



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

Policy:

Human Research Ethics

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1 OBJECTS OF THE UNIVERSITY

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

- (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 sets out the requirements for ethical review, approval, conduct and oversight of human research conducted under the auspices of the University of Notre Dame Australia (the University), enabling the University to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2025)* (the *National Statement*), the *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* (the *AIATSIS Code*), and the *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia*, as well as ensuring that human research conducted at the University is consistent with the Objects of the University.
- 2.2** This Policy supports the *Australian Code for the Responsible Conduct of Research (2018)* and the University's *Code of Conduct: Research* and the *Procedure: Managing Potential Breaches of the Code of Conduct: Research* by providing monitoring and oversight mechanisms for human research conducted under the auspices of the University, as well as referrals for research integrity breach investigations.

3 SCOPE

- 3.1** The scope of this Policy applies to human research, as defined in the *National Statement on Ethical Conduct in Human Research (2025)*.
- 3.2** It sets out the different processes by which human research conducted under the auspices of the University is reviewed and/or authorised or exempted from review and the role of the NHMRC registered University Human Research Ethics Committee (Notre Dame HREC).
- 3.3** Applies to any person (or persons) who conducts, assists or is involved with the conduct of human research under the auspices of the University of Notre Dame and may include:
 - 3.3.1 employees of the University who are employed under any type of employment contract
 - 3.3.2 persons who hold an adjunct, clinical academic or visiting appointment
 - 3.3.3 students enrolled in any program or course at the University
 - 3.3.4 honorary and emeritus title holders
 - 3.3.5 visiting students
 - 3.3.6 volunteers and occupational trainees
 - 3.3.7 all persons who have received, or who have purported to receive, an Ethics Approval, External Ethics Authorisation, or Ethics Review Exemption from a Notre Dame HREC
 - 3.3.8 all current and former supervisors of students of the University who are engaged in human research, and

4 PRINCIPLES

- 4.1** The University is committed to fostering a robust research culture that promotes ethical research, research integrity and respect for the dignity of the human person.
- 4.2** The University is committed to ensuring that all risks associated with human research are identified, assessed and managed in a proportionate manner to ensure the welfare, rights, dignity, safety and wellbeing of participants are protected, and that risks to researchers, the University and other affected parties are appropriately mitigated throughout the research lifecycle.
- 4.3** The University recognises the rights of Indigenous peoples to control the use of their data, wherever it is held, as well as the importance of access to data for Indigenous decision making and self-determination and is committed to ensuring cultural safety for Aboriginal and Torres Strait Islander communities, organisations and people who are involved in Indigenous human research activities at the University, whether as participants, researchers, partners in the research, stakeholders or as Notre Dame HREC members.
- 4.4** The University is committed to ensuring that health and medical human research adequately takes account of consumer and community perspectives, and references, where relevant, the NHMRC's *Statement on Consumer and Community Involvement in Health and Medical Research (2016)* and *Toolkit for Consumer and Community Involvement in Health and Medical Research (2020)*.
- 4.5 The University will**
 - 4.5.1 establish systems and processes to manage adherence to applicable codes, policies and guidelines for all human research, including processes for ethics review
 - 4.5.2 promote human research that is reviewed and conducted responsibly, ethically, legally, and in a manner that respects the dignity of the human person and protects their welfare, rights and cultural knowledges
 - 4.5.3 ensure human research meets relevant scholarly or scientific standards, and that those conducting human research are either adequately experienced and qualified or adequately supervised
 - 4.5.4 ensure that the review processes of Notre Dame HRECs incorporate the provision of specialist expertise in relation to Indigenous human research as required by the *National Statement*
 - 4.5.5 maintain, train and adequately resource Notre Dame HRECs registered with the NHMRC and sub-committees of the Notre Dame HRECs to conduct human ethics reviews according to the National Statement requirements, and
 - 4.5.6 provide training for researchers undertaking human research, including cultural safety training where relevant.
- 4.6 Researchers must ensure that**
 - 4.6.1 they evidence completion of human research ethics training and research integrity training when submitting applications to a Notre Dame HREC
 - 4.6.2 the ethics principles of research merit and integrity, justice, beneficence and respect are applied to human research as set out in the *National Statement*

- 4.6.3 relevant approvals, authorisations or exemptions to conduct human research are obtained prior to the commencement of human research. Retrospective ethics approval will not be considered as it is not permitted under the *National Statement*
- 4.6.4 all other required processes, institutional approvals or authorisations, are completed or granted prior to the commencement of human research
- 4.6.5 conditions of any approvals are adhered to throughout the conduct of the research
- 4.6.6 engagement with participants, communities, stakeholders and/or consumers related to their human research is appropriate, respects the dignity of the human person, and is culturally safe, and
- 4.6.7 they positively engage with ethics review, monitoring and research integrity processes.

5 ETHICS APPROVALS, AUTHORISATIONS, EXEMPTIONS, PERMISSIONS

- 5.1 All human research proposals must be submitted to the University's research ethics application process for review via one of the pathways outlined in the *Procedure: Human Research Ethics*.
- 5.2 Human research must not commence under the auspices of the University until ethics review has been completed and approval and/or authorisation or exemption is in place.
- 5.3 Funding for any human research will not be released by the University until the required ethics approvals and/or authorisations or exemptions have been granted.
- 5.4 The University is committed to proportionate review of applications by reference to the risk profile of the research and requirements of the *National Statement*.
- 5.5 External researchers requesting access to staff and students of the University as research participants must follow the process outlined in the *Procedure: Human Research Ethics*.

6 HREC MONITORING AND HREC AUDITS

- 6.1 The University and the Notre Dame HRECs are responsible for the monitoring and auditing of human research conducted under the auspices of the University and will monitor and report on human research for which it has provided ethical approval in a variety of ways, including but not limited to annual and final progress reporting.
- 6.2 Notre Dame HRECs have the discretion to conduct audits of human research projects (HREC Audits) in relation to all human research conducted under the auspices of the University at any time.

7 COMPLIANCE AND BREACHES

- 7.1 Alleged breaches of this Policy, non-compliance by a researcher or complaints in relation to the University ethics processes will be managed in accordance with the *Procedure: Managing and Investigating Breaches of the Code of Conduct: Research*.

8 ROLES AND RESPONSIBILITIES

- 8.1 The Pro Vice Chancellor Research (or delegate) is responsible for:
 - 8.1.1 maintaining a culture of research integrity and upholding responsible research conduct
 - 8.1.2 upholding research integrity related obligations in accordance with the University's

Legislative Compliance Register

- 8.1.3 resourcing of the Notre Dame HRECs, in accordance with the HREC Charter, and their operational compliance with the *National Statement*
- 8.1.4 an annual summary of human research activities, operations (including the operations of the Notre Dame HRECs) and governance, reported to the University Research Committee and Academic Council, and
- 8.1.5 recommending to the University Research Committee, the establishment and maintenance of at least one Notre Dame HREC registered with the NHMRC
 - 8.1.5.1 a decision to establish additional Notre Dame HRECs will be made on the basis of resourcing needs and with the advice of the Notre Dame HREC Chairs, and
 - 8.1.5.2 where multiple Notre Dame HRECs are established, the Pro Vice Chancellor Research (or delegate) is responsible for ensuring that these committees operate consistently and equivalently in parallel.
- 8.2 The responsibilities of the Notre Dame HREC are as set out in the HREC Charter.
- 8.3 The Director Research Services (or delegate) is responsible for ensuring that:
 - 8.3.1 the Notre Dame HRECs maintain registration with the NHMRC and that NHMRC reporting obligations are complied with, including annual NHMRC reporting
 - 8.3.2 the content required to be made public under the *National Statement* is made available
 - 8.3.3 complaint and appeals mechanisms (both anonymous and otherwise) are in place and available
 - 8.3.4 an appropriate training offering is provided to Notre Dame researchers and Notre Dame HREC members
 - 8.3.5 all applications for ethics review are reviewed, tracked and recorded in an applications register, and stored in compliance with University policy and procedure
 - 8.3.6 supporting HREC Audits, as set out in the *Procedure: Human Research Ethics*; and
 - 8.3.7 reviewing complaints and concerns and ensuring these are dealt with in accordance with the *Code of Conduct: Research* and the *Procedure: Managing Potential Breaches of the Code of Conduct: Research*.
- 8.4 Notre Dame researchers have responsibilities as set out in this Policy and in the *Procedure: Human Research Ethics*, as well as under the related *Code of Conduct: Research* and *Procedure: Managing Potential Breaches of the Code of Conduct: Research*.

9 RELATED DOCUMENTS

- 9.1 University policies and procedures
 - 9.1.1 *Procedure: Human Research Ethics*
 - 9.1.2 *Code of Conduct: Research*
 - 9.1.3 *Procedure: Managing Potential Breaches of the Code of Conduct: Research*
 - 9.1.4 *Policy: Research Data Management*
 - 9.1.5 *Procedure: Research Data Management*
 - 9.1.6 *Policy: Higher Degree by Research Supervision*

- 9.1.7 *Procedure: Higher Degree by Research Supervision*
- 9.1.8 *Procedure: Conflict of Interest*
- 9.1.9 *Procedure: Chemical Management*
- 9.1.10 *Procedure: Handling Human Biological Materials*
- 9.1.11 *Policy: Protecting Children*
- 9.1.12 *Procedure: Legislative Obligations – Working with Children Checks*
- 9.1.13 *Procedure: Protecting Children, Reporting Concerning Behaviour, and the Western Australian Reportable Conduct Scheme*
- 9.1.14 *Legislative Compliance Register*

9.2 National codes and standards

- 9.2.1 NHMRC, ARC & UA, *NHMRC National Statement on Ethical Conduct in Human Research (2025)*
- 9.2.2 NHMRC, ARC & UA, *Australian Code for the Responsible Conduct of Research (2018)*
- 9.2.3 NHMRC, *Guidelines under Section 95 of the Privacy Act 1988 (Cth) (2024)*
- 9.2.4 NHMRC, *Guidelines under Section 95A of the Privacy Act (1988) 1988 (Cth) (2024)*
- 9.2.5 Catholic Health Australia, *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)*
- 9.2.6 AIATSIS, *AIATSIS Code of ethics for Aboriginal and Torres Strait Islander Research (2020)*
- 9.2.7 AIATSIS, *A Guide to Applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*
- 9.2.8 NHMRC, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)*
- 9.2.9 NHMRC, *Keeping Research on Track II (2018)*
- 9.2.10 NHMRC, *Consumer and Community Involvement in Health and Medical Research (2016)*
- 9.2.11 NHMRC, *Toolkit for Consumer and Community Involvement in Health and Medical Research (2020)*
- 9.2.12 NHMRC, *Ethical Considerations in Quality Assurance and Evaluation Activities (2014)*
- 9.2.13 *National Principles for Child Safe Organisations (2019)*
- 9.2.14 *Commonwealth Child Safe Framework (2020)*

10 DEFINITIONS

- 10.1** For the purpose of this Policy, the *Procedure: Human Research Ethics*, and the *Human Research Ethics Committees: Charter*, the following definitions apply:

AIATSIS means the Australian Institute of Aboriginal and Torres Strait Islander Studies.

AIATSIS Code means the AIATSIS, *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*.

Consumer means patients and potential patients, carers, and people use health care services.

Ethics approval (not capitalised) means the successful outcome of an application for ethics

review by an external ethics review body.

Ethics Approval (*capitalised*) means the successful outcome of an application for ethics review via the Ethics Approval process.

Ethics review means the process by which human research is reviewed.

Ethics review processes means the processes by which human research is reviewed. There are three (3) ethics review processes at the University: the Ethics Approval process, the External Ethics Authorisation process (formerly named the Cross-Institutional Approvals process), and the Ethics Review Exemption process.

Ethics Review Exemption (*capitalised*) means the successful outcome of an application for ethics review via the Ethics Approval process.

External means external to the University.

External Ethics Authorisation (*capitalised*) means the successful outcome of an application for ethics review via the External Ethics Authorisation process (formerly named the Cross-Institutional Approvals process).

Full committee review means review by a Notre Dame HREC at a meeting. It is a review by the *full* committee, in contrast to review by a subcommittee

Funding means financial support, in-kind support, per capita payments or other payments or incentives provided by any entity supporting the research.

Human Research means the definition as set out in the *National Statement*.

HREC Audit means an audit of a human research project conducted in accordance with the requirements set out in the *Procedure: Human Research Ethics* and the Charter.

HREC Process Audit means a procedural fairness review of the process by which an application for ethics review was considered and determined.

Indigenous Human Research means human research that includes, but is not limited to, the following: the research is focused on a topic identified as being of specific benefit for, or identified as a priority by, Aboriginal and Torres Strait Islander people and communities; the research cohort (either through targeted, likely/foreseeable or incidental recruitment) has a significant proportion of Aboriginal and Torres Strait Islander people; the geographic location or recruitment strategy of the research is such that a significant number or proportion of the population is likely to be Aboriginal and Torres Strait Islander people and communities; the data gathered in the research will include analysis that specifically identifies Aboriginal and Torres Strait Islander people and communities; the research outcomes will have a specific impact on Aboriginal and Torres Strait Islander people and communities.

Low risk subcommittee review means a review conducted by a subcommittee of a Notre Dame HREC, formed in compliance with the conditions set out in the Charter.

National Statement means the NHRMRC, ARC & UA, *National Statement on Ethical Conduct in Research Involving Humans* (2025).

NHMRC means the National Health and Medical Research Council.

Notre Dame HREC means a Human Research Ethics Committee of the University that has been registered with the NHMRC.

Participant means anyone who is the subject of research in any of the ways set out in the *National Statement*.

Research means the definition of “research” in the *National Statement*.

The Charter means the *Human Research Ethics Committees: Charter*.

Version	Date of approval	Approved by	Amendment
1	7 Oct 2026	Vice Chancellor	Effective date - New Policy to replace <i>Policy: Ethics Approval for Research Involving Human Participants</i> .