GUIDELINE:
APPLYING FOR ETHICS APPROVAL (FULL ETHICAL REVIEW)

Purpose:	To outline the requirements and procedure for obtaining a Full ethical review for research involving humans
Responsible Executive:	PVC – Research
Responsible Office:	Research Office
Contact Officer:	Ethics Officer
Effective Date:	1 January 2013
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1 Introduction and purpose

1.1 The University of Notre Dame Australia (UNDA) requires anyone undertaking research involving humans, as defined in the *Policy: Ethics Approval for Research Involving Humans* ("Policy"), to obtain ethics approval.

1.2 UNDA has established three 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 *Guideline: Applying for Ethics Approval (Full Ethical Review)* ("Guideline") sets out the procedure to be followed in order to obtain a Full Ethical Clearance.

1.4 This Guideline must be read in conjunction with any relevant University policies, procedures and other guidelines as may apply from time to time.

2 Definitions

For the purposes of this Policy:

2.1 **Chief Investigator/Supervisor** means the UNDA researcher who is named as a Lead Investigator in relation to the research project that requires ethics approval, or if no UNDA researcher is named as a Lead Investigator, then the UNDA researcher who will be responsible for supervising the component of the research project in which UNDA will be involved.

2.2 **Ethics Committee** means the Ethics Committee of The University Of Notre Dame Australia established as a Standing Committee under clause 38 of the University's Statutes;

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

2.4 **HREC** means the Human Research Ethics Committee of UNDA or of another institution as the context requires;

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

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

2.7 **Policy** means the *Policy: Ethics Approval for Research Involving Humans*;

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

2.9 **Research Office** means the UNDA Research Office;

2.10 **SRC** means a School Research Committee of UNDA;

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

2.12 **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 When is a Full ethical review required?

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

3.2 The National Statement states that full ethical review by an HREC is required when research involves the participation of humans or impacts on humans and which does not qualify for low risk clearance including, but not limited to, research which involves:

- 3.2.1 the use of Databanks where individuals are identifiable (NS 3.2);
- 3.2.2 interventions and therapies (e.g. psychological interventions or clinical therapies) (NS 3.3);
- 3.2.3 any physically invasive procedure (e.g. blood or body fluid collection, exercise regimens or physical examination), and which is not part of ordinary clinical management (NS 3.3);
- 3.2.4 the use of human tissue samples (NS 3.4);
- 3.2.5 Human Genetics or human genetic samples (NS 3.5);
- 3.2.6 the use of Human stem cells (NS 3.6);
- 3.2.7 women who are pregnant (NS 4.1);
- 3.2.8 the human foetus (NS 4.1);
- 3.2.9 children or young people (NS 4.2) other than in normal school activities research;
- 3.2.10 people in dependent or unequal relationships (NS 4.3);
- 3.2.11 people highly dependent on medical care or people unable to give consent (NS 4.4);
- 3.2.12 people with a cognitive impairment, intellectual disability or mental illness (NS 4.5);
- 3.2.13 people who may be involved in illegal activities (NS 4.6);
- 3.2.14 Aboriginal and Torres Strait Islander people (NS 4.7);
- 3.2.15 the conduct of research in other countries (NS 4.8);
- 3.2.16 potentially sensitive or contentious issues (e.g. NS 2.1.5, 2.1.8);
- 3.2.17 placing undue pressure or coercion on participants (NS 2.2.9);
- 3.2.18 consent which is not entirely voluntary or where participants may be unable or incapable of giving voluntary informed consent (NS 2.2.12);
- 3.2.19 concealment, deception, partial disclosure or covert observation (NS 2.3.1, 2.3.2);
- 3.2.20 the collection or disclosure of personal information in a way that might involve a breach of a National Privacy Principle (as defined by the Commonwealth Privacy Act 1988);
- 3.2.21 any payment, gift or inducement, other than a reasonable reimbursement of participants for their participation (NS 2.2.10, 2.2.11);
- 3.2.22 identifying people as belonging to a specific group (e.g. racial, sexual, socio-economic) *and* which may expose the person/group to discrimination or misrepresentation (NS 2.1);

3.2.23 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);

3.2.24 utilising any form of passive consent (NS 2.3.1);

3.2.25 collecting, using or disclosing information which may identify individuals but which is collected or used without their consent i.e. a waiver of consent is required (NS 2.3.5 – 2.3.8);

3.2.26 possible conflicts of interest e.g. a researcher is a member of or has a previous association with an organisation being studied; or a researcher has or has previously had the illness or condition being studied (NS 5.4);

3.2.27 techniques such as questionnaires, interviews or surveys, where irrespective of the recording of the individual's identity, it might reasonably be expected that embarrassment, or psychological or spiritual harm could be caused to the participants (NS 3.1) ; and

3.2.28 causing or being likely to cause physical pain beyond mild discomfort (NS 1.6 – 1.9).

4 Procedure for applying for a Full Ethical review

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

4.2 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 Plain Language Statement, consent form, copy of survey/ questionnaire, other approvals etc) and submit the completed application to the SRC for review.

4.3 An SRC will review the application and, if it considers the application to be compliant with this Guideline and the Policy, will forward the full application to the Ethics Officer for review by the HREC.

4.4 The Ethics Officer will engage in an administrative review of the application to ensure that all required information has been submitted for the application to be considered by the HREC. If further information is required the Ethics Officer will advise the applicant of the further information required in order to progress their application.

4.5 Once the application is complete in the opinion of the Ethics Officer, it will be forwarded to the HREC.

4.6 On receipt of an application the HREC will, where possible and provided that the application contains all necessary information, ensure that the application is added it to the agenda for the next HREC meeting.

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

4.7.1 Approve the application for ethics clearance;

4.7.2 Provide ethics clearance on the condition that further information is submitted by the applicant or minor modifications are made to the project (in which case the project must be deferred until the applicant is advised that the clearance has become unconditional);

4.7.3 If significant issues are identified, require reconsideration of the application by the HREC once the issues have been addressed;

4.7.4 Refuse to approve the application for ethical clearance (although the researcher may be invited to resubmit once the application / project has been completely revised); or

4.7.5 Refer the application to the Ethics Committee if it considers that the application raises a potential conflict with the University's Objects

4.8 The HREC will then inform the SRC and the applicant in writing of the outcome. Where possible such notification will be made within five (5) business days of the HREC's decision.

4.9 Where an application is not approved, the HREC should ensure that the applicant is given appropriate feedback or advice including whether or not a revised proposal can be submitted to the HREC.

5 Other Policies and Documents

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

Australian Code for the Responsible Conduct of Research

Policy: Ethics Approval for Research Involving Humans

Guideline: Applying for Ethics Approval (Low Risk Clearance)

Application for Low Risk Review of a Project Involving Human Participants

Application for Full Review of a Project Involving Human Participants