Animal Ethics Committee Procedure Manual

Section 1 - Introduction

(1) As an accredited institution for the scientific use of animals, the University of Newcastle (the University) must ensure that animal use is ethically justified, prioritises animal welfare, and adheres to the principles of Replacement, Reduction, and Refinement (3Rs).

(2) In New South Wales, animal use for research and teaching is governed by the following legislation and guidelines:

a. Animal Research Act 1985 (NSW) (the Act);
b. Animal Research Regulation 2021 (NSW) (the Regulation);
c. Australian Code for the Care and Use of Animals for Scientific Purposes (the Code) incorporated by reference into the Animal Research Regulation 2021; and
d. Animal Research Review Panel Policies and Guidelines.

(3) Research involving animals at the University is also subject to:

a. Responsible Conduct of Research Policy;
b. Animal Research Regulatory Manual.

(4) The University's Animal Ethics Committee (AEC) functions in accordance with the Animal Ethics Committee Terms of Reference and operates within the University's broader governance framework for animal research, contributing to institutional excellence in research integrity and animal welfare standards.

(5) The Animal Ethics Executive Committee is a sub-committee of the Animal Ethics Committee and functions in accordance with the Animal Ethics Executive Committee Terms of Reference.

Section 2 - Purpose

(6) This Procedure Manual establishes the operational framework for the University of Newcastle's AEC and the Animal Ethics Executive Committee, in accordance with the Code. It ensures the committees operate effectively, comply with legislation and University policies, and support timely, competent ethical review of animal care and use.

Section 3 - Scope and Audience

(7) This Manual applies to all activities involving the use of animals for scientific purposes conducted under the auspices of the University, including research, teaching, testing, and other approved scientific activities, and applies regardless of the source of funding, location, or the purpose of the activity. This includes, but is not limited to:

a. the submission, review, assessment, and approval of animal ethics applications relating to research, teaching or other scientific activities;
b. AEC meeting procedures and decision-making processes;

c. ongoing oversight, monitoring, and compliance activities for approved projects;
d. the assessment and management of non-compliance, including but not limited to the suspension, modification, or withdrawal of animal ethics approvals.

(8) The Manual is intended for use by the AEC and University staff who have responsibilities for animal ethics oversight and related governance. It provides detailed information for how the AEC conducts its business, makes decisions and fulfills its statutory and institutional responsibilities.

(9) Researchers may refer to this Manual to understand how animal ethics applications are reviewed and decisions are made by the AEC. For day-to-day guidance on ethical conduct, competency, monitoring and reporting in relation to animal research, Researchers should refer to the Animal Research Regulatory Manual.

Section 4 - Definitions

(10) In the context of this document, the following definitions apply:

a. “AEC meeting cycle” means the period between submission deadline dates for consecutive AEC meetings, as published on Research Hub;
b. “activity” has the same meaning as defined by Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition (2013) (updated 2021);
c. “Animal Protocol” means any intervention, manipulation, treatment, or interaction with live animals that is part of the research or teaching activity, including but not limited to handling, restraint, sample collection, administration of substances, surgical interventions, behavioural testing, monitoring activities, and environmental modifications that may affect animal welfare.
d. “Animal Research Authority” or “ARA” means authority issued to any individual to carry out animal research for the purpose of a particular animal research project, in accordance with the Animal Research Act 1985 (NSW);
e. “application” means a request for ethical approval from the AEC to carry out an animal research project or activity;
f. “Chief Investigator” means any person assigned to a research project with ultimate responsibility for the intellectual, administrative, and ethical conduct of research;
g. “Investigator” means any person who uses animals for scientifix purposes, including but not limited to Researchers, teachers, undergraduate and postgraduate students involved in research or teaching activities, and people involved in product testing, environmental testing, produciton of biological products and wildlife surveys;
h. “Lead Animal Investigator” means the person identified on the animal ethics application as having primary responsibility for the day-to-day oversight of animal welfare and conduct of animal protocols for the approved project or activity and for making timely, informed decisions regarding the care and welfare of animals used in the project. The Lead Animal Investigator must have sufficient knowledge of the project and authority to respond to animal welfare issues, including emergencies. The Lead Animal Investigator may be, but does not need to be, the Chief Investigator.
i. “project” has the same meaning as defined by the Code;
j. “Research Team” means all persons listed on an animal ethics application as authorised personnel for the conduct of the approved project or activity.

Section 5 - AEC Structure and Decision Making

(11) Refer to the AEC Terms of Reference for AEC structure and decision making authority.

Section 6 - Ethics Application Submission and Pre-Review Process

Types of Submissions

(12) The AEC is responsible for considering ethics applications for new animal research projects and modifications to existing projects, as well as various reports throughout the research lifecycle. In accordance with the AEC Terms of Reference, the AEC may review, require modification, approve or reject applications for ethical approval of the use of animals for research or teaching purposes.

(13) For information relating to submission types and examples, refer to ResearchHub.

Submission and Distribution Requirements

(14) Ethics applications and reports must be completed to be considered by the AEC. Incomplete submissions will be returned to the research team and may be resubmitted once all required materials are provided.

(15) Items requiring full AEC consideration must be submitted by the published deadlines on ResearchHub. Late submissions will only be considered under exceptional circumstances, with written justification provided by the research team.

(16) Minor variations, urgent variations, requested reports and Registration of Animal Tissue Use are subject to rolling review by the Animal Ethics Executive Committee and are not bound by fixed submission deadlines.

(17) All agenda materials including ethics applications, reports and supporting documents are distributed to AEC members one week prior to the meeting date. This ensures members have adequate time to review materials, seek clarification, and prepare for informed discussion and decision making.

(18) The Animal Ethics Executive Committee will not be assigned new materials for review during the week between agenda distribution and the meeting except where urgent business is admitted in accordance with Clause 19.

(19) The Chair may include additional or urgent business items in the agenda where this is necessary to address time-criticla matters relating to animal welfare, safety, or regulatory compliance.

Initial Ethics Approval Application Process (Initial Application)

(20) Researchers must complete the relevant Initial Application form (available from Animal Ethics Resources page) and may consult with the following, as necessary, to assist with completion of the form:

a. Research Ethics Advisors (Category B / Academic members) for guidance on specific ethical queries;
b. Animal Ethics Office for procedural guidance and application requirements;
c. Animal Welfare Officer (AWO) for advice on animal welfare, veterinary procedures, drug protocols, and regulatory compliance;
d. BioResearch Facilities staff regarding space allocation, husbandry requirements, and access to specialised equipment.

(21) All Initial Applications must:

a. undergo peer review in accordance with the Research Peer Review Procedure for Ethics Applications prior to submission to the AEC; and
b. include a signed Head of School declaration confirming:

i. adequate peer review; and
ii. school support; and
iii. availability of resources.

(22) Where the Head of School has a direct association with the proposed research, the above declaration must be completed by the relevant College Pro Vice-Chancellor.

(23) Initial Applications and supporting documents must be submitted via email to AEC-Submissions@newcastle.edu.au.

(24) All Initial Applications must undergo a structured pre-review process, involving three stages, prior to being listed on the AEC meeting agenda, as set out in Table 1.

Table 1: Pre-Review Stages and Focus Areas

Stage	Conducted By	Focus Areas
Administrative Pre-Review	Animal Ethics Officer	Form version, completeness, personnel, training, funding, approvals, attachments.
Veterinary Pre-Review	Animal Welfare Officer (AWO)	Drugs, dosage, euthanasia, monitoring, welfare impact, logistics.
Ethics Pre-Review	Two AEC members (A/B and C/D) and the AEC Chair	Ethical justification, 3Rs, species, design, monitoring.

(25) The Administrative Pre-Review should be completed by the Animal Ethics Officer within 5 business days of receipt of the Initial Application. Applications that meet the required administrative and compliance checks must then proceed to Veterinary Pre-Review.

(26) The Veterinary Pre-Review should be completed by the Animal Welfare Officer within 5 business days of completion of the Administrative Pre-Review. Feedback from the Veterinary Pre-Review is compiled by the Animal Ethics Officer and provided to the research team for response and clarification, where required.

(27) Following receipt of the research team's response to the Veterinary Pre-Review, the Manager - Animal Ethics must assign the Initial Application to two AEC members and the AEC Chair for Ethics Pre-Review, based on expertise and availability. Ethics Pre Review consists of a single consolidated round of advisory feedback, intended to identify key ethical considerations, highlight matters that may warrant AEC attention, and support efficient and informed discussion at the full AEC meeting. Ethics Pre Review does not constitute approval, rejection, or ethical determination of the application.

(28) Following completion of Ethics Pre-Review, the Initial Application may be listed on the agenda for consideration at the next available AEC meeting. Applications are not required to have all ethical matters resolved prior to full AEC consideration. The final determination of whether ethical concerns are adequately addressed rests solely with the AEC.

(29) Investigators must respond to all feedback requests from pre-reviewers within 6 months. The Animal Ethics Officer will issue reminders at 3 and 5 months. If no response is received within 3 months, the application will be considered withdrawn and a new Initial Application must be submitted. Where Investigators anticipate that additional time is required due to legitimate circumstances (e.g. staffing changes, experimental design considerations, or external constraints), a written request for extension must be submitted to the Animal Ethics Office prior to the 6-month deadline. The Manager - Animal Ethics may approve a reasonable extension where justified.

Variations to Existing Projects

(30) Researchers must obtain AEC approval for any proposed changes to an animal research project with existing

ethics approval prior to implementing those changes and prior to project expiry.

(31) Variations are classified as minor, major or urgent. Examples of each are provided on ResearchHub.

Minor Variations

(32) A minor variation is a proposed change that:

a. does not introduce new animal protocols, species, or aims;
b. does not increase the level of pain, distress, or risk to animal welfare beyond that previously approved;
c. involves refinements, administrative updates, or limited adjustments that fall within the original ethical and welfare assessment; and
d. can be reasonably assessed without requiring reconsideration of the overall ethical justification of the project.

(33) An urgent minor variation is a time-critical minor variation required to address an immediate and unanticipated issue that, if not acted upon promptly, may adversely affect animal welfare, research continuity, or safety, but does not introduce new animal protocols, increase animal welfare impacts, or otherwise meet the definition of a major variation. Refer to Research Hub for guidance as to what will be accepted as an urgent variation.

Major Variations

(34) A major variation is a proposed change that:

a. introduces new or substantially modified animal protocols, species, strains, or experimental conditions; or
b. has the potential to increase animal welfare impacts, alter approved monitoring or humane endpoints, or introduce new or elevated risks; or
c. requires reconsideration of the ethical justification, harm–benefit assessment, or scientific design of the project; and
d. remains sufficiently related to the approved project such that it does not constitute a new research activity.

(35) An Urgent Major Variation is a time-critical major variation required to address an immediate and unanticipated risk to animal welfare, safety, or biosecurity, where delay to obtain prior approval would likely result in animal suffering, significant harm, or serious safety consequences. An urgent major variation involves changes that meet the definition of a major variation but require emergency consideration. Refer to Research Hub for guidance as to what will be accepted as an urgent variation.

Variation Submissions

(36) Variation applications must be submitted via RIMS, and include:

a. a completed eForm Application Coversheet summarising:
    i. the requested variation level (minor, major, urgent);
    ii. details of the proposed changes; and
    iii. identification of modified sections;
b. an updated application document with:
    i. all proposed changes marked using track changes;
    ii. previously accepted changes resolved to distinguish only new changes; and
    iii. no changes made outside of the sections identified in the eForm.

(37) On receipt of a variation application, the Animal Ethics Officer is responsible for completing an Administrative Pre-Review as per Table 1.

(38) Where the nominated variation level (i.e. minor, major, urgent) is considered inappropriate, the Animal Ethics Officer must inform the Manager - Animal Ethics who must then contact the relevant research team to seek revision or re-classification.

(39) Researchers must respond to feedback from Administrative Pre-Review or the AEC, within 3 months. The Animal Ethics Officer will issue reminders at 1 and 2 months. If no response is received within 3 months, the variation application will be considered withdrawn.

Major Variation Process

(40) Once the Administrative Pre-Review has been completed by the Animal Ethics Officer, the application must be assigned to two AEC members for Ethics Pre-Review as per the process for Initial Applications.

(41) Prior to assignment to Ethics Pre-Review, the AWO must be consulted by the Animal Ethics Officer for Veterinary Pre-Review where an application involves changes to animal protocols, monitoring, or welfare impacts that require veterinary input.

Minor Variation Process

(42) Minor variations must be reviewed by the Animal Ethics Executive Committee via an expedited pathway with recommendations made to the Animal Ethics Executive Committee Chair for determining the outcome of the minor variation application.

(43) The Animal Ethics Executive Committee should make recommendations to the Animal Ethics Executive Committee Chair within 5 business days of receiving the variation.

(44) In reviewing a minor variation, the Animal Ethics Executive Committee may seek advice from the AWO or other appropriate experts where such advice would assist in assessing potential animal welfare impacts or procedural implications. Consultation does not, of itself, determine whether a variation is minor or major.

(45) Where the Animal Ethics Executive Committee requires additional information or clarification all requests must be communicated to the Research team via the Animal Ethics Officer.

(46) The Animal Ethics Executive Committee may either approve or reject the minor variation application.

(47) Approved minor variations must be reported to, and ratified at, the next meeting of the full AEC.

(48) Where following review and any consultation, the Animal Ethics Executive Committee determines that a minor variation application should instead be treated as a major variation, the Animal Ethics Executive Committee may withdraw the minor variation and either:

a. reclassify it as a major variation and refer it to the AEC for review, with the Animal Ethics Executive Committee acting as Ethics Pre-Reviewers as per Table 1. The research team will be notified of this referral; or
b. determine that the proposed changes fall outside of the scope of the existing approval and require submission of a new Initial Application which will be returned to the research team for resubmission in accordance with Clause 31.

(49) Note: reclassification from minor variation to a new Initial Application should be rare, as such misclassifications should be identified during the Animal Ethics Office Administrative Pre-Review stage prior to Animal Ethics Executive Committee consideration.

Urgent Minor Variation Process

(50) Urgent minor variations may be reviewed and determined by the Animal Ethics Executive Committee via an

expedited process.

(51) Upon receipt of an Urgent Minor Variation submission, the Manager - Animal Ethics must conduct an expedited compliance and classification review to confirm that:

a. the proposed change meets the definition of a minor variation; and
b. urgent consideration is appropriate in the circumstances.

(52) Where confirmed as an urgent minor variation by the Manager - Animal Ethics, the Animal Ethics Executive Committee will review the application as soon as practicable, aiming to provide a decision within hours of receipt.

(53) The Animal Ethics Executive Committee may seek advice from the Animal Welfare Officer or other appropriate experts where such advice would assist in assessing animal welfare implications. Consultation does not alter the classification of the variation.

(54) The Animal Ethics Executive Committee may either approve or reject the urgent minor variation application.

(55) Approved urgent minor variations take effect immediately upon notification of the outcome to the Research team.

(56) All decisions made under the urgent minor variation pathway must be documented and reported to the next AEC meeting for noting and ratification.

(57) Where during expedited review the Animal Ethics Executive Committee determines that an application submitted as an urgent minor variation instead meets the definition of a urgent major variation, the Animal Ethics Executive Committee must not determine the outcome of the application and must initiate the emergency AEC determination process in accordance with Clauses 61-67.

Urgent Major Variation Process

(58) Urgent Variations that meet the definition of a major variation and require immediate consideration to protect animal welfare or safety must be determined by the AEC through an emergency or out-of-session process.

(59) Upon receipt of an Urgent Major Variation application, the Manager - Animal Ethics must conduct an expedited compliance and classification review to confirm that:

a. the proposed change meets the definition of a major variation; and
b. urgent consideration is appropriate in the circumstances.

(60) Where urgent consideration is warranted, the AEC Chair (or Deputy Chair) may convene an emergency AEC meeting or initiate an out-of-session determination, provided that:

a. quorum requirements are met; and
b. appropriate category representation is maintained in accordance with the Code.

(61) Emergency AEC meetings may be conducted by electronic or virtual means and may occur outside the scheduled AEC meeting cycle.

(62) For out-of-session determinations, all eligible AEC members must be provided with the application materials and a defined timeframe for response. Decisions are valid where quorum is met and the determination is agreed by the AEC acting collectively.

(63) The Animal Ethics Executive Committee may coordinate urgent circulation, collate expert advice (including veterinary input from the AWO), and support the emergency decision-making process but is not authorised to make

final determinations for major variations.

(64) Decisions made through emergency or out-of-session processes must be formally recorded and ratified at the next scheduled meeting of the AEC.

External Tissue Use Registration Process

(65) A Registration of Animal Tissue Use (Registration) is required when animal tissues or samples are sourced from external sources for use in activities conducted under the auspices of the University.

(66) Registrations are reviewed by the Animal Ethics Executive Committee to ensure that the proposed use of animal-derived material is consistent with ethical, legal, and institutional requirements, including appropriate sourcing and use.

(67) Detailed guidance for Researchers on when registration is required, how it is submitted, and how it relates to other approval pathways (including collaborative research) is provided in the Animal Research Regulatory Manual.

(68) Where the animal tissues or samples are obtained from an external source and their proposed use does not raise substantive ethical, welfare, or governance concerns, the Registration may be reviewed by the Animal Ethics Executive Committee under an expedited pathway, with a recommendation made to the Animal Ethics Executive Committee Chair for determination.

(69) A registration must be referred to the full AEC for consideration where the proposed use raises uncertainty or complexity that cannot be resolved through expedited review, including but not limited to:

a. unclear or insufficient information regarding the ethical sourcing or provenance of the tissues;
b. inconsistency between the proposed use and the scope of the original approval or consent under which the tissues were collected;
c. potential ethical, welfare, legal or reputational concerns associated with the proposed use;
d. circumstances where the Animal Ethics Executive Committee or Chair determines that full committee consideration is warranted.

Progress Report Process

(70) Approval for animal research projects is granted by the AEC for a defined period of up to 5 years.

(71) Annual progress reports are required to maintain ethics approval. Approval of the progress report must bein place prior to the anniversary of the project ethics approval and to ensure ongoing oversight of animal use.

(72) Continuation of approved projects is supported through the annual review process and issuance of Animal Research Authorities (ARAS). This process enables ongoing animal work within the approved period but does not extend the overall duration of ethics approval.

(73) Where a project is to continue beyond the approved period, a new animal ethics application must be submitted and approved by the AEC prior to further animal use.

(74) For wildlife and livestock research projects, progress report anniversary dates are standardised to align with University reporting requirements.

(75) Where standardised dates apply, the first progress report is due on the assigned date, not the actual approval anniversary. Subsequent reports follow the standardised annual cycle.

(76) Progress reports must be submitted in time for consideration at the AEC meeting immediately prior to the project

anniversary/expiry date. For example, projects expiring in February must have progress reports submitted for consideration at the January AEC meeting. This ensures adequate time for the full review process, including AEC feedback and research team response, prior to project expiry.

(77) Progress reports for teaching projects must include a student evaluation addressing the use of animals in achieving learning objectives. The evaluation must:

a. focus specifically on animal use (not general course content);
b. address the learning objectives outlined in the initial Application;
c. use the AEC Teaching Evaluation Questionnaire or an equivalent fit-for-purpose tool. The AEC will not accept Course Experience Surveys (CES) generated by the University. The evaluation must be specific to the educational use of animals and demonstrate achievement of approved learning objectives.

(78) For field-based wildlife research where a site inspection has not been completed, progress reports must include photos and/or videos of selected field protocols and equipment used, in line with Section 7 of ARRP Guidelines.

(79) Following submission of a progress report the Animal Ethics Officer must conduct an Administrative Pre-Review in accordance with Table 1.

(80) Progress reports that meet the above requirements will be listed on the meeting agenda for AEC consideration.

(81) Where a progress report is not finalised by the anniversary date the ethics approval will automatically expire. The Animal Ethics Officer will notify the research team in writing of the expiry and advise that a new Initial Application must be submitted before any project activities may recommence.

(82) Where an ethics approval expires, all animal use must cease immediately. The care and welfare of animals remains the responsibility of the institution and must continue without interruption. Arrangements may include the transfer of oversight to BioResearch Facilities staff, in consultation with the Animal Welfare Officer, until an appropriate outcome is determined.

(83) The AEC assesses progress reports to determine whether the approved use of animals remains ethically justified and compliant. In doing so, the AEC considers:

a. whether activities have been conducted in accordance with the approved protocol and any conditions of approvla;
b. whether animal welfare outcomes are consistent with those anticipated, including review of any adverse events or unexpected impacts;
c. whether the ongoing use of animals remains justified in light of the progress and outcomes of the project; and
d. whether any modifications, additional conditions, or other actions are required to support animal welfare and compliance.

(84) The AEC does not assess or require approval for additional analyses of previously collected tissues or samples, provided no further animal use or procedures are undertaken and no new animal welfare considerations arise.

(85) Where information contained in a progress report indicates a potential deviation from the approval, any AEC conditions, or University Policy or Procedure, the matter will be managed in accordance with the Non-Compliance Events Procedure (Section 9).

Final Reports – Reporting and Review Process

(86) A final reports is required upon completion, discontinuation, or replacement of a project by a new animal ethics approval.

(87) The final report must be submitted after completion of the project and no later than 2 months after the project end date. Submission of the final report is required to formally close the approval. Upon receipt of a final report, the Animal Ethics Officer must conduct an Administrative Pre-Review in accordance with Table 1.

(88) Following completion of the Administrative Pre-Review, final reports will be listed on the AEC meeting agenda for consideration. Ethics Pre-Reviewers are not assigned, instead, all AEC members must review the reports as part of their meeting preparation.

(89) Final reports are reviewed by the AEC to assess project outcomes and confirm that animal use was conducted in accordance with the ethical approval.

(90) Information from final reports is used to support the AEC Annual Report and legislative reporting requirements.

(91) Where information contained in a final report identifies or reasonably suggests that animal research activities were not conducted in accordance with the approval, any AEC conditions, or University policy or procedure, the matter will be managed in accordance with the Non-Compliance Events Procedure (Section 9).

Unexpected Adverse Events – Reporting and Review Process

(92) Requirements for the identification, management, and reporting of Unexpected Adverse Events are set out in the Animal Research Regulatory Manual.

(93) Upon receipt of an Unexpected Adverse Event Report, an initial review must be undertaken by the AEC Chair, the AWO and the Manager - Animal Ethics to assess:

a. the nature and severity of the event;
b. whether the event aligns with the ethical approval.

(94) Where an event has, or is likely to have, a significant or ongoing impact on animal welfare the report must be circulated to the Animal Ethics Executive Committee for immediate out of session consideration.

(95) Reports of unexpected adverse events with no significant or ongoing impact to animal welfare will be reviewed at the next ordinary meeting, unless an urgent request for review or modification is made by the research team.

(96) Any request for out-of-session AEC consideration arising from an unexpected adverse event will be managed in accordance with the procedure for handling urgent variations where applicable.

Requested Report Process

(97) Requested reports are reports specifically required by the AEC as a condition of ethics approval or ongoing oversight. These may include, but are not limited to, pilot studies, interim milestone reports, breeding reports, and other conditional reports specified by the AEC.

(98) All requested reports must be submitted via RIMS.

(99) Upon receipt of a requested report, the Animal Ethics Officer will conduct a Administrative Pre-Review in accordance with Table 1 to confirm:

a. the report addresses the specific requirements and scope outlined in the approval conditions; and
b. all required supporting documentation has been provided (for example, monitoring records, photographs, videos, data summaries, or other specified materials).

(100) Following the Administrative Pre-Review, the Animal Ethics Officer will forward the report to the Animal Ethics

Executive Committee for review. The Animal Ethics Executive Committee will determine whether:

a. the requested requirements have been satisfactorily met and make a recommendation to the AEC Executive Committee Chair that the project should proceed; or
b. the matter requires referral to the AEC for consideration.

(101) The outcome determined by the Animal Ethics Executive Committee Chair must be communicated to the research team via the Animal Ethics Office.

(102) Where the AEC Executive Committee Chair determines that the requested report requirements have been satisfied and the project or activity may proceed, the decision must be ratified at the next full AEC meeting.

(103) Where concerns are identified that require further information, modification, or additional conditions, the matter must be referred to the AEC, and the research team must be notified of this referral via the Animal Ethics Officer.

Section 7 - Committee Review, Decision Making and Implementation

Meeting Schedules and Procedures

(104) The routine meeting dates for the calendar year are published on the ResearchHub.

(105) The AEC may also hold additional meetings, if required, at times agreed by the members.

Submission Review Process at Meetings

(106) During review of submissions, the AEC assess whether any proposed or continued use of animals in a project is ethically justified by weighing:

a. potential impacts on animal wellbeing;
b. scientific or educational benefit; and
c. ethical issues identified by the applicant and AEC members.

(107) When considering ethics approval for the re-use of animals, the AEC considers:

a. the pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions;
b. the time allowed for recovery of the animals between activities;
c. whether an animal has fully recovered from the previous activities;
d. the pain and distress likely to be caused by the next and subsequent activities; and
e. the total time over which an animal will be used (as per the Code, Clause 2.3.15).

(108) Researchers may attend AEC meetings to discuss their application and respond to questions. Attendance is arranged via the submission e-form or by contacting the Animal Ethics Officer.

(109) Discussion of each application is led by the assigned Ethics Pre-Reviewers, or by the Animal Ethics Executive Committee if a minor variation has been referred to the AEC.

(110) All members are expected to read agenda materials in full and participate actively in discussion and decision-making. The Ethics Pre-Review process does not replace the responsibility of all members to consider each item

thoroughly.

Decision Making Process

(111) AEC decisions must be made in accordance with relevant legislative requirements, with particular reference to the principles outlined in the Code Clause 1.1, and where subject to a delegation of authority, the Delegation of Authority Framework. The decision-making process proceeds as follows:

a. Presentation of Application: Assigned Ethics Pre-Reviewers present their assessment of the application to the AEC.
b. Committee Discussion: All members are invited to contribute comments, questions, or concerns. The Chair must ensure that all views are heard and considered.
c. Recommendation: Ethics Pre-Reviewers propose a recommendation based on their review and the AEC discussion.
d. Consensus Seeking: The Chair must seek agreement from all members on the proposed recommendation. If consensus is reached and the meeting is in quorate, the recommendation is adopted.
e. Further Deliberation: If consensus is not reached, further discussion occurs to explore potential modifications to the project that may resolve concerns.
f. Majority Decision: If consensus remains unachievable after reasonable effort, the AEC may proceed to a majority decision. This occurs only after members have had time to reflect on their positions and further discussion has taken place. A decision may span multiple meeting cycles if required.
g. Recording Dissent: Any member who disagrees with the final decision may request that their dissenting view be formally recorded in the meeting minutes.

Decision Types and Implementation

(112) Decision by the AEC in relation to applications to commence, vary, or renew a project or activity must be categorised in accordance with Table 2.

(113) All AEC decisions must be clearly documented, including the decision outcome, any conditions imposed, and associated requirements and timelines for implementation.

(114) The Animal Ethics Office is responsible for ensuring all Researchers named on the application are notified in writing of AEC decisions within 7 business days.

Table 2 – AEC Ethics Application Decision Types and Implementation

Decision Type	Definition	Implementation
Ethics approval is granted.	The application is granted full ethics approval.	The AEC recommends an Animal Research Authority(ARA) to be issued to allow commencement of the project or activity.
Ethics approval is granted, subject to specified conditions (see Table 3).	Ethics approval subject to pre-commencement or ongoing conditions.	The AEC recommends an ARA be issued to allow commencement of the project or activity, subject to conditions detailed in the approval letter. The completion of conditions are tracked by the Animal Ethics Officer via an Outstanding Items Register.
Ethics approval is pending completion of minor modifications (administrative).	Clerical or administrative issues.	Researchers must revise their application. Upon confirmation by the Animal Ethics Officer that the administrative corrections requested by AEC have been addressed, the ethics approval notification and ARA recommendation will be issued.

Decision Type	Definition	Implementation
Ethics approval pending completion of minor modifications (ethical).	Minor ethical issues raised by AEC requiring satisfactory resolution.	Where the AEC has identified minor ethical concerns, completion of the required modifications will be reviewed by the assigned Ethics Pre-Reviewers or the Animal Ethics Executive Committee, as appropriate, to verify that the concerns have been satisfactorily addressed in accordance with the AEC's decision. Final ethics approval and the ARA recommendation will then be issued.
Application is Deferred – Major modifications.	Significant ethical issues that require full AEC review and the provision of additional information before a decision can be determined.	The research team must resubmit a revised application which will be reviewed by the AEC at a future meeting.
Not approved.	The application cannot be ethically approved.	The research team may submit a new application.
Referred for non-compliance review.	Potential breach of the Code or protocol.	Managed under Section 9.

(115) Specified conditions are categorised as either pre-commencement or ongoing, as outlined in Table 3.

(116) The ethics approval notification and ARA will specify:

a. which conditions must be met before the project or activity commences (pre-commencement conditions);
b. which conditions apply during the conduct of the project or activity (ongoing conditions);
c. timeline requirements for meeting the specified conditions; and
d. reporting requirements for specified conditions.

(117) Where pre-commencement conditions apply, a new ARA without conditions will be issued once those conditions have been met.

Table 3 – Specified Conditions Associated with Ethics Approval

Condition Type	Requirements	Examples
Pre Commencement Conditions	Must be fulfilled before the project or activity may commence and be reported to the AEC for approval prior to commencement. These reports are reviewed by the Animal Ethics Executive Committee as outlined in Section 5.	- Completion of pilot studies and submission of reports. - Observation of initial animal protocols by the AWO or an AEC subcommittee. - Site inspections or facility modifications. - Additional training requirements for personnel.
Ongoing Conditions	Become part of the ethics approval. Must be maintained throughout the project or activity period.	- Enhanced monitoring protocols or welfare assessments. - Regular interim reporting at specified milestones. - Modifications to experimental design, animal protocols, or timelines. - Consultation with specialists or external advisors.

(118) All conditions imposed by the AEC must be recorded in the Outstanding Items Register. The Animal Ethics Officer is responsible for:

a. updating the Register based on information received from the research team;
b. reporting the status of all outstanding conditions to the AEC at each meeting.

(119) The Outstanding Items Register is reviewed by the AEC at each meeting. Researchers are expected to respond promptly to enquiries and provide updates on progress, recognising that some conditions may require extended timeframes to fulfil due to experimental or project specific requirements.

(120) The research team is responsible for complying with all specified conditions of approval. Failure to comply may result in suspension or withdrawal of ethical approval. Commencement of the activity constitutes acceptance of all specified conditions by the research team. If the Chief Investigator disagrees with any condition, they may request a review of the AEC's decision.

(121) Where pilot studies are imposed as a condition of approval, the AEC will specify the requirements for the pilot phase. Ethical approval for the entire project or activity must be contingent on the review of pilot outcomes and any required amendments.

Deferred Applications

(122) The Animal Ethics Office is responsible for communicating any deferral decision with feedback outlining:

a. the specific issues that must be addressed;
b. required modifications, additional information, or procedural requirements needed (including peer review where applicable); and
c. timeline expectations for resubmission.

(123) Deferred applications may be resubmitted when the research team has addressed all identified issues.

(124) Resubmitted applications must undergo an Administrative Pre-Review (Table 1) before being listed on an agenda for AEC consideration.

(125) The AEC review should focus on whether the specific issues causing the prior deferral have been satisfactorily addressed, and whether any modifications create new concerns.

(126) Responses to deferrals should be received within two AEC meeting cycles, as defined in this procedure. Where a research team anticipates that additional time is required (for example to undertake substantive consultation, obtain expert advice, or revise study design), the research team must advise the Animal Ethics Office as soon as practicable. The AEC Chair (or their nominee) may approve an extension where a reasonable justification has been provided. Failure to respond within the required timeframe, without prior notification or an approved extension, will result in the application being classified as withdrawn. Written notification will be provided to the research team where an application is withdrawn.

(127) For progress reports, final reports, and inspection reports: Researchers must respond within two AEC meeting cycles. Withdrawal is not permitted due to regulatory and welfare obligations. These matters will be considered as a potential breach of Clause 2.4.34 of the Code and must be managed under the AEC Non-Compliance Management Procedure (Section 9).

(128) If a response has not been received within the specified time, the following reminders will be issued by the Animal Ethics Office:

a. Initial reminder: the outcome letter notifying of deferral will be reissued 15 working days prior to the next AEC meeting.
b. Secondary reminder: follow-up communication will be sent one week after the initial reminder if no response is

received from the initial reminder.

c. Final deadline: the final notification will request that a response must be received five working days prior to the relevant AEC meeting.

(129) For all other application types, failure to respond by the final deadline will result in the application being considered abandoned and a new application process must be commenced.

Applications Not Approved

(130) An applications will not be approved where the AEC determines it cannot be ethically justified, either due to fundamental ethical concerns that cannot resolved or because the proposed activity or project does not meet acceptable animal welfare standards.

(131) Reasons for non-approval include but are not limited to:

a. fundamental ethical objections to the proposed project or activity;
b. inadequate justification for animal use;
c. unacceptable animal welfare implications that cannot be mitigated;
d. failure to demonstrate adherence to 3Rs principles;
e. serious concerns about Researcher competence or institutional capacity; or
f. non-compliance with regulatory requirements that cannot be resolved.

(132) The Animal Ethics Office is responsible for communicating the non-approval decision with detailed rationale explaining the following:

a. the specific reason(s) for non-approval;
b. the fundamental concerns identified by the AEC; and
c. why the issues cannot be resolved through modification.

(133) Non-approval constitutes the final decision for the submitted application. Researchers may submit a new Initial Application addressing the fundamental concerns. This constitutes a new submission, not a resubmission.

(134) New applications must demonstrate substantial changes to address the ethical concerns that led to the original non-approval.

Final Reports

(135) When reviewing final reports the AEC may determine an outcome of:

a. Noted: The report is complete and no further action is required.
b. Deferred: Additional information is required before the report can be accepted.
c. Referred for Non-Compliance Review (as per Section 9).

Unexpected Adverse Event Reports

(136) When reviewing Unexpected Adverse Event Reports, the AEC will consider the research team’s description of the event and the actions already taken in response. To ensure animal welfare and prevent further harm, the AEC may take interim risk management actions, including but not limited to:

a. requesting further information or consultation with relevant stakeholders e.g. the Researchers, AWO, and/or BioResearch Facilities staff.
b. suspending or restricting elements of the ethical approval until identified risks are mitigated;

c. temporarily transferring responsibility for animal monitoring to BioResearch Facilities staff where necessary to ensure animal welfare.

(137) Following consideration of an Unexpected Adverse Event Report, the AEC will determine one of the following outcomes in relation to the status of the report:

a. Noted – The unexpected adverse event has been appropriately managed and documented. No further action is required.
b. Noted with Conditions – The activity or project may continue, subject to specified conditions to support appropriate management and prevent recurrence. Conditions may include, but are not limited to, enhanced monitoring protocols, additional training, procedural modifications, equipment servicing or replacement, follow-up reporting, or consultation with specialists.
c. Deferred – Additional information is required before the AEC can make a final determination regarding the unexpected adverse event. Researchers must respond to a deferred Unexpected Adverse Event Report by the submission deadline for the subsequent AEC meeting. Failure to provide a response by the required deadline will constitute a suspected non-compliance and will be managed in accordance with the AEC Non Compliance Events Procedure (Section 9).
d. Referred for Non-Compliance Review – The Unexpected Adverse Event Report constitutes a suspected breach of the ethics approval or the Code and must be managed under the AEC Non-Compliance Events Procedure (Section 9).

(138) The AEC will determine one of the following outcomes in relation to the continuation or cessation of the approved project or activity in which the unexpected adverse event occurred:

a. Continued – The project or activity may proceed without modification;
b. Suspended – Ethical approval of the project or activity is temporarily suspended until specified conditions are met (e.g., training, protocol modification, equipment servicing); or
c. Withdrawn - Ethics approval is withdrawn as the impact to animals can no longer be ethically justified, or non-compliance is confirmed.

(139) Events are recorded in the Unexpected Adverse Events Register which is maintained by the Animal Ethics Office.

Recording of Decisions

(140) All decisions of the AEC are minuted by the Animal Ethics Officer. Minutes must include the decision made, dissenting views, and the main points of discussion.

(141) Feedback to the research team after each AEC meeting will include the reason(s) for the decision, as required in the Code (Clause 2.2.27).

(142) The AEC may identify other issues that, while outside their area of responsibility, are required to be considered by the University administration (e.g. reputational or indemnity issues). In such instances the AEC must refer those matters to the Deputy Vice-Chancellor (Research and Innovation). Any such referral may impede the issuing of an Animal Research Authority.

(143) The Animal Ethics Officer must circulate the draft minutes of each AEC meeting to AEC members with the agenda papers for the subsequent meeting. Any comments or proposed corrections may be tabled for consideration and endorsement at that meeting.

(144) Where follow-up action is required as part of an AEC decision, the proposed action must be listed in the Outstanding Items Register by the Animal Ethics Officer for consideration as business arising.

(145) The Animal Ethics Officer must circulate the Outstanding Items Register with the agenda for each meeting.

Issuing of Animal Research Authorities (ARA)

(146) Where satisfied that a project or activity is ethically justified, the AEC may grant ethical approval and make a recommendation that an Animal Research Authority (ARA) be issued.

(147) In accordance with Section 25 of the NSW Animal Research Act, an ARA may be issued only by the University as an accredited research establishment, and only on the recommendation of its AEC.

(148) Ethical approval granted by the AEC is a necessary precondition for the issuing of an ARA but does not, of itself, authorise the commencement of animal research activities. Animal research activities may not commence until an ARA has been issued.

(149) The authority to issue an ARA is exercised by the University under an approved delegation of authority. The issuing of an ARA must be consistent with the scope, conditions, and duration of the ethical approval granted by the AEC and any additional institutional requirements.

(150) An ARA may be issued for a maximum period of 12 months. Where an approved project or activity is expected to extend beyond this period, the research team must apply for renewal of the ARA through submission of a project progress report to the AEC for review, ethical approval continuation and recommendation for re-issuance.

(151) Where an AEC ethical approval expires, is suspended, or is withdrawn, any associated ARA is no longer valid, and all animal research activities conducted under that authority must cease immediately unless otherwise directed by the AEC.

Appealing Decisions of the AEC

(152) If a Chief Investigator wishes to appeal a decision of the AEC, a written request must be lodged with the Animal Ethics Officer for consideration within 14 working days of the date of the notification of the decision.

(153) An appeal of an AEC decision may be lodged only on one or more of the following grounds:

a. Procedural Error: A departure from this Procedure, the AEC Terms of Reference, or the requirements of the Code has occurred that may have affected the decision.
b. Relevant Information not considered: Significant new information has been obtained that was not reasonably available to the research team at the time of the original review and that may materially affect the ethical assessment; or
c. Error of Fact: A demonstrable misunderstanding or misinterpretation of key factual information in the application may have occurred that materially influenced the decision.

(154) Appeals cannot be lodged solely on the basis of disagreement with the AEC's ethical judgment or weighing of harm and benefit.

(155) An appeal does not constitute a re-submission or new ethics review and must be confined to the grounds outlined above.

(156) The written appeal must include:

a. the specific grounds for appealing the AEC decision;
b. detailed response to the AEC's concerns or rationale;
c. any supporting evidence or documentation relevant to the appeal;
d. confirmation of the Investigator or Lead Animal Investigator's availability to attend the next AEC meeting.

(157) Appeals will be considered at the next scheduled AEC meeting following receipt of the written appeal. The Chief Investigator and/or Lead Animal Investigator must attend the meeting to present their case and respond to questions. Failure to attend will result in the appeal being withdrawn.

(158) The Chief Investigator and/or Lead Animal Investigator will not be present during the AEC's deliberations or decision-making on the appeal.

(159) In considering an appeal, the AEC will review:

a. the original decision and rationale;
b. the written appeal and supporting materials;
c. the Chief Investigator and/or Lead Animal Investigator's presentation and responses to Committee questions.

(160) Following consideration, the AEC may:

a. uphold the original decision;
b. modify the original decision; or
c. reverse the original decision.

(161) The Chief Investigator will be notified accordingly in writing of the appeal outcome, providing transparency in relation to how the determination was made.

(162) The AEC's decision on the appeal is final and there is no further avenue of appeal within the University.

Section 8 - Ongoing Oversight and Monitoring

Routine Inspections

(163) The AEC must conduct routine inspections of all licensed animal research premises at least annually in accordance with the Animal Research Review Panel guidelines. Routine inspections may be either scheduled or non-scheduled (unannounced).

(164) The Animal Ethics Officer will release the annual inspection schedule at the first AEC meeting of each calendar year, accompanied by a call for member participation.

(165) Each routine inspection should be conducted by an Inspection Team, usually comprised of:

a. AEC Chair;
b. one category B member (academic member / research ethics advisor);
c. one category C or D member; and
d. AWO.

(166) Routine inspections must assess:

a. compliance with approved animal protocols and procedures;
b. animal housing and welfare standards;
c. facility conditions and maintenance; and
d. record keeping and documentation.

(167) Inspection processes will include reasonable steps to minimise disruption to ongoing animal procedures where this does not compromise the purpose of the inspection. While inspections are generally conducted without prior

notice, arrangements may be made in specific circumstances to facilitate access or engagement with research personnel. Where possible, inspection teams will engage with available Investigators to discuss observations and findings at the time of inspection.

(168) Following a routine inspection, the Inspection Team must prepare a formal inspection report for submission to the next available full AEC meeting. The report must include:

a. confirmation that an inspection was conducted;
b. whether the facility /or property is fit for purpose;
c. significant findings, including areas of good practice and areas of concern;
d. any required follow up actions and recommendations; and
e. confirmation of resolution where previously identified issues have been addressed.

(169) The AEC must consider and discuss the inspection report and its findings at the meeting at which it is tabled. Any required actions arising from the inspection must be determined by the AEC and communicated to the relevant research team(s) and/or facility managers following that meeting.

(170) Research teams and/or facility managers must respond to actions arising from routine inspections by the submission deadline for the second AEC meeting following the meeting at which the inspection report was considered, unless an alternative timeframe is specified by the AEC.

(171) Failure to meet the response deadline will constitute a potential breach of Clause 2.4.34 of the Code and will be managed in accordance with the AEC Non-Compliance Management Procedure (Section 9).

(172) Where inspection findings raise immediate or serious concerns for animal welfare, human safety, or regulatory compliance, the AEC Chair in consultation with the AWO and the Animal Ethics Executive Committee may direct the immediate suspension or restriction of animal research activities pending further review. Any such interim action will be reported to the next AEC Meeting for ratification.

Ad Hoc Inspections

(173) Adhoc inspections are distinct from routine inspections in that they are initiated in response to specific concerns or emerging risks. As such, adhoc inspections may require immediate access, unannounced attendance, and the exercise of emergency welfare powers that are not ordinarily required during routine inspections.

(174) In accordance with ARRP Guidelines, adhoc inspections may be initiated in response to:

a. Adverse Event Reports indicating potential facility or procedural issues;
b. complaints or concerns raised about animal welfare or facility conditions;
c. non-compliance reports requiring on-site assessment;
d. follow-up to routine inspection findings requiring additional verification;
e. information received suggesting protocol deviations or welfare concerns;
f. request from regulatory bodies or institutional authorities.

(175) The following parties may initiate an adhoc inspection:

a. the AEC;
b. the Animal Ethics Executive Committee;
c. the AWO in consultation with the AEC Chair and/or Director, Research Ethics & Integrity where issues are emergent or urgent;
d. Researchers seeking advice on high-risk animal protocols or pilot activities requiring inspection or observation

to assess animal welfare impacts;

e. the Research Ethics and Integrity Unit.

(176) At a minimum, adhoc inspections must be conducted by the AWO. Attendance by the AEC Chair or other AEC members may be considered necessary based on the nature of the inspection or issues being assessed. Final Inspection Team composition will be determined by the party initiating the inspection according to the specific circumstances and expertise required.

(177) Adhoc inspections should be unannounced to ensure authentic assessment of day-to-day operations. However, where specific animal protocols need to be observed, inspections must be arranged with the research team ahead of time to facilitate observation of the relevant activities.

(178) Urgent inspections may be conducted immediately without prior notification where animal welfare concerns require immediate assessment.

(179) The following requirements of the Code (Clauses 2.1.5.4 and 2.5.6) should be adhered to during an adhoc inspection:

a. animal carers and inspection team members must take reasonable steps to first contact the responsible Researcher where emergency welfare intervention is considered necessary;
b. animal welfare must be the priority at all times and may necessitate immediate intervention including emergency treatment or humane killing of animals;
c. immediate interventions may be undertaken without prior research team consultation where animal welfare necessitates this action.

(180) Where authority for emergency interventions has been enacted:

a. the Chief Investigator / Lead Animal Investigator must be promptly advised of any actions taken and the reasons for emergency interventions;
b. all emergency interventions must be reported to the AEC in accordance with unexpected adverse event reporting procedures;
c. performance of necropsy and access to diagnostic investigations must be arranged as required by the circumstances.

(181) The AWO is responsible for ensuring that all adhoc inspections and any emergency interventions are comprehensively documented including:

a. the timing and nature of the inspection;
b. any immediate welfare interventions undertaken;
c. liaison and communications with Researchers, facility staff, and AEC representatives; and
d. any required follow-up actions and timeframes.

(182) Documentation must be provided to the Animal Ethics Office for inclusion in the official AEC records and reporting.

Section 9 - Non Compliance Events Procedure

Identification and Reporting of Non-Compliance Events

(183) Non-compliance means any failure to comply with:

a. an approved Animal Research Authority or ethics approval;
b. the Australian Code for the Care and Use of Animals for Scientific Purposes;
c. this Procedure, the Animal Research Regulatory Manual, or associated AEC Governance instruments; or
d. conditions imposed by the AEC.

(184) Potential non-compliance may be identified through various means, including but not limited to:

a. AEC or AWO inspections;
b. routine observation of animals and facilities by BioResearch Facilities or Animal Ethics Office staff;
c. information disclosed in applications or reports submitted to the AEC;
d. media reports, and anecdotal information;
e. formal complaints from University staff, students, or external parties;
f. concerns identified during AEC meetings.

(185) All potential instances of non-compliance must be directed to the Animal Ethics Office via animal-ethics@newcastle.edu.au.

(186) Matters involving urgent animal welfare concerns must be communicated immediately to:

a. the AEC Chair (or Deputy Chair in their absence);
b. the AWO for animal health, welfare, or veterinary concerns;
c. the Operations Manager, BioResearch Facilities for facility-related emergencies (infrastructure failures, security breaches, environmental hazards, suspected disease outbreaks);
d. both AWO and Operations Manager, BioResearch Facilities where concerns involve both animal welfare and facility issues.

(187) The person reporting the concern must submit a formal report containing all relevant information to the Animal Ethics Office following any immediate intervention, regardless of who conducted the intervention. The report must be provided in writing (e.g. by email or institutional reporting forms via the ServiceNow portal).

(188) In instances where the person making the report wishes to remain anonymous, complaints can be made to the Research Ethics and Integrity Unit via the ServiceNow portal. After initial review the Research Ethics and Integrity Unit it will be determined if the matter is referred to the AEC or managed under the University's Research Breach Investigation Procedure.

(189) Initial assessment of reported non-compliance by the Manager - Animal Ethics should commence as soon as practicable and ordinarily within five business days of receipt, noting that urgent animal welfare matters must be addressed immediately.

General Framework

(190) Matters of non-compliance must be graded in accordance with Table 4.

(191) Detailed grading criteria and examples are available in the Non-Compliance Grading Reference Table on ResearchHub.

Table 4 AEC Non-Compliance Grading

Grade	Detail	Management Pathway
Administrative/technical	The matter is limited to procedural compliance issues.	Manager – Animal Ethics

Grade	Detail	Management Pathway
Minor	Minor deviations from the ethics approval are evident, with no or minimal welfare implications.	AEC
Moderate	Notable deviations from the ethics approval are evident and represent minor welfare impacts and/or near-miss learning opportunities.	AEC -where no realised animal welfare impact. Research Breach Investigation Procedure for moderate deviations with realised animal welfare impact.
Serious	Major deviations from the ethics approval are evident with significant welfare risks or regulatory implications requiring intervention.	Research Breach Investigation Procedure

(192) For the purposes of this procedure, a non-compliance event becomes a potential research breach where the matter is graded as “moderate” with realised impact on animal welfare, or “serious” and is therefore required to be managed under the University's Research Breach Investigation Procedure.

(193) The Chief Investigator, Lead Animal Investigator, and any Researcher directly involved in the potential non-compliance must be notified by the Manager - Animal Ethics of the management pathway.

(194) Where appropriate and not in breach of confidentiality provisions, the Manager - Animal Ethics may inform the complainant of the proposed management pathway.

(195) At any stage of the initial assessment of the non-compliance and management process in this document, the AEC Chair may decide to take immediate action in order to ensure animal welfare or prevent a recurrence of the non-compliance.

(196) This action may include ordering emergency treatment, relocation of animals, or the emergency euthanasia of animals if deemed essential for animal welfare.

(197) Actions taken by the AEC Chair may precede a response to the complainant or the alleged person/s involved, if deemed urgent.

(198) Communication of required actions will be provided to all relevant parties as soon as practicable by the Manager - Animal Ethics.

(199) If there is ongoing potential for adverse effects on animal welfare, the AEC or AEC Chair may suspend the ethical approval of the project by issuing an instruction to the project’s Chief Investigator to immediately cease all activities involving animals in the project (other than ongoing maintenance of the animals).

(200) Suspension notices will be automatically copied to Associate Dean (Research) for the College, Head of School (or their nominee), and the Operations Manager, BioResearch Facilities to ensure compliance with the suspension and to facilitate any support measures which may be required for maintenance of animal welfare.

(201) Routine care of animals may be assigned to BioResearch Facilities technicians if required during assessment of non-compliance by the AEC. This must be overseen by the AWO and/or Operations Manager, BioResearch Facilities as necessary.

Direct Reports of Potential Non-Compliance

(202) Where potential non-compliance is reported directly to the Animal Ethics Office or identified by the AWO, an initial assessment must be conducted by the Manager - Animal Ethics.

(203) This initial assessment process applies to potential non-compliance related to animal research activities and animal welfare. Any potential breaches of the Australian Code for the Responsible Conduct of Research that are not directly related to the conduct of animal research, will be referred directly to the Research Ethics and Integrity Unit by the Manager - Animal Ethics for management via the Research Breach Investigation Procedure without grading or initial assessment.

(204) Upon receipt of a direct report of potential non-compliance, the Manager - Animal Ethics will:

a. document the report in the AEC Non-Compliance Register with date, time, source, and nature of concern;
b. assign a unique reference number for tracking;
c. acknowledge receipt of the report in writing and notify the Chief Investigator and Lead Animal Investigator that a potential non-compliance has been raised;
d. request any additional information from the complainant, Chief Investigator and Lead Animal Investigator and/or research team members identified in the non-compliance (including students); and
e. initiate immediate welfare interventions if required before proceeding with formal assessment.

(205) The initial assessment by the Manager - Animal Ethics will entail:

a. review of all available information and documentation;
b. determining the nature and scope of the potential non-compliance;
c. consultation with relevant personnel (AWO, BioResearch Facilities staff, Researchers, Animal Ethics Executive Committee) as appropriate;
d. assessment of animal welfare implications; and
e. determining whether a potential non-compliance has occurred.

(206) Where the non-compliance relates to an activity that may affect an animal's welfare or present a breach to legislation, the report will be forwarded to the Animal Ethics Executive Committee for review.

(207) The Animal Ethics Executive Committee will take immediate corrective action to ensure animal wellbeing is not compromised. This may include:

a. clarification from the project Chief Investigator, Lead Animal Investigator, and/or Researchers identified in the non-compliance (including students);
b. clarification from the AWO and/or animal technicians; and/or
c. suspension of activities.

(208) Following any immediate corrective actions, the Animal Ethics Executive Committee must grade the potential non-compliance using the categories identified in Table 4.

(209) Matters graded as 'Moderate' with realised impact on animal welfare, or 'serious' must be referred to the Research Ethics and Integrity Unit under the Research Breach Investigation Procedure.

(210) Matters graded as 'minor' or 'moderate' with no realised impact on animal welfare must be placed on the next AEC meeting agenda for consideration and final determination of outcomes.

(211) Where the initial assessment determines that the reported activities were compliant with the ethics approval and institutional requirements, the matter will be:

a. documented in the AEC Non-Compliance Register with rationale for the determination;
b. the complainant (where identifiable) will be notified of the outcome and rationale;

c. the research team/ Chief Investigator/Lead Animal Investigator will be formally notified that no non-compliance was found and that their conduct was determined to be appropriate;
d. where notifications were made to institutional officials, supervisors, or other parties during the initial assessment process, those parties will be formally advised of the outcome that no breach occurred;
e. any record of the investigation must reflect the outcome that no breach occurred, ensuring protection of the Researcher's reputation and professional standing; and
f. closed with no further action required.

AEC Identified Potential Non-Compliance

(212) Where potential non-compliance is identified during AEC business (including through Unexpected Adverse Event Reports, progress reports, applications, or inspections), the matter must be graded by the AEC and managed in accordance with Table 4.

(213) Matters graded as 'Moderate' with realised impact on animal welfare, and all matters graded as 'Serious', must be referred to the Research Ethics and Integrity Unit for management under the Research Breach Investigation Procedure. Immediate actions to ensure animal welfare may be taken prior to or concurrent with referral.

Management Pathways

Manager Animal Ethics Pathway

(214) Where the non-compliance is determined to be Administrative/Technical (procedural compliance issues with no animal welfare impact), the Manager - Animal Ethics must:

a. handle the matter directly through administrative resolution;
b. document the outcome in the AEC Non-Compliance Register; and
c. report the resolution to the next AEC meeting via the Register.

AEC Pathway

(215) Where the non-compliance does not relate to an activity that may affect animal welfare or present a breach to legislation, policy or procedure, but is not Administrative/Technical in nature, the report will be tabled for grading at the subsequent AEC meeting.

(216) The AEC will determine:

a. if additional information is required;
b. specific questions to be addressed; and
c. evidence or documentation needed.

(217) Formal outcomes of the discussion will be issued by the AEC to relevant parties via the Animal Ethics Office;

(218) The Manager - Animal Ethics will be responsible for:

a. collating responses from Researchers and other parties;
b. ensuring completeness of responses; and
c. gathering any additional evidence required by the AEC.

(219) All responses and evidence will be tabled for discussion at the next available AEC meeting for determination of outcomes.

(220) The Chief Investigator and/or Lead Animal Investigator (or nominee) may be invited to attend the meeting to:

a. contribute to discussion of the non-compliance;
b. respond to subcommittee recommendations; and
c. provide additional context or information.

(221) The Chief Investigator and/or Lead Animal Investigator must not be present during deliberations to inform the AEC's final decision.

(222) Outcomes from the AEC may include the following measures directed to the research team and/or the AEC/Institution as appropriate to the circumstances:

a. corrective actions to address identified issues;
b. recommended preventive measures to avoid recurrence;
c. additional training or procedural corrections; and/or
d. referral to the Research Ethics and Integrity Unit where the matter represents a more serious issue than initially assessed, or constitutes a potential breach of the Code.

(223) The Animal Ethics Officer is responsible for communicating outcomes to relevant parties, including:

a. Chief Investigator, Lead Animal Investigator, and involved personnel;
b. Research Ethics and Integrity Unit (for noting);
c. Head of School (or their nominee) as responsible for overseeing any implemented corrective and preventative actions;

(224) The Animal Ethics Officer must add the following items to the Compliance Register to ensure appropriate follow-up:

a. any scheduled follow-up review if required by the AEC (e.g. AWO monitoring, site inspections);
b. monitoring of implementation of corrective actions.

Status and Details

Status	Current
Effective Date	14th September 2026
Review Date	14th September 2027
Approval Authority	Academic Senate
Approval Date	11th August 2026
Expiry Date	Not Applicable
Responsible Executive	Craig Simmons Deputy Vice-Chancellor (Research and Innovation)
Enquiries Contact	Jodie Marquez Director, Research Ethics & Integrity

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.

"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.

"Personnel" - In relation to a party, any employee, officer, agent, contractor, sub-contractor, student or volunteer of that party.

"Postgraduate" - Any qualification being at the level of Graduate Certificate or above.

"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.

"Undergraduate" - Refers to any qualification up to and including the level of a Bachelor Honours degree.

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