THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Policy:

Ethics Approval for Research Involving Human Participants

Effective: May 2006

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:	June 2022

Contents

1 OBJECTS OF THE UNIVERSITY

The University's Objects are defined in Section 5 of its Act of Parliament:

The Objects of the University are:

(a) the provision of university education, within a context of Catholic faith and values; and
(b) the provision of an excellent standard of -
    i. teaching, scholarship and research;
    ii. training for the professions; and
    iii. pastoral care for its students.

2 PURPOSE

2.1 This policy, *Ethics Approval for Research Involving Human Participants* ("Policy") has been formulated to ensure appropriate ethics approval of any research involving human participants in which The University of Notre Dame ("University") is involved.

2.2 The requirements for applying for ethics approval outlined in this Policy are intended to ensure that any research involving human participants complies with the requirements of the *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) ("National Statement") and that the welfare and rights of participants in research are protected.

2.3 This Policy must be read in conjunction with the National Statement and any relevant University Policies, Procedures and Guidelines as may apply.

3 SCOPE

This Policy binds all staff, students and University researchers.

4 PRINCIPLES

4.1 Any research involving humans as participants requires ethics approval in accordance with this Policy before the research can be undertaken.

4.2 The need to obtain ethics approval is predicated on the need to protect the welfare and rights of participants in research, the researcher(s), the University and the community in general.

4.3 No research project is to be commenced by a University researcher until the required ethics approval has been obtained.

4.4 Funding for any research involving humans will not be released by the University until the required ethics approval has been granted.

4.5 Research involving humans, for the purposes of this Policy, is research conducted with or about people, or their data or tissue. Human participation in research includes, but is not limited to, the involvement of human beings through:

4.5.1 taking part in surveys, interviews or focus groups;

4.5.2 undergoing psychological, physiological or medical testing or treatment;

4.5.3 being observed by researchers;
4.5.4 researchers accessing their personal documents or other materials;
4.5.5 the collection and use of their biospecimens (e.g. blood, skin, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
4.5.6 access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing or unpublished source or database.

4.6 Research that does not directly involve humans but can impact upon them also requires ethics approval. Examples of this includes, but is not limited to,
4.6.1 human remains or cell lines (where the remains can be directly linked to living humans either on a direct familial or significant cultural basis);
4.6.2 sites of community, cultural, historical or religious significance to a definable group of humans; and
4.6.3 findings which have a direct and significant impact upon the personal or professional affairs of a definable group of humans.

5 CATEGORIES OF ETHICS REVIEW

5.1 The University has established four categories of ethics approval, taking into consideration the type of research and the degree of risk involved in the research, as follows:
5.1.1 Course Clearance: Ethics approval which may be provided by a School Research Committee for University courses where data will be collected from human participants by students as part of the teaching or assessment.
5.1.2 Low Risk Ethics approval: Ethics approval which may be provided by a sub-committee of the HREC for research projects which can be categorised as low risk research.
5.1.3 Cross-Institutional Approval: Approval which may be provided by the Research Ethics Officer for research projects with ethics approval from another NHMRC-registered HREC and categorised as low risk research.
5.1.4 Full Review Ethics approval: Ethics approval which must be provided by the full HREC for research projects which cannot be categorised as low risk.

5.2 Guidelines as to which category of ethics approval is required and the procedures for applying for each type of ethics approval are set out in the following documents as amended from time to time:
5.2.1 *Procedure: Applying for Ethics Approval of a Course (Course Clearance*);
5.2.2 *Procedure: Applying for Ethics Approval (Low Risk Review)*;
5.2.3 *Procedure: Applying for Ethics Approval (Cross-Institutional Approval)*, and
5.2.4 *Procedure: Applying for Ethics Approval (Full Ethical Review)*.

5.3 If a University researcher is unsure as to which category of ethics approval is required for their research project the Research Ethics Officer should be contacted for clarification.

5.4 If a research project involves multiple institutions, HREC approval is required from all institutions involved. Research cannot commence until HREC approval is received from all institutions involved. Researchers must provide a copy of each HREC approval letter to the Research Ethics Officer.

5.5 Health research involving Aboriginal and Torres Strait Islander peoples and communities must have approval from the relevant state-based Aboriginal-specific HREC (e.g. W.A Aboriginal Health Ethics Committee, Aboriginal Health and Medical Research Council of NSW). Approval must be obtained prior to submitting an ethics application to the University's HREC.

5.6 If a research project involves multiple institutions and has HREC approval(s) from other institution(s), the University researcher is still required to obtain ethics approval from the University's HREC prior to the University's involvement in the research. For research not qualifying for Cross-Institutional approval, original supporting documentation and approval letter/s can be submitted, rather than duplicating information into the University's forms.

5.7 Where external researchers (i.e. no University researcher is involved) seek to recruit University staff or students as potential research participants, permission is required from the Dean of the school, if potential participants are school-specific, or the Head of Campus, if potential participants are Campus-specific. Researchers must provide evidence of HREC approval from the institution where the research originates.

6 ROLES AND RESPONSIBILITIES

6.1 Responsibilities of University of Notre Dame Australia

6.1.1 The Pro Vice Chancellor, Research is responsible for the University's overall governance with respect to ethics approval for research involving human participants.

6.1.2 The University must ensure and promote that research involving human participants complies with the following national and state based legislation:

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

6.1.2.2 *Australian Code for the Responsible Conduct of Research* (2018),

6.1.2.3 Guidelines under Section 95A of the *Privacy Act* (1988),

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

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

6.1.2.6 *Guidelines for Ethical Research in Australian Indigenous Studies* (2012)

6.1.2.7 Other codes, policies and legislation, where relevant.

6.1.3 The University must ensure that these documents are available and promoted to all University researchers.

6.1.4 The Research Ethics Officer is responsible for ensuring that the university HREC is registered with the NHMRC and that annual reports are submitted to the NHMRC, as required.

6.1.5 The Research Ethics Officer is responsible for the monitoring of approved research projects with the support and assistance of the HREC.

6.2 Responsibilities of University Researchers

6.2.1 The end date of the approved project is 3 years from the HREC approval date.

6.2.2 The project must be conducted in accordance with the approved application, including any conditions and amendments imposed by the HREC.

6.2.3 Researchers must comply with the Standard Conditions of Approval as outlined in *Procedure: Applying for Ethics Approval (Full Ethics review)* and *Procedure: Applying for Ethics Approval (Low Risk Review)* and *Procedure: Applying for Ethics Approval (Cross-Institutional Approval).*

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

7 RELATED DOCUMENTS

7.1 *Policy: Responsible Conduct for Research*
7.2 *Procedure: Applying for Ethics Approval (Low Risk Review)*
7.3 *Procedure: Applying for Ethics Approval (Cross-Institutional Approval)*
7.4 *Procedure: Applying for Ethics Approval (Full Ethical Review)*
7.5 *Procedure: Applying for Ethics Approval (Course Clearance)*
7.6 *Guideline: Participant Information Sheet and Consent Form for Research involving Human Participants*
7.7 *National Statement on Ethical Conduct in Research Involving Humans (2007, updated 2018)*
7.8 *Australian Code for the Responsible Conduct of Research (2018)*
7.9 *Guidelines under Section 95A of the Privacy Act (1988)*
7.10 *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)*
7.11 *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)*
7.12 *Guidelines for Ethical Research in Australian Indigenous Studies (2012)*

8 DEFINITIONS

For the purpose of this Policy, the following definitions apply*:*

Adverse Effects means a clinical sign, symptom or condition that is causally related to the procedure, task or activity conducted on or with human participants.
Chief Investigator/Supervisor means the University researcher who is named as a Lead Investigator in relation to the research project that requires ethics approval, or if no University researcher is named as a Lead Investigator, then the University researcher who will be responsible for supervising the component of the research project in which the University will be involved.
Code means the *Australian Code for the Responsible Conduct of Research* (2018).
Discomfort means a negative accompaniment or effect of research, less serious than harm.
HREC means the Human Research Ethics Committee of the University.
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.
Multi-centre research means a research project conducted jointly by researchers affiliated with different institutions or a research project conducted by a University researcher who is also affiliated with another institution.
National Statement means the *National Statement on Ethical Conduct in Research Involving Humans* (2007, updated 2018).
NHMRC means the National Health and Medical Research Council.
Participant means anyone who is the subject of research in any of the ways set out in the National Statement section Purpose, Scope and Limits of this Document.
Pro Vice Chancellor, Research means the person who holds the position of Pro Vice Chancellor,

Research.

Research means an original investigation undertaken to gain knowledge, understanding and insight (as defined in the Code).

Research Ethics Officer means the person who holds the position of Research Ethics Officer at the University.

Research Office means the Research Office at the University.

SRC means a School Research Committee at the University.

University Researcher means any staff member or student who conducts research on behalf of or under the auspices of the University of Notre Dame Australia.

Version	Date of approval	Approved by	Amendment
1	May 2006	Vice Chancellor	New Policy.
2	June 2007	Vice Chancellor	Minor changes to Principles.
3	May 2009	Vice Chancellor	Updated nomenclature.
4	July 2012	Vice Chancellor	Updated nomenclature.
5	December 2012	Vice Chancellor	Introduction of new low risk and cross-institutional review procedure.
6	September 2017	Vice Chancellor	Updated nomenclature.
7	January 2019	Vice Chancellor	Updated nomenclature and National guidelines, updated Policy template.
8	17 April 2019	Vice Chancellor	Inclusion of Cross-Institutional approval procedure.