

Guideline Conduct of Ethical Human Research

ECU has a responsibility to ensure that all human research is performed in an ethical manner. This document outlines the requirements for the conduct of ethical research involving human participants at researchers at ECU. It provides guidance for staff and students in considering the many ethical issues involved in conducting research with human participants and the associated institutional requirements.

Definitions

TERM	DEFINITION
Human Research Ethics Committee (HREC)	A committee constituted in accordance with the requirements and with membership as per the National Statement on Ethical Conduct in Human Research (2007) (the National Statement).
Low risk research	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.
Proportional Review Checklist	This checklist is the first step in submitting a new research project in the Research Ethics Management System. The checklist comprises a series of questions to determine if the proposed work requires human or animal research ethics review and the level of review required.
Research	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, inventions and understandings. This could include synthesis, collation, evaluation and analysis of previous Research to the extent that it is new and creative and/or that it informs policy and professional practice.
Research Ethics Management System (REMS)	The Research Ethics Management System is the University's online ethics review software. It supports the governance of research at ECU.
Researcher	A Researcher is a person who conducts Research. For the purpose of this policy and unless otherwise stated this will be understood to include staff, students, adjunct, honoraries and visiting fellows.

1. Governing Principles

1.1 People who conduct research with human participants have an obligation to ensure that:

- a. the welfare and rights of the participants take precedence over the expected benefits to human knowledge.
- b. the free and informed consent of participants involved in research projects is obtained; and
- c. research projects take into account local, cultural and social attitudes.

- 1.2 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.
- 1.3 All research activity conducted by ECU staff and students, must be recorded in the ECU Research Ethics Management System (REMS) prior to the commencement of research activities. This applies whether or not research involves humans or animals or neither. The process of recording the research will determine the ethical review requirements and will include completion of a mandatory Research Data Management Plan.
- 1.4 Data collection or recruitment of participants must not commence until the research activity has been recorded in REMS, the appropriate ethics review pathway has been determined and official notification has been issued to confirm that all governance requirements have been satisfied or formal advice is provided that ethics approval is not required.

2. Human Research Ethics Committee (HREC)

- 2.1 The ECU Human Research Ethics Committee (HREC) was established by University Council in 1990 and reports to Academic Board. Responsibilities of the HREC include:
 - a) administration of guidelines;
 - b) the application of policy;
 - c) consideration of applications for ethics approval;
 - d) monitoring of approved research projects;
 - e) advising the University on the rights and welfare of human participants and ethics issues;
 - f) provision of assistance to staff and students in the consideration of ethical issues involved in conducting research with human participants; and
 - g) enhancing the University community's understanding of the importance of ethical research.
- 2.2 The Human Research Ethics Committee operates according to the National Statement. The terms of reference of the HREC are available from the [ethics review committee website](#).
- 2.3 HREC membership shall be in compliance with the requirements of the National Statement. Members of the HREC are appointed by ECU Academic Board.

3. Ethics Subcommittees

- 3.1 The National Statement sanctions institutional establishment of non- HREC levels of ethical review for low risk and negligible risk research. ECU has established Ethics Subcommittees to provide a non-HREC level of ethical review of research being undertaken at ECU. The risk level of the project will be determined by the Proportional Review Checklist in REMS and will be allocated for review by the appropriate review committee. Any research project identified as involving more than low risk will be referred to the HREC for review.

4. Applying for ethics approval

- 4.1 All research and research-related activity must be submitted in REMS where it will be determined if the activity requires ethical review and the most appropriate review pathway. Alternatively, the project may qualify for an 'Out of Scope' or 'Exempt from Review' notification.
- 4.2 ECU researchers involved in research activities which have undergone ethical review and approval by another institution's ethics committee are required to submit the project in REMS for reciprocal ethics approval.

5. Approval of applications

- 5.1 Researchers will be formally notified when their ethics application has been approved. All applications are approved with standard conditions of approval however, some projects may have further specific approval conditions which will be outlined in the approval email.

6. Responsibilities of researchers

- 6.1 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.
- 6.2 Any proposed amendment to an approved research project must be submitted for review and approval by the Human Research Ethics Committee or Subcommittee prior to implementing the changes.
- 6.3 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 (2018). Researchers should also refer to the ECU Research Data Management Guidelines.

7. Reporting and Monitoring

- 7.1 The National Statement states that researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes.
- 7.2 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.
- 7.3 Adverse Events and/or unexpected outcomes must be reported immediately to the Research Ethics Team.

8. Concerns and complaints

- 8.1 Enquiries, concerns or complaints should be made initially to the Research Ethics Officer. The Australian Code for the Responsible Conduct of Research (2018) further outlines a framework for dealing with allegations of research misconduct. Researchers should also refer to the ECU policy "Conducting Research with Integrity" and associated guidelines.

9. Related Documents:

- 9.1 Other documents which are relevant to the operation of this guideline are as follows:
- [Conducting Research with Integrity Policy](#)
 - [Australian Code for the Responsible Conduct of Research 2018](#)
 - [National Statement on Ethical Conduct in Human Research \(2007\)](#)
 - [Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research \(2003\)](#)
 - [Research Misconduct Guideline](#)
 - [Research Data Management Guideline](#)

Contact Information

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