

Policy Title: Conduct of Ethical Human Research

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1. INTENT

This document outlines the policy and procedures for the conduct of ethical research involving human participants at Edith Cowan University. It provides guidance for staff and students in considering the many ethical issues involved in conducting research with human participants.

2. ORGANISATIONAL SCOPE

This policy applies to all staff, affiliated researchers and students involved in research and research-related activities at ECU.

3. DEFINITIONS

TERM	DEFINITION
“Human Research Ethics Committee (HREC)” means	a committee constituted in accordance with the terms of reference and membership laid down in the National Statement.
“Low risk research” means	research is ‘low risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
“Research” means	the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes.
“Researcher” means	any person who conducts research involving human participants.

4. POLICY CONTENT

- 4.1 People who conduct research with human participants have an obligation to ensure that:
- the welfare and rights of the participants take precedence over the expected benefits to human knowledge.
 - the free and informed consent of participants involved in research projects is obtained; and
 - research projects take into account local, cultural and social attitudes.

- 4.2 The University has a responsibility to the community to ensure that research projects are performed in an ethical manner. Researchers conducting research with human participants must comply with the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* (the National Statement) and, where relevant, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)* (the Values and Ethics Guidelines). Some human research may also be subject to specific statutory regulation, at Commonwealth and State and Territory levels.

- 4.3 The *Australian Code for the Responsible Conduct of Research (2007)* indicates that dissemination of research findings is an important part of the research process, passing on the benefits to other researchers, professional practitioners and the wider community.

4.4 Human Research Ethics Committee (HREC)

The Human Research Ethics Committee (HREC) was established by University Council in 1990 and reports to Academic Board. Responsibilities of the HREC include:

- administration of guidelines
- the application of policy
- consideration of applications for ethics approval
- monitoring of approved research projects
- advising the University on the rights and welfare of human participants and ethics issues
- provision of assistance to staff and students in the consideration of ethical issues involved in conducting research with human participants
- enhancing the University community's understanding of the importance of ethical research.

The Human Research Ethics Committee operates according to the National Statement. The terms of reference of the HREC are available from the ethics website: <https://intranet.ecu.edu.au/research/research-ethics/ethics-committees>.

HREC membership shall be in compliance with the National Statement. Members of the HREC are appointed by the Academic Board. The HREC includes members in each of the following categories:

- a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- at least two lay people, one man and one woman, who have no affiliation with ECU and do not currently engage in medical, scientific, legal or academic work;
- at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- at least one lawyer, where possible one who is not engaged to advise ECU; and
- at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

4.5 Ethics Subcommittees

The National Statement allows institutions to establish non-HREC levels of ethical review for low risk research. The HREC has established Ethics Subcommittees to provide a non-HREC level of ethical review. Student researchers who are undertaking low risk undergraduate, Honours and/or Masters by Coursework research projects may submit their application for ethics approval to an Ethics Subcommittee. Any research project identified as involving more than low risk will be referred to the HREC for review.

4.6 Applying for ethics approval

Investigators must submit an application for all human research projects. The process for applying for ethics approval is available from the ethics website: <https://intranet.ecu.edu.au/research/research-ethics/human-ethics-applications/applying-for-ethics-approval>

4.7 Approval of applications

A human research project must obtain ethics approval before it commences. Recruitment of participants and/or data collection must not commence until ethics approval has been obtained.

4.8 Responsibilities of researchers

Researchers have responsibilities for the ethical design and conduct of research. Researchers should demonstrate, in each research proposal, that the research has merit and reflects the ethical values of justice, beneficence and respect for humans.

The National Statement further outlines the responsibilities of researchers.

Requirements for the management of research data are provided in the *Australian Code for the Responsible Conduct of Research (2007)*. Researchers should also refer to the ECU policy on research data management.

4.9 Reporting and Monitoring

The National Statement indicates that researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes.

All approved research projects are subject to monitoring conditions. This includes completion of an annual report (for projects and activities longer than one year) and a final report at the completion of the research project.

Monitoring may also include more frequent reporting, inspections of research sites, data or consent documentation, and/or interviews with research participants.

4.10 Concerns and complaints

Enquiries, concerns or complaints should be made initially to the Senior Research Ethics Advisor. The *Australian Code for the Responsible Conduct of Research (2007)* further outlines a framework for dealing with allegations of research misconduct. Researchers should also refer to the ECU policies on responsible research conduct and research misconduct.

5. ACCOUNTABILITIES AND RESPONSIBILITIES

In relation to this policy, the following positions are responsible for the following:

Policy Owner

The Policy Owner being the Director, Office of Research and Innovation, has overall responsibility for the content of this policy and its operation in ECU.

Staff/students

Staff/students are required to comply with the content of this policy and to seek guidance in the event of uncertainty as to its application.

6. RELATED DOCUMENTS:

Other documents which are relevant to the operation of this policy are as follows:

Australian Code for the Responsible Conduct of Research (2007)

<https://www.nhmrc.gov.au/guidelines-publications/r39>

National Statement on Ethical Conduct in Human Research (2007)

<https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) <https://www.nhmrc.gov.au/guidelines-publications/e52>

Responsible Research Conduct

http://www.ecu.edu.au/GPPS/policies_db/policies_view.php?rec_id=0000000325

Research Misconduct

http://www.ecu.edu.au/GPPS/policies_db/policies_view.php?rec_id=0000000375

Research Data Management

http://www.ecu.edu.au/GPPS/policies_db/policies_view.php?rec_id=0000000327

7. CONTACT INFORMATION

For queries relating to this document please contact:

Policy Owner	Director, Office of Research and Innovation
All Enquiries Contact:	Senior Research Ethics Advisor
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8. APPROVAL HISTORY

Policy approved by:	Vice-Chancellor
Date policy first approved:	March 1996
Date last modified:	November 2015
Revision history:	November 2007 (AB106/07) 20 November 2015 – reviewed in light of academic organisational restructure. Section 4.5 updated to remove references to Faculty Ethics Subcommittees and minor cosmetic changes made. Approved by revised Policy Owner.
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