POLICY:
ETHICS APPROVAL FOR RESEARCH INVOLVING HUMANS

Purpose: To outline the University’s policy and procedure for ethics approval in relation to research involving humans.

Responsible Executive: Pro-Vice Chancellor, Research
Responsible Office: Research Office, Fremantle/Broome & Sydney
Contact Officer: Ethics Officer
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1 Introduction and purpose

1.1 This policy *Ethics Approval for Approval of Research Involving Humans* (“Policy”) has been formulated to ensure appropriate ethics clearance of any research involving humans in which The University of Notre Dame (“UNDA”) is involved.

1.2 The requirements for applying for ethics approval outlined in this Policy are intended to ensure that any research involving humans complies with the requirements of the *National Statement on Ethical Conduct in Human Research* (“National Statement”) and that the welfare and rights of participants in research are protected.

1.3 This Policy must be read in conjunction with:
   1.3.1 the National Statement; and
   1.3.2 any relevant UNDA policies, procedures and guidelines as may apply from time to time.

2 Definitions

For the purposes of this Policy:

2.1 **Ethics Officer** means the person who holds the position of Ethics Officer at UNDA from time to time;

2.2 **HREC** means Human Research Ethics Committee of UNDA;

2.3 **National Statement** means the *National Statement on Ethical Conduct in Research Involving Humans* (2007) published by the NHMRC;

2.4 **NHMRC** means the National Health and Medical Research Council;

2.5 **Pro Vice Chancellor Research** means the person who holds the position of Pro Vice Chancellor Research at UNDA from time to time;

2.6 **Research Office** means the UNDA Research Office;

2.7 **SRC** means one of the School Research Committees of UNDA;

2.8 **UNDA** means The University of Notre Dame Australia;

2.9 **UNDA researcher** means any person, including but not limited to, UNDA staff and students, who wishes to carry out research on behalf of, or under the auspices of, UNDA or as part of their role or studies with UNDA.

3 General Principles

3.1 Any research involving humans requires ethics approval in accordance with this Policy before the research can be undertaken.
3.2 The need to obtain ethics clearance 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.

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

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

3.5 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:

3.5.1 taking part in surveys, interviews or focus groups;
3.5.2 undergoing psychological, physiological, or medical testing;
3.5.3 being observed by researchers;
3.5.4 allowing researchers access to their personal documents or other materials;
3.5.5 the collection and use of their body organs, tissues or fluids (e.g. blood, skin, urine, saliva, hair, bones tumour and other biopsy specimens) or their exhaled breath;
3.5.6 allowing access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing or unpublished source or database.

3.6 Research that does not directly involve humans but can impact upon them also requires ethics approval. Examples of this may include research involving:

3.6.1 human remains (where the remains can be directly linked to living humans either on a direct familial or significant cultural basis);
3.6.2 sites of community, cultural, historical or religious significance to a definable group of humans; and
3.6.3 findings which have a direct and significant impact upon the personal or professional affairs of a definable group of humans.

3.7 Although some research may not initially require ethics approval, any change in the use of the data for a broader or different purpose may result in ethics clearance later being required. It is the responsibility of the UNDA researcher to ensure that any such changes are notified to the HREC using the form Request for an Amendment to an Approved Research Project and, if appropriate, the relevant procedure for obtaining clearance is followed.

4 Categories of ethics approval

4.1 UNDA has established three categories of ethics approval, taking into consideration the type of research and the degree of risk involved in the research, as follows:

4.1.1 Unit Clearance - Ethics approval which may be provided by an SRC for unit-based research projects.

4.1.2 Low Risk Ethics Clearance – Ethics approval which may be provided by a sub-committee of the HREC for research projects which can be categorised as low risk.

4.1.3 Full Review Ethics Clearance – Ethics approval which must be provided by the full HREC for research projects which cannot be categorised as low risk.
4.2 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:

4.2.1 Guideline: Applying for Ethical Approval of a Unit (Unit Clearance);
4.2.2 Guideline: Applying for Ethics Approval (Low Risk Clearance); and
4.2.3 Guideline: Applying for Ethics Approval (Full Ethical Review).

4.3 If a UNDA researcher is unsure as to which category of ethics approval is required for their research project the Ethics Officer should be approached for clarification.

4.4 Cross-institutional recognition of ethics approval from an HREC of a Catholic institution may be granted on a case-by-case basis. Original supporting documentation and cross-institutional HREC approval must be submitted to the Senior Deputy Vice Chancellor via the Ethics Officer.

5 Responsibility for providing ethics approval

5.1 Ethics approval is provided by the HREC, an HREC sub-committee, an SRC or Ethics Officer in accordance with the Guidelines set out in clause 4.2 above, depending on the type of approval required.

5.2 In assessing applications the following principles are to be applied by the person or body responsible for providing ethics approval:

5.2.1 Research involving human participants must meet established ethical, professional and cultural norms;

5.2.2 In every piece of research involving human interventions there must be a balance between the cost of the human interventions to those participating in them (e.g. in terms of discomfort, personal risk, loss of privacy or other sort of harm) and the value to be achieved by carrying out the research; and

5.2.3 Core principles with regard to the protection of participants are: integrity, including respect for persons, beneficence and justice; consent; research merit and safety.

5.3 In addition, the person or body carrying out the assessment must comply with any relevant requirements or considerations as may be contained in other documents such as Terms of Reference, Duty Statements, information documents or guides, regulations, policies and procedures.

6 Conditions of ethics approval

Ethics approval is granted on the basis of a number of conditions. It is important that UNDA researchers are familiar with, and abide by, these conditions:

6.1 Any serious or unexpected adverse effects on research participants must be reported immediately to the Research Office;

6.2 Any unforeseen events which might affect the continued ethical acceptability of the research project must be reported immediately to the Research Office;

6.3 The HREC must be notified of, and approve, any amendments to the original protocol, including but not limited to, changes to the membership of the research team, the research design or methodology, research tools, or research participants' recruitment method (such changes to be notified by submission of a Request for Amendment to Approved Research Project form); and
6.4 An annual report is required to be submitted to the Research Office on the anniversary of ethics approval and a final report to be submitted upon research completion.

7 Research involving children

Where a research project involved the participation of children under the age of 18 years, or the use of data relating to children, a Research Involving Children form must be attached to the application for ethics approval.

8 Research involving other organisations

8.1 Where the assistance or agreement of another organisation is required to undertake the research project involving humans, the appropriate written permission is required to access staff, clients or other information of that organisation.

8.2 Where external research involves UNDA staff or students, written permission of the HREC is required for the research to occur, irrespective of whether or not approval has been granted by the institution where the research originates.

9 Other Policies and Documents

National Statement on Ethical Conduct in Research Involving Humans (2007)

Australian Code for the Responsible Conduct of Research

Guideline: Applying for Ethics Approval (Low Risk Clearance)

Guideline: Applying for Ethics Approval (Full Ethical Review)

Guideline: Application for Ethical review of a Unit

Application for Low Risk Review of a Project Involving Human Participants

Application for Full Review of a Project Involving Human Participants

Policy: Monitoring of Approved Research Projects