Research Peer Review Procedure for Ethics Applications

Section 1 - Introduction

(1) The University of Newcastle (University) has a responsibility to ensure that research proposals submitted for ethics approval are methodologically sound and of a high scholarly standard. Peer review of research provides expert scrutiny of a research project, helps to maintain high standards, and encourages accurate, thorough and credible research reporting.

(2) This Procedure outlines the responsibilities and process requirements required for peer review of all research proposals submitted to the Human Research Ethics Committee (HREC) as more than low-risk, or to the Animal Ethics Committee (AEC) for ethics approval.

(3) Applications for ethics approval to the HREC or AEC will not be accepted if the completed peer review does not comply with this Procedure.

(4) This Procedure should be read in conjunction with the Guide to Peer Review (NHMRC).

Section 2 - Scope

(5) This Procedure:

a. applies to all animal research proposals being submitted by University Researchers to the AEC; and
b. applies to all human research proposals being submitted by University Researchers to the HREC.

Section 3 - Audience

(6) This document should be read and understood by:

a. University Researchers conducting animal or human based research;
b. Conjoint/Honorary/Affiliated Researchers conducting animal or human based research;
c. Coursework and honours students and Higher Degree by Research (HDR) candidates conducting animal or human based research;
d. Peer reviewers;
e. Heads of School; and
f. College Pro Vice-Chancellors.

Section 4 - Document Specific Definition

(7) In the context of this document:

a. “peer review” is as defined by the Australian Code of the Responsible Conduct of Research and means the “impartial and independent assessment of research by others working in the same or a related field”. The peer reviewer must have sufficient standing to competently review the merit and protocols of the research project.

Section 5 - Responsibilities

College Responsibilities

(8) College Pro Vice-Chancellors are responsible for overseeing peer reviews of animal and human-based research projects in their respective Colleges by:

a. establishing formal processes in their College for the peer review of research proposals prior to their submission to the University's HREC or AEC;
b. ensuring that the peer reviews conducted are of the highest rigor and are undertaken in accordance with this procedure;
c. providing suitable peer reviewers, which includes experienced Researchers in the general field of study or specific methodology of the proposal under review;
d. seeking an external peer reviewer in circumstances where a suitable peer reviewer cannot be identified internally; and
e. supporting the training of College peer reviewers to ensure a systematic and consistent approach when conducting peer review.

Peer Reviewer Responsibilities

(9) Peer reviewers have responsibility for ensuring that a review of the research proposal is undertaken against the criteria listed in the peer review report form for:

a. AEC (Independent peer review of scientific merit of a research protocol involving the use of animals); and
b. HREC (Human Research Ethics Committee Peer Review Declaration) applications.

(10) Peer reviewers in human research ethics should review the research proposal against the questions listed on the Peer Reviewer Response form.

(11) Peer reviewers need to ensure that they are independent of the Researchers. That is, they must not be part of the research team for the project, or have any significant personal relationship or other conflicts of interest with members of the research team.

(12) Where the research proposal is for a project to be undertaken by a University student as part of their program of study, the student's supervisor or supervisors cannot be a peer reviewer for the proposal.

(13) Peer reviewers in human research ethics should sign a confidentiality agreement where there are confidentiality or commercial-in confidence issues.

Researcher Responsibilities

(14) Researchers seeking peer review for human based research, must make a submission to the College for peer review through the formal process which has been established by their College. This submission must include:

a. a 2–3 page summary of the research proposal that covers:
    i. a brief literature review;
    ii. the aims of the proposed research;

iii. the proposed study sample;
iv. the design, methodology and/or research procedures; and
v. statistical model and power estimates if appropriate.

b. a copy of the draft ethics application to the HREC (including attachments).

(15) Researchers seeking peer review for animal-based research must provide the nominated peer reviewer a copy of their draft ethics application to the AEC (including all relevant attachments).

(16) Researchers must address any issues identified during the peer review prior to submission of an application to the ethics committee.

Head of School Responsibilities

(17) For human ethics submissions to the HREC, the primary Researcher's Head of School must complete the Head of School Declaration confirming the completion of a peer review and endorsing the undertaking of the research.

(18) Please also see Clause 20.

College Pro-Vice Chancellor Responsibilities

(19) The Head of School Declaration is to be completed by the College Pro Vice-Chancellor or their nominee where the Head of School has a conflict of interest with the research or the research team. Such Conflicts of Interest should be declared as per the relevant Policy and Procedure (see Disclosure of Interest Policy).

Section 6 - Peer Review Process Requirements

(20) Peer review is not a function of the HREC or the AEC except in as much as the AEC or HREC must be assured that a peer review has been properly conducted. Peer review must be undertaken in accordance with the process approved by the applicable College, including use of a documented standard protocol and its attachment to the signed peer review form.

(21) For AEC, Researchers have the choice of using an internal or external peer reviewer (i.e. internal colleague or external colleague from another institution).

(22) An internal peer review is not required where the research proposal has been peer reviewed in the course of a grant being awarded by a recognised granting body operating a competitive academic grants scheme. Researchers submitting to the HREC or AEC for approval will be required to confirm in writing that the research methods described in the ethics application match the funded activities described in the grant application. HREC requires details of the grant, its reference number and a copy of the application to the granting body in the application for ethics approval. For AEC this is only requested if the University is not the administering body.

(23) A prior internal peer review is not required for low and minimal risk human research proposals. Methodological review of these submissions will be undertaken during the ethical review process.

(24) Peer review of research to be considered for HREC or AEC approval will be reviewed by at least one peer reviewer unless clause (22) applies.

(25) The peer review needs to be responsive to the relatively narrow research time window open to some Researchers, particularly students. Peer reviews should be completed and returned to the Researcher in a timely manner and within 10 working days of submission, although shorter turnaround is strongly encouraged. Electronic submission of peer review documents, approvals, and feedback to applicants is strongly recommended.

(26) Any issues identified through the peer review are to be addressed by the applicant to the satisfaction of the peer reviewer prior to the submission of an application for consideration by the HREC or AEC.

Status and Details

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Enquiries Contact	Rebecca Dyson Senior Manager, Research Integrity Research and Innovation Services

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.

"Risk" - Effect of uncertainty on objectives. Note: An effect is a deviation from the expected, whether it is positive and/or negative.

"Working day" - Any day other than Saturday, Sunday, or a public holiday in Newcastle, on which business may be conducted.

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

"Candidate" - With regard to Higher Degree by Research it has the same meaning as student. For all other instances it is a person considered for appointment to a position.

"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.

"College" - An organisational unit established within the University by the Council.

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