THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Procedure:

Applying for Ethics Approval (Cross-Institutional Approval)

Effective: 17 April 2019

Audience: Staff and Students

Policy Category: Academic
Policy Sub-category: Research

Key words:	research, ethics, HREC, human participants
Policy Owner:	PVC, Research
Responsible Officer:	Research Ethics Officer
Review Date:	1 June 2022

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1 PURPOSE

1.1 The University of Notre Dame Australia ('the 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, *Applying for Ethics Approval (Cross-Institutional Approval)* sets out the procedure to be followed in order to obtain approval for research deemed to be "Low Risk" and with ethics approval from another NHMRC-registered HREC.

2 RELATED POLICIES

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 CROSS-INSTITUTIONAL APPROVAL IS REQUIRED

3.1 Where research involves low risk, as defined in the National Statement, and has ethics approval from another NHMRC-registered HREC, Cross-Institutional Approval can be sought.

3.2 Research, where the risk for participants is more than discomfort, is not low risk and therefore, requires a full ethical review.

3.3 Examples of the types of research projects that may be eligible for low risk review may include, but are not limited to:

3.3.1 The use of standard tests and questionnaires administered appropriately to normal participant populations, with data recorded in such a manner that participants are not and cannot be identified in any report or other published output;

3.3.2 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;

3.3.3 Interviews with participants, of a non-sensitive nature, with data recorded in such a manner that participants are not and cannot be identified;

3.3.4 Interviews with participants, of a non-sensitive nature, with data recorded and disseminated in such a manner that participants are identified (and possibly named) based on informed consent;

3.3.5 Research 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;

3.3.6 Research which can be characterised as evaluative or quality improvement activity;

3.3.7 Anonymous surveys of a group of individuals;

3.3.8 Analyses of records collected by an organisation where individuals are not identifiable;

3.3.9 The use of secondary data sources or archival materials based on informed consent, such as patient health information from a hospital;

4 APPLYING FOR CROSS-INSTITUTIONAL APPROVAL

4.1 It is the responsibility of the Chief Investigator/Supervisor for the University arm of the research project to apply for Cross-Institutional Approval of a research project.

4.2 The applicant must complete the *Application for Cross-Institutional approval of a research project involving Human participants* form, attaching the original ethics application, supporting documentation and HREC approval letter/s to a SRC.

4.3 The applicant must ensure that the research project aligns with the Objects of the University.

4.4 The SRC will engage in an administrative review of the application and if it considers the application to be compliant with this Procedure and the Policy, will forward the application to the Research Ethics Officer.

4.5 The Research Ethics Officer will engage in an administrative review of the application to ensure that the research project qualifies as Low Risk Research, all required information has been submitted and that there is no indication in the application that the research activity could be in conflict with the Objects of UNDA.

4.6 In the event that the Research Ethics Officer is of the view that the application cannot be deemed Low Risk, the Research Ethics Officer will 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.

4.7 If further information is required, the Research Ethics Officer will advise the Chief Investigator/Supervisor of the further information required in order to progress their application.

4.8 If the research activity may be in conflict with the Objects of the University, the Research Ethics Officer will seek the advice of the HREC Chair and the Pro Vice Chancellor, Research (PVCR). If the HREC Chair and PVCR considers that the application is inappropriate, the Research Ethics Officer may be instructed to seek further information from the applicant and/or SRC, send the application back to the researcher and request that they resubmit their application with amendments, or refer the application to the Ethics Committee.

4.9 Once the application is complete in the opinion of the Research Ethics Officer, a Cross-Institutional approval letter will be provided by the Research Ethics Officer to the applicant, with a copy sent to the SRC Chair.

4.10 Where possible, such notification will be made within five business days of the application being received.

4.11 The HREC will note that the application has received cross-institutional approval at the next scheduled HREC meeting.

5 CONDITIONS OF APPROVAL

5.1 Cross-Institutional approval is valid until the end date provided by the Primary HREC.

5.2 The Chief Investigator must immediately report to all approving HRECs anything which might affect ethical acceptance of the research project including:

- 5.2.1 Adverse effects on participants,
- 5.2.2 Significant unforeseen events,
- 5.2.3 If a complaint is made about the conduct of the project,
- 5.2.4 Other matters that may affect continued ethical acceptability of the project.

5.3 Proposed changes or amendments to the research project must be applied for by the Chief Investigator and approved by the Primary HREC before these may be implemented. A copy of these amendments and approval letter must be forwarded to the Research Ethics Officer.

5.4 If an extension is required beyond the end date of the approved project, the Chief Investigator must forward proof of extension approval from the Primary HREC to the UNDA Research Ethics Officer.

5.5 Higher degree students must also have their candidacy approved prior to commencing research.

5.6 UNDA HREC reserves the right not to accept the Primary HREC's approval, in which case, the applicant will be required to resubmit their application in the appropriate form.

5.7 Failure to comply with the National Statement and with the conditions of approval may result in the suspension or withdrawal of approval for the research project.

6 RELATED DOCUMENTS

6.1 Procedure: Applying for Ethics Approval (Low Risk review)

6.2 Procedure: Applying for Ethics Approval (Full Ethical Review)

6.3 Procedure: Applying for Ethics Approval (Course Clearance)

6.4 Guideline: Participant Information Sheet and Consent Form for Research involving Human Participants

6.5 National Statement on Ethical Conduct in Research Involving Humans (2007, updated 2018)

6.6 Australian Code for the Responsible Conduct of Research (2018)

6.7 Guidelines under Section 95A of the Privacy Act (1988)

6.8 Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)

7 DEFINITIONS

7.1 For the purpose of this Procedure, the definitions outlined in the Policy, *Ethics Approval for Research involving Human Participan*ts, apply.

7.2 In addition, the following definitions apply to this Procedure:

7.2.1 ***Conflict of interest*** means circumstances where a person has a real, perceived or potential opportunity to prefer their own interest, or those of any other person or organisation, to the interests of the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

7.2.2 ***Data collection tool*** means the instrument or method used to collect data from the participants e.g. questionnaire, interview questions, spreadsheet for collection of medical record information etc.

7.2.3 ***Discomfort*** means a negative accompaniment or effect of research, less serious than harm***.***

7.2.4 ***Ethics Committee*** means the Ethics Committee of The University of Notre Dame Australia established as a Standing Committee under clause 41 of the University's Statutes.

7.2.5 ***HREC sub-committee*** means two or three members of the HREC with expertise relevant to the application, with one internal and one external member (where

possible).

7.2.6 ***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.

7.2.7 ***Primary HREC*** means the HREC who has provided approval for research projects which are not led by the University.

Version	Date of approval	Approved by	Amendment
1	17 April 2019	Vice Chancellor	New Procedure.

8 PROCESS SUMMARY

Process Step	***Responsibility***
Completing the *Application for Cross-Institutional approval of a research project involving Human participants* form.	Chief Investigator
Administrative review of the application and if compliant with this Procedure and the Policy, submit to Research Ethics Officer.	School Research Committee
Administrative review of the application to ensure that all required information has been submitted, there is no indication in the application that the research activity could be in conflict with the Objects of the University, ethics approval letter from Primary HREC is valid and the project qualifies as low risk.	Research Ethics Officer
Chief Investigator will be informed whether Cross-Institutional Approval is granted usually within 5 business days of the Research Ethics Officer receiving the application.	Research Ethics Officer
Research project will be conducted adhering to the conditions of ethics approval.	All researchers named in the ethics application with ultimate responsibility with Chief Investigator