

RESEARCH INVOLVING HUMANS AND/OR ANIMALS FOR ETHICAL CLEARANCE POLICY AND PROCEDURE



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1 PURPOSE

- 1.1 The University has fully constituted Ethics Committees with responsibility to ensure that the ethical implications of any research undertaken are afforded serious consideration prior to the commencement of a project and that such research is consistent with legislative and statutory requirements.

2 SCOPE

- 2.1 These processes apply to all staff and students of the University involved in research.

3 POLICY STATEMENT

- 3.1 Before conducting any research investigation involving human and/or animal subjects, staff and students of the University are required to obtain an ethical clearance for the proposed investigation and to ensure that all the required reports are lodged in the prescribed fashion.
- 3.2 In order to provide ethical clearance, the relevant Committee must be satisfied that:
- the research is not in conflict with University policy, complies with Commonwealth and State legislation, and is in keeping with those codes of practice promulgated by authorised agencies;
 - the research is necessary to the improvement of human and/or animal health and welfare, or that it will significantly contribute to knowledge;
 - the advantages gained will justify any discomfort or risk involved for the subject(s)/participant(s); and
 - there is no alternative to the use of human and/or animal subjects to achieve the aim(s) of the research.
- 3.3 All projects involving human subjects shall be conducted in conformity with the National Health and Medical Research Council's, hereafter the NH&MRC, [National Statement on Ethical Conduct in Human Research \(2007\)](#) and the [Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research \(2003\)](#).
- 3.4 All projects involving animal subjects shall be conducted in conformity with the NH&MRC's [Australian Code for the Care and Use of Animals for Scientific Purposes \(2013\)](#).

- 3.5 Research protocols involving human and/or animal experimentation must be preserved in the form in which they were approved. In the event that an approved protocol requires amendment, the revised protocol must be reconsidered by the relevant Committee.
- 3.6 Infringements of, or non-compliance with, University policy, Commonwealth and State legislation, or recognized codes of practice, in particular those of the NH&MRC, must be reported immediately to the Chair (or nominee) of the relevant ethics Committee. The Chair (or nominee) shall have the authority to:
- suspend the project until such time as the ethical concerns are addressed; or
 - terminate the project. (Clauses 5.5.7 to 5.5.10 of the National Statement on Ethical Conduct in Human Research, and clause 2.4.18 of the Australian Code for the Care and Use of Animals for Scientific Purposes).

4 PROCEDURE

- 4.1 An application for approval to undertake research involving human and/or animal subjects shall be submitted to the Research Division for the consideration of the relevant Committee.
- 4.2 The relevant Committee shall determine whether or not the proposed project is acceptable on ethical grounds.
- 4.3 Where a project is deemed ethically acceptable, the Committee shall issue a written ethical clearance which shall include an authorization code and details of those methods of surveillance to ensure that the project continues to conform to approved ethical standards.
- 4.4 Where a project is deemed ethically unacceptable, the Committee shall advise the applicant in writing of its concerns. The project shall not commence until such time as these concerns are addressed to the Committee's satisfaction.
- 4.5 Each Committee shall maintain a record of all proposed research projects which shall include (but not be limited to) the following items of information:
- Animal Ethics (as per clause 2.2.30 of the Australian Code for the care and use of animals for scientific purposes):
 - project identification number
 - name(s) of chief investigator(s)
 - short title of project
 - ethical approval or non-approval with date
 - commencement and completion dates
 - animal species and numbers approved
 - protocol category
 - purpose of the project, and
 - date(s) designated for review
 - Human Ethics (as per clause 5.2.24 of the National Statement on Ethical Conduct in Human Research):
 - names of the institutions to which the research proposal is provided
 - project identification number
 - names of the principal researcher/s
 - title of the project
 - correspondence between the review body and the researcher about the review
 - acceptance or rejection of any changes to the proposal
 - proposed date of completion of the proposal
 - formal advice of final ethical approval or non-approval with date

- terms and conditions, if any, of approval of any proposal
 - duration of the approval
 - name of any other review body whose opinion was considered
 - mechanisms to be used to monitor the conduct of the research, and
 - relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.
- 4.6 In the event that an approved research protocol is revised or amended, or an extension of time is required, the chief investigator(s) is required to submit a modification application for approval to the Research Division for consideration by the relevant Committee.

5 RESPONSIBILITIES

Compliance, monitoring and review

- 5.1 The Human Research Ethics Committee and the Animal Ethics Committee assess all project applications and monitoring is carried out on annual and final reports from all research projects. Researchers are required to adhere to the Code of Conduct for Research, and all other relevant legislation or guidelines as shown below.
- 5.2 The Deputy Vice-Chancellor (Research) and the Research Division are responsible for ensuring these procedures are followed.

Reporting

- 5.3 Both the Animal Ethics Committee and Human Research Ethics Committee submit annual reports on the activity in the previous calendar year to the Research Committee. AEC also reports annually to the State Government of each state within which University is licensed to use animals for scientific purposes, and HREC reports annually to the NHMRC.

Records management

- 5.4 Staff must maintain all records relevant to administering this policy and procedure in a recognised University recordkeeping system.

6 DEFINITIONS

- 6.1 Terms not defined in this document may be in the University [glossary](#).

7 RELATED LEGISLATION AND DOCUMENTS

[Animal Ethics Committee Terms of Reference](#)

[Australian Code for the care and use of animals for scientific purposes \(2013\)](#)

[Code of Conduct for Research](#)

[Human Research Ethics Committee Terms of Reference](#)

[National statement on ethical conduct in human research](#)

[Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research \(2003\)](#)

8 FEEDBACK

- 8.1 University staff and students may provide feedback about this document by emailing policy@cqu.edu.au.

9 APPROVAL AND REVIEW DETAILS

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Advisory Committee to Approval Authority	Research Committee
Administrator	Deputy Vice-Chancellor (Research)
Next Review Date	25/05/2019

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