

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 (UON).

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

(7) The [National Statement on Ethical Conduct in Human Research](#) (National Statement) recommends that institutions adopt processes of review that eliminate the unnecessary duplication of ethical review. In support of this principle, the [National Health and Medical Research Council \(NHMRC\) National Certification Scheme](#) certifies the ethical review processes of an institution's HREC in specific categories of research.

(8) The UON HREC may recognise the prior approval of an external HREC where the HREC undertaking the review has been certified by the [NHMRC](#) to review research proposals within the certified category of research.

Registration of External HREC Approval

(9) The UON HREC may recognise the approval of an external HREC where:

- a. a formal agreement is in place with the external institution; or
- b. the proposal has been previously reviewed and approved within the nominated certification category of an external HREC currently certified by the [NHMRC](#).

(10) Acceptance of a registration of external HREC approval will be at the discretion of the Chair, or a Deputy Chair, of the UON HREC.

(11) Formal approval from the UON HREC may be required, in addition to any external HREC approval, for protocols involving UON students and/or staff as research participants.

(12) Researchers should seek advice from the Research Integrity Unit where they are uncertain as to the type of approval required.

Approval from the Human Research Ethics Committee for Collaborative Research

Principal Investigators

(13) Generally, where a UON researcher is the principal investigator on a research project involving human participants, they are required to obtain ethical approval from the UON HREC. However, the UON Researcher may submit a registration of external HREC approval to the UON HREC in situations where:

- a. the research will not occur at UON;
- b. research participants are to be recruited from an organisation or site external to UON; or
- c. the researcher already has an existing approval from a relevant and eligible external HREC (see clauses 9 to 12).

Associate Co-Investigators

(14) A UON researcher who is an associate researcher or co-investigator on a research project initiated at another institution that involves human participants, is required to obtain ethical clearance from the UON HREC if:

- a. they are a UON 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 UON;
- c. a research grant or contract for the project is to be primarily administered by UON;
- d. it is intended to use the letterhead or brand of UON in any documentation provided to study participants; or
- e. the research has not been approved by an institutional HREC recognised by the [NHMRC](#) in Australia, or its equivalent body in other countries.

(15) Where an application to the UON HREC is required, protocols previously approved by an eligible external HREC (see clauses 9 to 12) may be submitted as a registration of external HREC approval.

(16) 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 UON are required to:

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

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

(18) 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.

(19) 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 UON HREC must register the external approval with the UON HREC and provide all of the associated documentation.

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Enquiries Contact	Research Ethics and Integrity Unit

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.