



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

GUIDELINE:

APPLYING FOR ETHICS APPROVAL (UNIT CLEARANCE)

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| Purpose: | To outline the requirements and procedure for obtaining a Unit Clearance for research involving humans |
| Responsible Executive: | PVC – Research |
| Responsible Office: | Research Office |
| Contact Officer: | Ethics Officer |
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1 Introduction and purpose

- 1.1 The University of Notre Dame Australia (UNDA) requires anyone undertaking research involving humans, as defined in the *Policy: Ethics Approval for Research Involving Humans* (“Policy”), to obtain ethics approval.
- 1.2 UNDA has established three categories of ethics approval, taking into consideration the type of research and the degree of risk involved in the research, as set out in the Policy.
- 1.3 This *Guideline: Applying for Ethics Approval (Unit Clearance)* (“Guideline”) sets out the procedure to be followed in order to obtain a Unit Clearance.
- 1.4 This Guideline must be read in conjunction with any relevant University policies, procedures and other guidelines as may apply from time to time.

2 Definitions

For the purposes of this Policy:

- 2.1 **Ethics Officer** means the person who holds the position of Ethics Officer at UNDA from time to time;
- 2.2 **HREC** means the Human Research Ethics Committee of UNDA;
- 2.3 **National Statement** means the *National Statement on Ethical Conduct in Research Involving Humans* (2007) published by the NHMRC;
- 2.4 **NHMRC** means the National Health and Medical Research Council;
- 2.5 **Policy** means the *Policy: Ethics Approval for Research Involving Humans*;
- 2.6 **Pro Vice Chancellor Research** means the person who holds the position of Pro Vice Chancellor Research at UNDA from time to time;
- 2.7 **Research Office** means the UNDA Research Office;
- 2.8 **SRC** means a School Research Committee of UNDA;
- 2.9 **UNDA** means The University of Notre Dame Australia;
- 2.10 **UNDA researcher** means any person, including but not limited to, UNDA staff and students, who wishes to carry out research on behalf of, or under the auspices of, UNDA or as part of their role or studies with UNDA.
- 2.11 **UNDA unit** means a unit run by UNDA as part of a UNDA course;
- 2.12 **Unit Coordinator** means the person in charge of coordinating the UNDA unit in relation to which the Unit Clearance is sought.

3 When is a Unit Clearance required?

- 3.1 UNDA units where information, data or samples are collected from human participants by students as part of the teaching or assessment require ethics clearance in the form of a Unit Clearance.
- 3.2 A Unit Clearance does not apply to:
 - 3.2.1 data collected for the purpose of later publication or data collected for funded research; or
 - 3.2.2 students undertaking a project for the purposes of Honours or higher degree by research; or
 - 3.2.3 research that is not deemed as low risk.
- 3.3 A Unit Clearance includes low risk approval by an SRC and the low risk checklist should be completed.

4 Procedure for applying for a Unit Clearance

- 4.1 It is the responsibility of the Unit Coordinator to apply for a Unit Clearance.
- 4.2 The Unit Coordinator must complete an *Application for Ethics Review of a Unit* form attaching all relevant documentation which may include but is not limited to a Unit Clearance Checklist, a Plain Language Statement, consent form and copy of survey/questionnaire and submit the completed application to the SRC for review.
- 4.3 An SRC will review the application in accordance with the Policy and may:
 - 4.3.1 approve the application with no conditions;
 - 4.3.2 approve the application on the condition that further information is submitted by the applicant or minor modifications are made to the project (in which case the project must be deferred until the applicant is advised that the clearance has become unconditional);
 - 4.3.3 if significant issues are identified, require reconsideration of the application by the SRC once the issues have been addressed; or
 - 4.3.4 deny the application (although the applicant may be invited to resubmit once the application and project have been revised).
- 4.4 The SRC will notify the applicant and the Ethics Officer in writing of the outcome of its review of the application.
- 4.5 When the application has been approved by the SRC, the SRC will forward to the Ethics Officer a copy of the application together with notice of any revisions required or conditions imposed by the SRC.
- 4.6 The Ethics Officer will allocate a reference number to the application for record keeping and undertake a final review of the application which will confirm:

- 4.6.1 that, in the opinion of the Ethics Officer, the application is low risk;
 - 4.6.2 that the application includes all necessary information and documentation; and
 - 4.6.3 that there is no indication in the application that the research activity could be in conflict with the Objects of the University.
- 4.7 In the event that the Ethics Officer is of the view that the application is not low risk or that further information or documentation is required, the Ethics Officer may seek further information from the applicant and/or SRC or send the application back to the SRC in which case the SRC must advise the applicant of the issues and request that they resubmit their application in the appropriate form.
- 4.8 In the event that the Ethics Officer considers that the research activity could be in conflict with the Objects of the University, the Ethics Officer will seek the advice of the Pro Vice Chancellor Research. If the Pro Vice Chancellor Research considers that the application is inappropriate he or she may instruct the Ethics Officer to seek further information from the applicant or send the application back to the researcher and request that they resubmit their application with amendments.
- 4.9 Once the Ethics Officer is satisfied that the applicant is low risk and contains all relevant information and documentation, the Ethics Officer will approve the application and notify the HREC of approval at its next meeting.