



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

# Procedure:

## Applying for Ethics Approval (Course Clearance)

Effective: 17 April 2019

Audience: Staff and Students

Policy Category: Academic  
Policy Sub-category: Research

Key words:	ethics, human participants, research activity
Policy Owner:	Pro Vice Chancellor, Research
Responsible Officer:	Research Ethics Officer
Review Date:	June 2022

## Contents

1	PURPOSE.....	3
2	RELATED POLICIES AND REGULATIONS .....	3
3	WHEN A COURSE CLEARANCE IS REQUIRED.....	3
4	APPLYING FOR A COURSE CLEARANCE .....	3
5	CONDITIONS OF APPROVAL.....	4
6	RELATED DOCUMENTS .....	5
7	DEFINITIONS: .....	5
8	PROCESS SUMMARY: .....	6

## 1 PURPOSE

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- 1.1 The University of Notre Dame Australia (“University”) requires anyone undertaking research involving human participants, as defined in the *Policy: Ethics Approval for Research Involving Human Participants* (“Policy”), to obtain ethics approval.
- 1.2 The University has established four levels 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 Procedure sets out the processes to be followed in order to obtain a Course Clearance.
- 1.4 This Procedure must be read in conjunction with any relevant University policies, procedures and other guidelines as may apply from time to time.

## 2 RELATED POLICIES AND REGULATIONS

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This Procedure should be read in conjunction with the following policies:

- 2.1 *Policy: Ethics approval for Research involving Human Participants*
- 2.2 *Policy: Responsible Conduct of Research.*

## 3 WHEN A COURSE CLEARANCE IS REQUIRED

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- 3.1 A University course where research activity is conducted by students as part of the teaching or assessment requires ethics clearance in the form of a Course Clearance.
- 3.2 A Course Clearance *does not* apply to the following:
  - 3.2.1 data collected for the purpose of later publication;
  - 3.2.2 data collected for funded research;
  - 3.2.3 students undertaking a project for the purposes of Honours or Higher Degree by Research; or
  - 3.2.4 any activity involving research that is not deemed “Low Risk” as defined in the National Statement and the *Procedure: Applying for Ethics Approval (Full Ethical Review)*.

## 4 APPLYING FOR A COURSE CLEARANCE

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- 4.1 It is the responsibility of the Course Coordinator to apply for a Course Clearance.
- 4.2 The Course Coordinator must complete the *Course Clearance Checklist* to determine whether the course research activity can be classified as low risk, using the National Statement as a guide.
- 4.3 The Course Coordinator must ensure that the research activity aligns with the Objects of the University.
- 4.4 The Course Coordinator must complete the *Application for Ethical Review of a Course* form, attaching all relevant documentation which may include, but is not limited to, the Course Clearance Checklist, a Participant Information Sheet, Consent Form and copy of the data collection tool/s and submit the completed application to the School Research Committee (SRC) for review.
- 4.5 The SRC will review the application in accordance with the Policy and the National Statement

and may:

- 4.5.1 Approve the application with no additional requirements;
  - 4.5.2 Approve the application on the condition that further information is submitted by the Course Coordinator or modifications are made to the project prior to final approval i.e. Conditional approval;
  - 4.5.3 Refer the application to the Research Ethics Officer for HREC review if the SRC are of the view that the research activity does not qualify for a Course Clearance i.e. Not approved.
- 4.6** The SRC will notify the Course Coordinator in writing of the outcome of its review of the application.
  - 4.7** When the application has been approved by the SRC, the SRC will forward to the Research Ethics Officer a copy of the application together with notice of any revisions required or conditions imposed by the SRC.
  - 4.8** In the event that the Research Ethics Officer is of the view that the application is not low risk, does not qualify for a Course Clearance or that further information or documentation is required, the Research 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.
  - 4.9** In the event that the Research Ethics Officer considers that the research activity could be in conflict with the Objects of the University, the Research Ethics Officer will seek the advice of the Pro Vice Chancellor, Research (PVCR). If the PVCR considers that the application is inappropriate they may instruct the Research Ethics Officer to seek further information from the applicant or send the application back to the researcher and request that a resubmission of the application with amendments.
  - 4.10** The SRC and Research Ethics Officer will maintain a record of the Course Clearance.

## 5 CONDITIONS OF APPROVAL

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- 5.1** The Course Coordinator must report immediately anything which might affect ethical acceptance of the course research activity, including:
  - 5.1.1 Adverse effects on participants;
  - 5.1.2 Significant unforeseen events;
  - 5.1.3 If a complaint is made about the conduct of a student;
  - 5.1.4 If a student has conducted an activity beyond the scope of what was approved or has failed to comply with the approved Course Clearance conditions; or
  - 5.1.5 Other matters that might affect continued ethical acceptability of the research activity.
- 5.2** Proposed changes or amendments to the course must be applied for using an Amendment application form and approved by the SRC before these may be implemented. This includes; change in focus of the course, replacement of Course Coordinator or student projects significantly different to those outlined in the Course Clearance application form.
- 5.3** Any equipment used must meet current safety standards. Purpose built equipment must be tested and certified by independent experts for compliance with safety standards.

## 6 RELATED DOCUMENTS

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- 6.1 *Procedure: Applying for Ethics Approval (Full Ethical Review)*
- 6.2 *Procedure: Applying for Ethics Approval (Low Risk Ethical Review)*
- 6.3 *Guideline: Participant Information Sheet and Consent Form for Research involving Human Participants*
- 6.4 *National Statement on Ethical Conduct in Research Involving Humans (2007, updated 2018)*
- 6.5 *Australian Code for the Responsible Conduct of Research (2018).*

## 7 DEFINITIONS:






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- 7.1 For the purpose of this Procedure, the definitions outlined in the *Policy: Ethics Approval for Research involving Human Participants*, apply.
- 7.2 In addition, the following definitions apply to this Procedure:
  - 7.2.1 **Data collection tool** means the instrument or method used to collect data from the participants e.g. questionnaire, interview questions, spreadsheet for collection of information etc.
  - 7.2.2 **Low Risk research** means the only foreseeable risk to participants is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research cannot be deemed low risk.
  - 7.2.3 **Research activity** means a task to be completed by students as part of coursework, which involves collecting data from human participants.
  - 7.2.4 **Course Coordinator** means the person in charge of coordinating the University course in relation to which the Course Clearance is sought.

Version	Date of approval	Approved by	Amendment
1	December 2012	Vice Chancellor	New Procedure
2	September 2017	Vice Chancellor	Updated nomenclature and wording of information.
3	17 April 2019	Vice Chancellor	Updated nomenclature and National guidelines.

## 8 PROCESS SUMMARY:

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<b>Process Step</b>	<b>Responsibility</b>
Complete Course Clearance checklist to determine whether the research project qualifies for a Course Clearance.	Course Coordinator
	
Completing Course Clearance application form and submit to School Research Committee.	Course Coordinator
	
Review of application in accordance with the Policy, Procedure and National Statement.	School Research Committee
	
Course Coordinator will be informed of the review outcome.	School Research Committee
	
Course Clearance application and approval letter forwarded to Research Ethics Officer for record-keeping.	School Research Committee
	
Research activity conducted in accordance with the conditions of ethics approval.	Course Coordinator