THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Procedure:

Applying for Ethics Approval (Low Risk Review)

Effective: 17 April 2019

Audience: Staff and Students

Policy Category: Academic
Policy Sub-category: Research

Key words:	research, ethics, HREC, human participants
Policy Owner:	Pro Vice Chancellor, Research
Responsible Officer:	Research Ethics Officer
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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 (Low Risk Review)* sets out the procedure to be followed in order to obtain approval for research deemed to be "Low Risk."

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 LOW RISK ETHICAL REVIEW IS REQUIRED

3.1 Where research involves low risk, as defined in the National Statement, a Low Risk Ethical review 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, such as patient health information from a hospital;

3.3.9 The use of secondary data sources or archival materials based on informed consent.

4 APPLYING FOR A LOW RISK ETHICAL REVIEW

4.1 It is the responsibility of the Chief Investigator/Supervisor to apply for a Low Risk ethical review of a research project.

4.2 The applicant must complete the *Low Risk Review Checklist* to determine whether the research project can be classified as low risk, using the National Statement as a guide.

4.3 The Chief Investigator/Supervisor must ensure that the research project aligns with the Objects of the University.

4.4 If the research project is University-led i.e. the Chief Investigator of the project overall is a University researcher, the applicant must complete the *Application for Low Risk Review of a Project Involving Human Participants* form, attaching all relevant documentation which may include, but is not limited to, the Low Risk Review Checklist, a Participant Information Sheet, Consent Form, copy of the data collection tool/s, any other approvals, and submit the completed application to a School Research Committee (SRC) for review.

4.5 If the research project is not University-led i.e. the Chief Investigator of the project overall is not a researcher of the University, and has ethics approval by another NHMRC-registered HREC, the project may be eligible for a Cross-Institutional Ethics Approval.

4.6 A SRC will review 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 for HREC review.

4.7 The Research Ethics Officer will engage in an administrative review of the application to ensure that the research project qualifies for a low risk ethical review, 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 the University.

4.8 In the event that the Research Ethics Officer is of the view that the application does not qualify for Low Risk review, 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.

4.9 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.

4.10 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.

4.11 Once the application is complete in the opinion of the Research Ethics Officer, it will be forwarded to a HREC sub-committee for review to be conducted outside of scheduled HREC meetings.

4.12 The HREC sub-committee will have approximately one week to review the application and form one of the following decisions:

- 4.12.1 Approve the application with no additional requirements.
- 4.12.2 Approve the application on the condition that further information is submitted by the applicant or amendments are made to the project prior to final approval i.e. Conditional approval.
- 4.12.3 If significant issues or risk greater than discomfort is identified, a full ethical review

will be required i.e. Not approved (researcher to submit a full ethical review application).

4.12.4 Decline approval of the application i.e. Not approved.

4.12.5 Refer the application to the University's Ethics Committee if it is considered that the application raises a potential conflict with the University's Objects.

4.13 The HREC will inform the Chief Investigator/Supervisor in writing of the outcome via the Research Ethics Officer, with a copy sent to the SRC Chair and, if a HDR project, the HDR student.

4.14 Where possible, such notification will be made within five business days of the application being sent to the HREC sub-committee.

4.15 The HREC will note that the application has received ethics approval at the next scheduled HREC meeting.

4.16 Where an application is not approved, the HREC sub-committee will ensure that the Chief Investigator/Supervisor is provided with appropriate feedback or advice including whether or not a revised proposal can be submitted to the HREC.

5 CONDITIONS OF APPROVAL

5.1 The project must be conducted in accordance with the approved application, including any conditions and amendments imposed by the HREC and any subsequent conditions that the HREC may require.

5.2 The Chief Investigator/Supervisor must immediately report 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 any aspect of the research project must be applied for using an Amendment application form and approved by the HREC before these may be implemented.

5.4 An Annual Ethics Report for the project must be provided on the anniversary of approval.

5.5 A Final Ethics Report for the project must be provided at the conclusion of the project.

5.6 If, for any reason, the project does not proceed or is discontinued, a Final Report for the project must be provided.

5.7 If an extension is required beyond the end date of the approved project, a request for an extension in an Annual Ethics Report is required.

5.8 Any equipment used must meet current safety standards. Purpose built equipment must be tested and certified by independent experts for compliance with safety standards.

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

5.10 The Chief Investigator must notify the Research Office of any changes in contact details.

5.11 The HREC may conduct random audits and/or require additional reports concerning the research project.

5.12 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 (Cross-Institutional Approval)*
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.

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	November 2018	Vice Chancellor	Updated nomenclature and National guidelines.
4	17 April 2019	Vice Chancellor	Inclusion of cross-institutional approval procedure.

8 PROCESS SUMMARY

Process Step	***Responsibility***
Completing low risk review checklist to determine whether the research project qualifies for a low risk review.	Chief Investigator
Completing low risk review ethics application form and submit to School Research Committee.	Chief Investigator
Preliminary ethical and technical review of ethics application and if compliant with Policy and Procedure submit to Research Ethics Officer.	School Research Committee
Administrative review of ethics 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 and the project qualifies for low risk review. Application forwarded to HREC sub-committee for review.	Research Ethics Officer
Low Risk ethical review of ethics application in accordance with the National Statement and other relevant policies and guidelines.	HREC
Chief Investigator will be informed of the ethics review outcome usually within 5 business days of the HREC sub-committee 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