THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Procedure:

Applying for Ethics Approval (Full Ethical Review)

Effective: December 2022

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
Review Date:	December 2024

Contents

1 PURPOSE

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 process to be followed in order to obtain ethics approval involving a full ethical review from the Human Research Ethics Committee.

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

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 FULL ETHICAL REVIEW IS REQUIRED

3.1 Full ethical review is required for any research project that is not deemed "low risk" in accordance with the National Statement.

3.2 The National Statement (NS) states that a full ethical review by a Human Research Ethics Committee (HREC) is required when research involves the participation of humans or impacts on humans and does not qualify for low risk review. Such research includes, but is not limited to:

3.2.1 Potential for physical pain beyond mild discomfort (NS 2.1).

3.2.2 Potential for psychological distress (NS 2.1).

3.2.3 Identifying people as belonging to a specific group (e.g. racial, sexual, socio-economic), which may expose the person/group to discrimination or misrepresentation (NS 2.1).

3.2.4 Consent which is not entirely voluntary or where participants may be unable or incapable of giving voluntary informed consent (NS 2.2.12).

3.2.5 Concealment, deception, partial disclosure or covert observation (NS 2.3.1, 2.3.2).

3.2.6 Collection or disclosure of personal information in a way that might involve a breach of a National Privacy Principle (as defined by the *Guidelines under Section 95A of the Privacy Act (1988)* (NS 2.3).

3.2.7 Data methodology, such as questionnaires, interviews or surveys, where irrespective of the recording of the individual's identity, it might reasonably be expected that embarrassment, or spiritual harm could be caused to the participants (NS 3.1).

3.2.8 Collecting individual data from databanks/databases where individuals are identifiable (NS 3.1).

3.2.9 Clinical interventions and/or therapies (NS 3.1).

3.2.10 Any physically invasive procedure (e.g. blood or biospecimen collection, exercise regimens or physical examination), and which is not part of ordinary clinical management (NS 3.2).

3.2.11 Collection and use of human biospecimens (NS 3.2).

3.2.12 Human genetics and/or collection and use of human genetic information (NS 3.3).

3.2.13 Animal-to-human xenotransplantation (NS 3.4)

3.2.14 Women who are pregnant and the human foetus (NS 4.1).

3.2.15 Direct contact with children or young people under the age of 18 years (NS 4.2).

3.2.16 People in dependent or unequal relationships (NS 4.3).

3.2.17 People highly dependent on medical care or people unable to give consent (NS 4.4).

3.2.18 People with a cognitive impairment, intellectual disability or mental illness (NS 4.5).

3.2.19 People who may be involved in illegal activities (NS 4.6).

3.2.20 Collecting information, the disclosure of which outside the research could place participants at risk of criminal prosecution or civil liability or be damaging to their financial standing, employability, professional or personal relationships (NS 4.6).

3.2.21 Aboriginal and Torres Strait Islander peoples their data and/or cultural knowledges (NS 4.7).

3.2.22 Conducting research projects in other countries (NS 4.8).

3.2.23 Potential/perceived conflicts of interest for the researcher/s involved (NS 5.6).

3.3 Full ethical review is required for any research project that involves children and/or vulnerable persons. These include:

3.3.1 Children/Young people under 18 years (researchers will have direct contact).

3.3.2 People highly dependent on medical care who may be unable to give consent.

3.3.3 People with a cognitive impairment, intellectual disability or a mental illness.

3.3.4 Aboriginal and/or Torres Strait Islander peoples.

3.3.5 People in other countries (researchers will travel overseas).

4 APPLYING FOR FULL ETHICAL REVIEW

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

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

4.3 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 Full Ethical Review of a Project Involving Human Participants form*, attaching all relevant documentation which may include, but is not limited to, a Participant Information Sheet, Consent Form, copy of the data collection tool/s, other approvals etc. and submit the completed application to Research Ethics Officer.

4.4 If the research project is not a University-led i.e. the Chief Investigator of the project overall is not a University researcher, the applicant can submit the original supporting documentation and approval letter/s to the Research Ethics Officer rather than duplicating information into the University's forms.

4.5 Researchers must submit with their application a Research Data Management Plan (RDMP) as outlined in the *Policy: Research Data Management* and *Procedure: Research Data Management*.

4.6 Researchers must also submit a current WWC Check with their application where the research project involves child related activities and must comply with all working with children requirements imposed as part of their ethics approval.

4.7 The Research Ethics Officer will engage in an administrative review of the application to ensure that 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 If further information is required the Research Ethics Officer will advise the applicant of the further information required in order to progress their application.

4.9 If the research activity may be in conflict with the Objects of the University, the Research Ethics Officer will seek advice from 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; send the application back to the applicant and request an amended application or refer the application to the University Ethics Committee.

4.10 Once the application is complete, in the opinion of the Research Ethics Officer, it will be forwarded to the HREC for review at the next scheduled HREC meeting.

4.11 At the meeting the HREC will conduct a full ethics review of the application in accordance with the National Statement and may:

4.11.1 Approve the application with no additional requirements.

4.11.2 Approve the application on the condition that further information is submitted by the applicant or amendments are made to the proposal prior to final approval i.e. Conditional approval.

4.11.3 Defer the decision to the next scheduled HREC meeting if significant issues are identified which needs to be addressed by the applicant prior to reconsideration by the full HREC i.e. Defer.

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

4.11.5 Refer the application to the University's Ethics Committee if the HREC considers that the application raises a potential conflict with the University's Objects.

4.12 The HREC will inform the Chief Investigator/Principal Supervisor in writing of the outcome via the Research Ethics Officer, with a copy sent to the HDR or other research student.

4.13 Where possible, such notification will be made within seven business days of the HREC meeting.

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

5 CONDITIONS OF ETHICS 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/Principal Supervisor must immediately report anything which might affect ethical acceptance of the research project including:
Adverse effects on participants,

5.2.1. Significant unforeseen events,

5.2.2. If a complaint is made about the conduct of the project,

5.2.3. 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 (Low Risk Review)

6.2 Procedure: Applying for Ethics Approval (Cross-Institutional Approval)

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 Policy: Research Data Management and Procedure: Research Data Management

6.6 NHMRC National Statement on Ethical Conduct in Human Research (2023)

6.7 NHMRC Australian Code for the Responsible Conduct of Research (2018)

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

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

6.10 NHMRC Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)

6.11 AIATSIS Code of ethics for Aboriginal and Torres Strait Islander Research (2020).

6.12 NHMRC Consumer and Community Involvement in Health and Medical Research (2016)

6.13 National Principles for Child Safe Organisations (2019)

6.14 Commonwealth Child Safe Framework (2020)

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 **Child** means an individual(s) under the age of 18 years and Children has a similar meaning.

7.2.2 **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.

7.2.3 **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.

7.2.4 **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** means Human Research Ethics Committee.

7.2.6 **NS** means *National Statement on Ethical Conduct in Human Research.*

7.2.7 **Vulnerable person**[1] means an individual aged 18 years and above who is or may be unable to take care of themselves, or is unable to protect themselves against harm or exploitation by reason of age, illness, trauma or disability, or any other reason.

[1] Australian Government Department of Social Services website

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	January 2019	Vice Chancellor	Updated nomenclature and National guidelines.
4	June 2019	Vice Chancellor	Inclusion of cross-institutional approval procedure.
5	December 2022	Vice Chancellor	Updated to reflect Research Office and Faculty restructure, inclusions of RDMP and child safe requirements.
6	21 August 2023	University Secretary	Administrative update to reference NHMRC National Statement on Ethical Conduct in Human Research (2023).

8 PROCESS SUMMARY

Process Step	***Responsibility***
Complete full review ethics application form and submit to Research Ethics Office.	Chief Investigator /Principal Supervisor
Administrative review of ethics application to ensure that 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. Application forwarded to HREC review at next scheduled meeting.	Research Ethics Officer Research Ethics Officer
Full ethical review of ethics application in accordance with the National Statement and other relevant policies and guidelines.	HREC
Chief Investigator/PS will be informed of the ethics review outcome usually within 7 business days of the HREC meeting.	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 /Principal Supervisor