

Collaborative Research and Ethics Approval Guideline

Section 1 - Introduction

(1) This Guideline outlines the conditions for collaborative research ethics approval for both animal and human research.

Section 2 - Audience

(2) Researchers undertaking animal and/or human-based collaborative research under the auspices of the University of Newcastle (the University).

Section 3 - Guidelines for Collaborative Animal Based Research

(3) The [Australian code for the care and use of animals for scientific purposes](#), enacted in the [Animal Research Regulation](#) which is enacted under the [Animal Research Act](#), stipulates that where parts of an animal-based project take place at different institutions, each institution's Animal Ethics Committee must be cognisant of all aspects of the project and must ensure that any cumulative impact of procedures on animals is considered. This Guideline outlines the requirements of the regulatory framework in relation to collaborative animal-based research.

(4) In accordance with 2.6.8 of the [Australian code for the care and use of animals for scientific purposes](#), animal-based researchers will notify the Animal Care and Ethics Committee (ACEC) in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to an Animal Ethics Committee of another institution.

(5) Animal-based researchers should refer to the [Animal Care and Ethics Committee Methodology Document 41](#) "Collaborative research using animals" for advice on the information that needs to be provided to the ACEC.

Section 4 - Guidelines for Collaborative Human Based Research

(6) The [National Statement on Ethical Conduct in Human Research](#) (National Statement) recommends that institutions adopt processes that eliminate the unnecessary duplication of ethical review. The HREC of an institution can be registered with the National Health & Medical Research Council (NHMRC) by declaring their compliance with the National Statement, and are known as registered institutions.

(7) This Guideline outlines the conditions under which the University Human Research Ethics Committee (HREC) may recognise the approval of an external HREC, as well as circumstances in which ethical clearance from the University HREC is not required.

Registration of an External HREC Approval

(8) The University HREC may recognise the prior approval of an external HREC where:

- a. a formal agreement is in place with the external institution; or
- b. the project has been previously reviewed and approved by a HREC that is registered with the NHMRC.

(9) Recognition of an external HREC approval may be at the discretion of the Chair or a Deputy Chair of the University HREC.

(10) In addition to any external HREC approval, approval from the University HREC may be required for projects involving University students and/or staff as research participants.

(11) Researchers should seek advice from the Research Integrity Unit (see [Human Ethics Officer Contacts](#)) where they are uncertain as to the type of approval required.

Approval for Collaborative Research

Principal Investigators

(12) Generally, where a University researcher is the principal investigator on a research project involving human participants, they are required to obtain ethical approval in accordance with the University's policies, procedures and delegations of authority. However, the University Researcher may register an external HREC approval to the University HREC for recognition in situations where:

- a. the research will not occur at the University;
- b. research participants are to be recruited from an organisation or site external to the University; and
- c. the researcher already has an existing approval from a relevant and eligible external HREC (see clauses 8 to 11).

Associate Co-Investigators

(13) A University researcher who is an associate researcher or co-investigator on a research project involving human participants initiated at another institution is required to obtain ethical clearance in accordance with the University's policies, procedures and delegations of authority if:

- a. they are a University Student and the research is to be used towards meeting the requirements of a course/program of study;
- b. the research is to be conducted at the University;
- c. a research grant or contract for the project is to be primarily administered by the University;
- d. it is intended to use the letterhead or brand of the University in any documentation provided to study participants; or
- e. the research has not been approved by an institutional HREC registered with the [NHMRC](#) in Australia, or its equivalent body in other countries.

(14) Where an application to the University HREC is required, projects previously approved by an eligible external HREC (see clauses 8 to 11) may be submitted as a registration of external HREC approval.

(15) In all other cases of collaborative research involving human participants (i.e, where clauses 13 and 14 do not apply), co-investigators who are associated with the University are required to:

- a. hold written evidence that the project has been approved by an institutional ethics committee registered

- with the [NHMRC](#) in Australia, or its equivalent body in other countries; and
- b. prior to the research commencing, forward a copy of the written evidence of ethical approval to the Human Research Ethics Officer (see [Human Ethics Officer Contacts](#)).

Section 5 - Roles and Responsibilities

(16) All University Researchers must follow relevant policies and procedures established by the University and the relevant ethics committee/s.

(17) Animal based researchers must adhere to the requirements of the [Australian code for the care and use of animals for scientific purposes](#) and the ACEC documentation on collaborative research.

(18) Human based researchers:

- a. must adhere to the [National Statement on Ethical Conduct in Human Research](#).
- b. seeking to have the approval of an external human research ethics committee recognised by the University HREC must register the external approval with the University HREC and provide all of the associated documentation.

Status and Details

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| Status | Historic |
| Effective Date | 17th April 2019 |
| Review Date | 17th April 2022 |
| Approval Authority | Deputy Vice-Chancellor (Research and Innovation) |
| Approval Date | 12th April 2019 |
| Expiry Date | 9th November 2022 |
| Responsible Executive | Paula Jones General Manager, Research & Innovation Division +61 2 49215300 |
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Glossary Terms and Definitions

"University" - The University of Newcastle, a body corporate established under sections 4 and 5 of the University of Newcastle Act 1989.

"Course" - When referring to a course offered by the University, a course is a set of learning activities or learning opportunities with defined, assessed and recorded learning outcomes. A course will be identified by an alphanumeric course code and course title. Course types include core courses, compulsory courses, directed courses, capstone courses and electives. For all other uses of this term, the generic definition applies.

"Student" - A person formally enrolled in a course or active in a program offered by the University or affiliated entity.

"Program" - When referring to learning, a program is a sequence of approved learning, usually leading to an Award. For all other uses of this term, the generic definition applies.

"Research" - As defined in the Australian Code for the Responsible Conduct of Research, or any replacing Code or document.

"Staff" - Means a person who was at the relevant time employed by the University and includes professional and academic staff of the University, by contract or ongoing, as well as conjoint staff but does not include visitors to the University.