POLICY:

Human Ethics and Animal Ethics:
Monitoring of approved research.

Purpose: This document outlines the University’s policy on monitoring of approved research projects involving human participants and/or animals.

Responsible Executive: Deputy Vice-Chancellor Research & Quality
Responsible Officer: Research Office
Contact Officer: Ethics Officer
Effective Date: 20 July 2011
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POLICY: MONITORING OF APPROVED RESEARCH PROJECTS

**1. Definitions**

1.1 “the AEC” means the Animal Ethics Committee of Murdoch University;

1.2 “application” means any application made by a researcher to the HREC for approval of a research project;

1.3 “the Code” means the *NHMRC Code of Practice for the Care and Use of Animals for Scientific Purposes* as amended from time to time;

1.4 "the National Statement” means the *NHMRC National Statement on Ethical Conduct in Human Research* as amended from time to time;

1.5 "the University" means The University of Notre Dame Australia;

1.6 “the HREC” means the Human Research Ethics Committee of the University of Notre Dame Australia.

**2. Principles**

2.1 The *NHMRC National Statement on Ethical Conduct in Human Research* is the foundation document informing research involving humans at the University.

2.2 The *NHMRC Code of Practice for the Care and Use of Animals for Scientific Purposes* is the foundation document informing research involving animals at the University.

2.3 The National Statement and the Code require that there is appropriate monitoring of the conduct of all approved ongoing research until completion.

2.4 Monitoring of approved research projects is carried out to ensure that the research project is being or has been conducted in the manner proposed to, and approved by, the HREC and/or AEC in order to ensure that the welfare and rights of the research participants and/or animals are adequately protected.

**3. Conditions of HREC approval**

3.1 Compliance by researchers with the monitoring requirements set out in this policy and any additional monitoring requirements imposed by the HREC and/or AEC is a condition of approval to undertake research under the auspices of the University.

3.2 All research projects must be conducted in accordance with the approved application, including any conditions imposed by the HREC and/or AEC from time to time and any approved amendments.
3.3 Any researcher involved in a research project at the University which has ethics approval must immediately report to the Ethics Officer anything that may warrant a review of the ethical approval of the research project, including, but not limited to, any:

(a) adverse events affecting research participants;
(b) significant unforeseen events which affect the carrying out of the research project; and
(c) any other matters that may affect continued ethical acceptability of the research project.

3.4 If the research project is discontinued before the expected date of completion, researchers must inform the HREC or Ethics Officer in writing as soon as possible, giving reasons for the discontinuation.

4. Completion of Annual Report Form

4.1 An ethics report form must be submitted to the HREC annually for the duration of the research project and upon completion of the project. The form will be sent by the HREC to the Chief Investigator when it falls due. The form must be signed by the Chief Investigator and submitted to the HREC by the specified date.

4.2 All applicable sections of the research report must be completed and sufficient information provided. Further pages may be attached if necessary. If the HREC deems a research report unsatisfactory, it may at its discretion:

(a) withdraw its approval of the research project; or
(b) require the research report to be resubmitted within a specified period.

4.3 If approval is withdrawn by the HREC, it will notify the Chief Investigator in writing and the Chief Investigator must immediately, upon receipt of the notification by the HREC, ensure that the research project ceases.

4.4 The HREC may, at its discretion, request more frequent reports or require additional surveillance to ensure that the project continues to conform to ethical standards.

4.5 The AEC may also impose requirements in relation to annual reporting. If so, this clause 4 shall apply to the AEC reporting requirements as if they were requirements of the HREC.

5. Completion of Amendment Application Form

5.1 Any amendments to the methods and/or procedures outlined in the original application or to a change in the number of participants in the project or the duration of the project must be proposed to the HREC in accordance with this clause 5.

5.2 Applications to amend a research project must be made by submitting a completed Amendment Application Form, signed by the Chief Investigator, to the Ethics Officer.
5.3 The Amendment Application Form must include a clear explanation of the rationale and justification for the amendment.

5.4 If the proposed amendments result in amendments to an information sheet or consent form related to the project, the amended version of the forms must be submitted with the Amendment Application Form.

5.5 The Ethics Officer may request further information from the Chief Investigator.

5.6 Where the Ethics Officer is of the view that the proposed amendment does not result in significant changes to the procedures or ethical implications of a project, he/she may approve the amendment by notifying the Chief Investigator in writing.

5.7 Where the Ethics Officer is of the view that the amendment proposes a significant change to the procedures and/or ethical implications of a project, he/she will refer the application to the full HREC.

5.8 The HREC will consider the application at its next scheduled meeting and may, at its discretion:

(a) approve the amendment unconditionally; or
(b) approve the amendment with conditions; or
(c) request further information or the resubmission of the Amendment Application Form; or
(d) reject the amendment.

5.9 No amendment will take effect until approved by the Ethics Officer or the HREC in accordance with this clause 5.