document outlines the University's policy on ethics approval for research involving humans.
Responsible Executive:	Provost
Responsible Office:	Office of the Provost, Research
Contact Officer:	Academic Officer
Effective Date:	March 2006
Modification History:	Approved May 2006 reformatted August 2006; minor change to Principle June 2007, substitution of expedited for low risk nomenclature May 2009

Principles

1. The National Statement on Ethical Conduct in Research Involving Humans is the foundation document informing research at The University of Notre Dame Australia.
2. The need to obtain ethics clearance is predicated on the need to protect the welfare and rights of participants in research, the researcher(s), the University and the community in general.
3. Research involving humans must meet established ethical, professional and cultural norms.
4. Research must demonstrate an appropriate balance between the cost of human interventions and the value to be achieved in carrying out the research. Thus, harm or risk to participants and researchers must be both minimised and outweighed by the benefits to participants or others.
5. Core principles with regard to the protection of participants are: integrity, including respect for persons, beneficence and justice; consent; research merit and safety.
6. Research that does not directly involve humans but can impact upon them also requires ethics approval.
7. Research that can impact on humans without their participation includes 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 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.
8. Where research undertaken may not initially require ethics approval, any change in the use of the data for a broader or different purpose may demand ethics clearance.
9. Research projects which are designed as a learning exercise or form part of a unit assessment may require ethics approval.
10. Low Risk review may be obtained for non-invasive projects where generally there is no risk to participants or researchers above the everyday norm.
11. Full ethics approval is required for research with potential for physical, psychosocial, or community harm.
12. The School Research Committee is authorised to provide low risk review of applications for ethics clearance in accordance with the approved guidelines.
13. If the assistance or agreement of another organisation is required to undertake the research project, written permission is required to access staff, clients or other information. Likewise, permission is required for research involving UNDA staff or students undertaken by external research, irrespective of whether or not approval has been granted by the institution where the research originates.

14. The granting of ethics approval remains the prerogative of the Human Research Ethics Committee.
15. Ethics approval is granted on the basis of a number of conditions: that any serious or unexpected adverse effects on research participants or any unforeseen events which might affect the continued ethical acceptability of the research project is reported immediately to the Office of the Provost; and the Human Research Ethics Committee must be notified of, and approve, any changes to the original protocol or membership of the research team.
16. Funds attracted from successful grants (which involve ethical issues) will not be released until ethics approval has been granted.

Procedures

1. Ethics approval is obtained by the submission of an application form to the School Research Committee. There is a form for each of the three levels of research project: unit-based (low risk review); low risk research (low risk review); high risk research (full clearance).
2. In determining the appropriate level of the research project, the researcher should consult the Low Risk Review Checklist or the Unit Clearance Checklist.
3. Unit clearance applications are completed by the unit coordinator and submitted to the School Research Committee prior to the commencement of the unit.
4. Low Risk review applications and full clearance applications must be submitted to the School Research Committee in advance of data collection: the project cannot be commenced until such time as the researcher is notified the project has been granted ethics approval.
5. Researchers seeking low risk review or full ethics approval must submit, along with their application, the checklist (if relevant), a draft research proposal, an information and consent letter for participants (as per University guidelines) and letters of approval from organisations/groups taking part in or facilitating the research.
6. Staff and students should read this policy in conjunction with the *Policy: Research Integrity* and *Policy: Code of Conduct for Research* and the *Information Booklet: Determining what level of ethical clearance is required*.