



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

POLICY:
HUMAN ETHICS MONITORING OF
APPROVED RESEARCH PROJECTS

Purpose:	This document outlines the University's policy on monitoring of approved research projects involving human participants
Responsible Executive:	Pro Vice-Chancellor Research
Responsible Office:	Research Office
Contact Officer:	Ethics Office
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1 Definitions

"National Statement" is the NHMRC National Statement on Ethical Conduct in Human Research (2007).

"the University" is The University of Notre Dame Australia

"the HREC" is the Human Research Ethics Committee

"the SRC" is the School Research Committee

2 Principles

- 2.1 The [National Statement on Ethical Conduct in Human Research \(2007\)](#) is the foundation document informing research at The University of Notre Dame Australia.
- 2.2 The National Statement requires that there is appropriate monitoring of the conduct of all approved ongoing research until completion.
- 2.3 Monitoring of approved projects is to establish that a research project is being or has been conducted in the manner proposed to, and approved by, the HREC in order to ensure that the welfare and rights of the research participants are adequately protected. Compliance with monitoring requirements is a condition of approval.

3 Conditions

- 3.1 The project must be conducted in accordance with the approved application, including any conditions and amendments that have been approved. You must comply with all of the conditions imposed by the HREC, and any subsequent conditions that the HREC may require.
- 3.2 Amendments to the research design must be reviewed and approved by the HREC before commencement.
- 3.3 If an extension of the approval period is required, a request must be submitted to the HREC.
- 3.4 It is a condition of approval that researchers immediately report anything that might warrant review of the ethical approval of the protocol, including any:
 - adverse events affecting participants
 - significant unforeseen events
 - any other matters that may affect continued ethical acceptability of the project
- 3.5 If the research project is discontinued before the expected date of completion, researchers should inform the HREC as soon as possible, giving reasons.
- 3.6 Where it deems it is warranted, the HREC may ask for more frequent reports or may require additional surveillance to ensure that the project continues to conform to ethical standards.

4 Procedures for Completion of Annual Report Form

- 4.1 An ethics report form must be submitted annually and following completion of the project. The [Annual Report Form](#) will be sent to the Chief Investigator approximately one month before the due date.
- 4.2 Researchers should answer all applicable sections and provide sufficient information. Further pages may be attached if necessary.
- 4.3 The form must be signed by the Chief Investigator.
- 4.4 If there is no response to the initial request, a second reminder is sent at the due date.

- 4.5 If required, another reminder will be provided via email or a telephone call after the due date has passed in order to investigate whether there is a valid reason for the non-response (e.g. CI may be on leave).
- 4.6 If there is no response, the SRC Chair will be contacted for aid in requesting reports from CIs in their school.
- 4.7 If there is no response, the project will be listed on the agenda of the next HREC meeting as report overdue.
- 4.8 Once reviewed by the HREC, the CI is advised in writing of possible consequences of not responding to the request for a report, including;
- (a) The HREC could withdraw approval for the project;
 - (b) The project could be reported to the Pro Vice Chancellor Research for being in breach of the National Statement;
 - (c) Other project/s of the CI could be suspended.
- 4.9 If ethics approval is withdrawn, a researcher must not continue the research until such time as the annual report is submitted and the HREC are satisfied that the matter is concluded.
- 4.10 If the project is already complete, the HREC may decide to suspend any other project/s of the same CI until such time as the Final Report has been provided and the HREC is satisfied that the matter is concluded.
- 4.11 If following this, the appropriate report is still not provided the HREC shall notify the Pro Vice Chancellor Research who may take any action appropriate under the University's regulations, policies and procedures.

5 Procedures for Completion of Amendment Application Form

- 5.1 Proposed changes or amendments to the methods and procedures outlined in the original application must be applied for, in an [Amendment Application Form](#), and approved by the HREC before these may be implemented.
- 5.2 In the Amendment Application Form, the rationale behind and justification for the amendment must be clearly explained.
- 5.3 If this change requires amendments to an information sheet or consent form related to the project, the amended version of the forms must be submitted.
- 5.4 Any change in the number of participants or duration of the project should be advised.
- 5.5 Amendment Application Forms should be submitted to the Ethics Officer.
- 5.6 Should a request for an amendment propose a significant change to the procedures and ethical implications of a project, the amendments will be referred to the full HREC, which could request the resubmission of an application form.

6 Procedures for Adverse Effects

- 6.1 The HREC requires that all Chief Investigators report immediately anything that might affect ethical approval of the project, including:
- adverse events affecting participants
 - significant unforeseen events
 - any other matters that may affect continued ethical acceptability of the project
- 6.2 Reports of adverse events should be submitted to the Ethics Officer.