Animal Research Regulatory Manual

Section 1 - Introduction

(1) The University of Newcastle (University) recognises the value of research involving animals and supports the use of animals in research where:

a. the welfare of research animals is assured;
b. the principles of Replacement, Reduction, and Refinement (the 3Rs), and responsibilities as described in the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition (2013) (the Code), and A Guide to the Care and Use of Australian Native Mammals in Research and Teaching are applied; and
c. the research complies with the relevant legislation and is ethically sound with potential benefits to humans, animals, or the environment.

(2) In accordance with the Animal Research Act 1985 No 123 (the Act) and Animal Research Regulation 2021 (NSW) (the Regulation), the University will maintain accreditation as an animal research establishment.

(3) This Manual must be read in conjunction with the University's associated policies, applicable legislation, and any associated information regarding the use of animals in research, including but not limited to:

Legislation

a. Animal Research Act 1985 No 123;
b. Animal Research Regulation 2021 (NSW);
c. Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition (2013);
d. Prevention of Cruelty to Animals Act 1979;
e. Poisons and Therapeutic Goods Act 1966 No 31;
f. Poisons and Therapeutic Goods Regulation 2008;
g. Drug Misuse and Trafficking Act 1985;

University Policies, Procedures and Guidelines

a. Responsible Conduct of Research Policy;
b. Collaborative Research Procedure;
c. Research Peer Review Procedure for Ethics Applications.

External Resources:

a. Best Practice Methodology in the Use of Animals for Scientific Purposes (2018);
b. Use of Animals in NHMRC Funded Research;
c. A Guide to the Care and Use of Australian Native Mammals in Research and Teaching;
d. Genetically Modified and Cloned Animals;
e. PREPARE Guidelines for Planning Animal Research;
f. Animal Research: Reporting of In Vivo Experiments (ARRIVE) Guidelines;

g. Department of Primary Industries - The Use of Restricted Drugs and the Conduct of Restricted Acts of Veterinary Science in Animal Research.

Section 2 - Scope and Audience

(4) This Manual applies to:

a. the breeding, care, and use of all animals at the University for the purposes of research and teaching, as defined by the Animal Research Act 1985 No 123. While it provides comprehensive expectations for ethical and compliant animal research, operational procedures for the Animal Ethics Committee (AEC) are outlined in the Animal Ethics Committee Procedure and Terms of Reference;
b. all staff, students, and affiliates involved in the care and use of animals for scientific purposes under the auspices of the University, including research, teaching and testing activities.

Section 3 - Intent

(5) This Manual and its associated documents ensure that all personnel engaged in animal research comply with ethical guidelines and legislation. Operational and governance-related procedures for the AEC are described separately in the Animal Ethics Committee Procedure Manual and Terms of Reference.

Section 4 - Document Specific Definitions

(6) In the context of this Manual, the following definitions apply:

a. “Acclimatisation period” means the length of time given to animals that are newly received by the University for physiological, behavioural and nutritional acclimatisation prior to their use in a research project. The minimum acclimatisation period 5 days, unless otherwise approved by the AEC.
b. “Adverse Event” means any occurrence, wether anticipated or unanticipated, and whether arising as a single incident or a cumulative series of events, that results in, or has the potential to result in, a negative impact on the health, wellbeing, or welfare of an animal held under an approved animal research protocol. This includes outcomes that exceed the predicted severity, frequency, or duration described in the approved protocol.
c. “Animal” means as defined by the Code - any live non-human vertebrate (that is, fish, amphibians, reptiles, birds, and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods. The University includes embryos and fetuses that have progressed beyond half the gestation or incubation period in this definition.
d. “Animal Care staff” refers to personnel responsible for the routine care, husbandry, and day-to-day management of animals. This includes the provision of food, water, environmental maintenance, and general oversight of animal conditions. While animal care staff may observe animals during routine activities and report any unexpected or concerning findings in accordance with facility procedures, they are not responsible for conducting monitoring required under an approved animal protocol. Responsibility for protocol-specific monitoring and animal welfare outcomes remains with the Investigator. Activities undertaken by animal care staff do not replace or reduce the montoring requirements of Investigators as specified in the approved protocol.
e. “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.

f. “Animal Research Authority” or “ARA” means an authority issued to any individual to carry out animal research for the purpose of a particular research project (as outlined in the Act, Clause 25). The authority is issued by an accredited research establishment, in this case, the University.

g. “Chief Investigator” means any person assigned to a research project with ultimate responsibility for the conduct of the research, in accordance with University policies. The Chief Investigator retains overall responsibility for project oversight. Responsibility for day-to-day animal welfare decision-making is assigned to the Lead Animal Investigator, where applicable.

h. “Competent” as defined in the Code, means the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

i. “Distress” means that an animal is in a negative mental state and has been unable to adapt to stressors to sustain a state of wellbeing. Distress may manifest as abnormal physiological or behavioural responses, a deterioration in physical and psychological health, or a failure to achieve successful biological function. Distress can be acute or chronic and may result in pathological conditions or death.

j. “Harm” means the negative impact on the wellbeing of an animal (including pain and distress).

k. “Investigator” means any person who uses animals for scientific 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, production of biological products and wildlife surveys.

l. “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 procedures 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.

m. “Method Development” refers to a novel technique, or one for which insufficient published guidance exists to reasonably predict animal welfare outcomes, and therefore, requires controlled evaluation under a pilot study.

n. “Monitoring” means the purposeful and documented assessment of an animal’s wellbeing, conducted by competent personnel to identify signs of pain, distress, illness, or abnormality to trigger appropriate responses in accordance with an approved monitoring strategy. Monitoring is a welfare assessment, not a cursory visual check, and must be sufficient to confirm the presence and observable condition of all animals for which the investigator is responsible. Monitoring begins when animals are allocated to a research project and continues until the project concludes.

o. “Pain” means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress, and modify species-specific traits of behaviour, including social behaviour.

p. “Researcher” means any University staff, conjoint/honorary appointments, students, Higher Degree by Research (HDR) candidates and volunteers who conduct research or contribute to research at or on behalf of the University.

q. “Scientific Purposes” means as defined in the Code – “all activities conducted with the aim of acquiring, developing, or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.”

r. “Supervisor” refers to a person identified on the Animal Research Authority as competent for the relevant animal protocol and species, and who is authorised to provide direct supervision.

s. “Teaching activity” means any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose includes imparting or demonstrating knowledge or techniques to achieve

an educational outcome in science, as specified in the relevant curriculum or competency requirements.

Section 5 - Roles and Responsibilities

University

(7) To ensure the highest level of care for animals, the University will:

a. maintain an Animal Ethics Committee (AEC) as required by legislation, with an agreed Terms of Reference and procedures;
b. ensure, through the AEC, that all animal research and teaching at the University complies with the relevant legislation and national and international guidelines and codes;
c. provide the AEC with resources and the authority to fulfil its Terms of Reference and operate as set out in the relevant legislation and national and international guidelines and codes;
d. ensure that practices, procedures and protocols for the care and management of animals are developed and reviewed on a regular basis so as to encompass current best practice;
e. ensure that adequate numbers of competent people are employed to provide care for animals;
f. provide mechanisms for training, assessment and ongoing competency maintenance, including refresher training at intervals consistent with ARRP Guideline 17; and ensure that training promotes an appreciation of the ethical issues associated with the use of animals for scientific purposes;
g. maintain the role of the Animal Welfare Officer as the role responsible for the direction of competent animal care;
h. support availability and access to appropriate veterinary and diagnostic services.
i. maintain transparent procedures to manage and report any adverse events or complaints that may arise from the use of animals for scientific purposes, in accordance with the University's Research Breach Investigation Procedure, the Animal Ethics Committee Procedure Manual, and relevant legislation.

(8) The University accepts the responsibility to respond effectively to recommendations made by the AEC to ensure that all animal research within the University remains in accordance with the legislation, national guidelines, and Codes.

(9) The Deputy Vice-Chancellor (Research and Innovation) is responsible for overall institutional governance for the care and use of animals.

College

(10) College Pro Vice-Chancellors are responsible for overseeing peer reviews of animal-based research and teaching projects in their respective Colleges in accordance with the Research Peer Review Procedure for Ethics Applications.

School

(11) The Chief Investigator'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.

Chief Investigator and Lead Animal Investigator

(12) Animal research projects may involve two distinct roles with complementary responsibilities:

a. the Chief Investigator who has overall responsibility for project governance, compliance, and accountability to the University and the AEC; and

b. the Lead Animal Investigator who has primary responsibility for the day-to-day conduct of animal protocols and for making informed, timely decisions relating to animal welfare.

(13) In some projects, the Chief Investigator and Lead Animal Investigator may be the same person. In other projects, these roles will be held by different individuals. Both arrangements are acceptable, provided the responsibilities described below are clearly met.

Chief Investigator

(14) Chief Investigators must comply with the University's Responsible Conduct of Research Policy, including but not limited to Clause 17, which outlines specific responsibilities for Chief Investigators.

(15) In addition, the Chief Investigator is responsible for:

a. overall responsibility for the conduct of the research project in accordance with University policies and the Code (including Clause 2.4.5);
b. acting as the person accountable to the AEC for compliance with all ethical approvals and conditions;
c. ensuring that a suitably qualified and experienced Lead Animal Investigator is nominated where the Chief Investigator does not personally fulfill that role;
d. ensuring that responsibilities for animal welfare decision-making are clearly assigned and understood within the research team;
e. ensuring that appropriate systems are in place for animal monitoring and welfare assessment, staff training and supervision, and record-keeping in accordance with approved monitoring strategies and University Monitoring Standards;
f. ensuring that sufficient financial, infrastructural, and institutional resources are available to support the ethical and compliance conduct of the approved animal research project;
g. fully disclosing and discussing ethical issues in research project applications;
h. ensuring that AEC decisions, conditions, amendments, and feedback, are communicated to all members of the research team;
i. ensuring that unexpected adverse events are reported promptly to the AEC;
j. submitting accurate and comprehensive progress an final reports as required;
k. ensuring that the project adheres to the principles of the 3R’s (Replacement, Reduction, Refinement);
l. ensuring that project design and conduct reflect best-practice scientific and animal-use methodology.

(16) The Chief Investigator may provide strategic leadership and governance oversight of the project without being directly involved in day-to-day animal protocols, provided that a suitably qualified Lead Animal Investigator is nominated and operational animal welfare responsibilities are met.

(17) The Chief Investigator:

a. must hold qualifications and experience appropriate to the discipline and scope of the project;
b. must be a staff member of an Accredited Research Establishment for which the University of Newcastle AEC acts as the nominated AEC (i.e. the University of Newcastle or Hunter New England Local Health District), unless otherwise approved on a case-by-case basis;
c. cannot be an honours student, postgraduate coursework student, or research higher degree candidate;
d. must be accessible to the AEC and University staff for matters relating to project governance, compliance, and reporting; and
e. must meet mandatory training requirements as specified in this Manual.

Lead Animal Investigator

(18) The Lead Animal Investigator is responsible for overseeing the day-to-day conduct of animal protocols and for operational animal welfare decision-making.

(19) This role exists to ensure that animal welfare decisions are made by a person who has:

a. direct knowledge of the animals and animal protocols;
b. sufficient authority to act without delay; and
c. the availability to respond to routine and emergent welfare issues.

(20) The Lead Animal Investigator may, but does not need to be, the Chief Investigator.

(21) The Lead Animal Investigator is responsible for:

a. all aspects of animal welfare and protocol compliance throughout the project's duration, per the Code;
b. providing direct oversight of animal protocols conducted under the approved project;
c. ensuring compliance with all conditions approved by the AEC, including ensuring all team members understand the approved protocols, and ensuring protocols are performed in accordance with the approved project;
d. making timely informed decisions relating to animal welfare, including decisions about intervention, treatment, or euthanasia based on approved monitoring criteria;
e. responding to emergent or unanticipated animal welfare issues within appropriate timeframes;
f. ensuring that animals are monitored in accordance with the approved monitoring strategy and University Monitoring Standards;
g. ensuring that animal monitoring is conducted and documented in accordance with approved monitoring strategies and University Monitoring Standards, and that monitoring records accurate reflect the condition and presence of animals at the time of assessment. Endorsing or permitting monitoring records that are incomplete, inaccurate, or inconsistent with observed animal condition constitutes non-compliance;
h. acting as the primary point of contact for animal facility staff and research personnel regarding animal welfare matters;
i. promptly escalating significant welfare concerns and unexpected adverse events in accordance with this Manual; and
j. being contactable or ensuring appropriate on-call arrangements are in place, to allow timely animal welfare decisions at all times when animals may be affected.

(22) The Lead Animal Investigator must maintain regular direct involvement with the project and cannot be an administrative figurehead or senior Researcher with minimal day-to-day project involvement.

(23) The Lead Animal Investigator must:

a. have demonstrated competence and experience in the animal protocols and species described in the approved project;
b. have sufficient familiarity with the project and animals to exercise sound welfare judgment;
c. hold the authority, supported by the Chief Investigator, to implement immediate welfare interventions where required.
d. be a member of staff of an Accredited Research Establishment for which the University of Newcastle AEC acts as its nominated AEC (i.e. the University of Newcastle, or Hunter New England Local Health District). If the Lead Animal Investigator is not associated with one of these institutions, acceptance of the application will be determined on a case-by-case by the AEC and the University;
e. not be an honours, postgraduate student or research higher degree candidate; and

f. must meet mandatory training requirements as specified in this Manual.

Alternate Lead Animal Investigator

(24) The Alternate Lead Animal Investigator serves as the designated person responsible for the project in the absence of the Lead Animal Investigator. This individual must possess equivalent expertise and capability to assume full responsibility for animal welfare and protocol compliance when required.

(25) The Alternate Lead Animal Investigator role ensures that qualified oversight of animal welfare and protocol compliance is maintained at all times, even during periods when the Lead Animal Investigator is unavailable due to leave, illness, or other commitments. Projects lacking a suitable Alternate Lead Animal Investigator may face delays or suspension if the Lead Animal Investigator becomes unavailable, as animal welfare must be continuously monitored by qualified personnel throughout the project.

(26) The Alternate Lead Animal Investigator:

a. may be a postgraduate student or Higher Degree by Research candidate, provided they meet all requirements of this clause and are capable of independnetly fulfilling the responsibilities of the role when required;
b. must possess experience and demonstrated expertise comparable to the Lead Animal Investigator in the animal protocols outlined in the project;
c. must demonstrate practical capability in all critical animal protocols to ensure competency in animal handling, monitoring, and welfare assessment;
d. must maintain sufficient familiarity with the project, including its protocols and associated welfare risks to assume responsibility when required;
e. must be readily accessible to research personnel animal facility staff, and AEC members when the Lead Animal Investigator is unavailable;
f. must meet mandatory training requirements as specified in this Manual; and
g. must be capable of responding to emergent animal welfare issues within appropriate timeframes.

(27) The Alternate Lead Animal Investigator's specific responsibilities include:

a. maintaining comprehensive knowledge of all project details, including approved animal protocols, and monitoring parameters;
b. assuming full responsibility for the project when the Lead Animal Investigator is unavailable;
c. participating regularly in project activities to maintain procedural competency and familiarity;
d. ensuring consistent application of approved protocols during transitions of responsibility;
e. making critical welfare decisions, including intervention or euthanasia, when the Lead Animal Investigator is unavailable;
f. communicating promptly with the Lead Animal Investigator regarding any significant developments;
g. maintaining equivalent record-keeping standards when assuming responsibility; and
h. reporting to the AEC as required during periods of primary responsibility.

Investigators

(28) All individuals who are named investigators on approvals for research or teaching involving animals must:

a. be aware of their responsibilities under the Code, particularly Chapter 2.4;
b. be familiar with, and adhere to, the requirements outlined in this Manual and its associated procedures;
c. review and understand the full content of the project on which they are named, including all animal protocols, monitoring requirements, and conditions of approval;

d. complete all mandatory training required by the University or AEC prior to participating in animal research, including:
    i. CARE modules (Code and Animal Research Ethics);
    ii. any additional competency-based training relevant to their role or animal protocols;
e. be knowledgeable about the species they work with, including:
    i. understanding species-specific welfare needs; and
    ii. applying appropriate handling, care, and procedural techniques.
f. perform only those animal protocols for which they are listed and approved on the Animal Research Authority, and only after the Lead Animal Investigator has confirmed their competency or supervision arrangements;
g. participate in animal monitoring as directed by the Lead Animal Investigator, and report any concerns or adverse events promptly;
h. maintain accurate records of animal monitoring and any procedures undertaken in accordance with the Research Data and Primary Materials Management Procedure. Monitoring records must not be completed or signed unless the monitoring has been conducted as required and the welfare status and presence of animals have been adequately assessed.

Animal Ethics Committee (AEC)

(29) The AEC is responsible for:

a. reviewing and determining ethical approval of animal research applications, variations, and reports in accordance with the Code and relevant legislation;
b. ensuring that monitoring strategies are appropriate, effective, and ethically justified;
c. reviewing adverse event reports and determining appropriate actions, including suspension or modification of protocols;
d. participating in inspections and oversight of animal care and use activities;
e. providing feedback and conditions of approval to Investigators; and
f. supporting a culture of ethical animal use and continuous improvement across the University.

Animal Welfare Officer

(30) The Animal Welfare Officer is responsible for:

a. conducting regular monitoring of animal care and use programs, including inspections of facilities and review of animal health and welfare records;
b. reviewing the health status of experimental and breeding animals and advising on appropriate care, treatment or intervention strategies;
c. investigating issues related to animal welfare, including adverse events, and providing recommendations for resolution and prevention;
d. performing or arranging necropsies and facilitating access to diagnostic services for animals that die or are euthanised as part of an unexpected adverse event;
e. acting as the first point of contact for Investigators, students, and animal facility staff on veterinary clinical care, refinement of animal protocols, and welfare advice;
f. leading the development and delivery of training programs and professional development for research staff and students involved in animal based research and teaching;
g. participating in AEC pre-review processes where veterinary expertise is required, including review of drug protocols, monitoring strategies, and euthanasia methods; and
h. supporting a culture of ethical animal use and compliance across the University's research programs.

Operations Manager, BioResearch Facilities

(31) For animals housed within the BioResearch managed faciltiies, the Operations Manager, BioResearch Facilities will ensure that:

a. the practices and protocols for the care and management of animals are based on current best practice;
b. animal care staff are competent in routine husbandy and are able to identify generla indicators of animal health, behaviour, and signs of pain and distress for the species in their care; and
c. routine husbandry activities are performed at a frequency sufficient to ensure that animals with obvious signs of illness or injury are identified, and appropriate action is initiated in accordance with facility procedures.

(32) These activities do not replace or constitute monitoring required under an approved animal research protocol. Responsiblity for monitoring animal wellbeing in accordance with approved protocols rests with the Research team, as described in this Manual.

(33) The Operations Manager, BioResearch Facilities is responsible for providing details of the training and experience of BioResearch Facilities staff to the AEC, and for giving information about how inexperienced staff will be supervised until they are considered competent for the animal protocols they perform in the following circumstances:

a. on a 6 monthly basis when reporting on research projects to the AEC; and
b. when new persons are added to a research project.

Section 6 - Animal Research Policy

(34) The University is committed to compliance with the Animal Research Act 1985 (NSW), Animal Research Regulation 2021 (NSW), and the Code.

(35) The University will:

a. maintain current accreditation as an Animal Research Establishment in New South Wales, and in other jurisdictions where animal research is conducted under the University's auspices; and
b. only supply animals for research or teaching, either within the University or externally, when it holds a current NSW Animal Suppliers Licence and in accordance with the conditions of that licence.

(36) The University supports the ethical use of animals in research and teaching, guided by the principles of Replacement, Reduction, and Refinement (the 3Rs). It promotes a culture of care, responsibility, and continuous improvement in all activities involving animals.

(37) The University does not support or permit animal research involving animal protocols that are prohibited under NSW legislation, including forced swim tests and forced smoke inhalation experiments. It also does not support the use of animals in cosmetic testing or any activity that fails to meet the ethical justification requirements of the Code.

(38) In accordance with the governing principles of the Code, the AEC will only approve research projects where the use of animals is essential, justified, and compliant with the Code.

(39) The institution has assigned oversight of animal research to the Deputy Vice-Chancellor (Research and Innovation) (DVCRI) and the Pro Vice-Chancellor (Research) (PVCR).

(40) The DVCRI, PVCR and other nominated persons and bodies are responsible for ensuring that animal research is conducted in accordance with this Manual and for managing any breaches of compliance.

(41) All animal research conducted at the University and its affiliated centres and institutes requires ethics approval by the AEC and an Animal Research Authority (ARA) issued by the DVCRI or PVCR.

(42) No project or animal protocol may commence without prior ethics approval from the AEC and the issuing of a valid ARA.

(43) The Research Ethics and Integrity Unit (REIU) supports the University and its affiliated centres and institutes in the ethical conduct of animal research by coordinating the review of ethics applications, facilitating monitoring of approved research activities, delivering training in animal research ethics and compliance, and leading the development and maintenance of institutional policies and procedures.

(44) The DVCRI or PVCR is responsible for ensuring that the University's animal research governance framework is subject to independent external review at least once every four years, in accordance with the Code. External reviews are coordinated by the Animal Ethics Office in consultation with the AEC Chair and the Manager - Animal Ethics.

(45) External reviews may be conducted by the NSW Department of Primary Industries & Regional Development (DPIRD), Animal Research Review Panel (ARRP), or another independent body approved by the University.

(46) The scope of external review includes assessment of:

a. institutional compliance with the Code and relevant legislation;
b. AEC operations and decision making processes;
c. facility inspections and monitoring practices;
d. education and training programs;
e. records and reporting systems.

(47) Investigators may be asked to provide documentation or participate in interviews as part of the review process. This may include:

a. ethics applications and monitoring records;
b. adverse event reports; and
c. facility access and inspection participation.

(48) The Animal Ethics Office will notify affected Investigators in advance and provide guidance on documentation requirements and timelines.

(49) The University will respond to recommendations arising from external reviews and implement continuous improvement measures where required.

Principals of Ethical Use of Animals in Research and Training

(50) Animal use must be ethically justified, with clear scientific, educational, or societal benefit. The AEC will only approve projects where the use of animals is essential and cannot be replaced by alternative methods.

(51) All research must demonstrate active consideration of the principles of:

a. Replacement: use non-animal alternatives wherever possible;
b. Reduction: use the minimum number of animals necessary to achieve valid results;
c. Refinement: modify animal protocols to minimise pain, distress, and lasting harm.

(52) Projects must be scientifically sound and undergo peer review prior to ethics submission, in accordance with the University's Research Peer Review Procedure for Ethics Applications.

(53) Investigators must fully disclose all animal protocols, risks, and welfare considerations in their ethics applications. The AEC may request additional information or impose conditions to ensure ethical conduct.

(54) Ethical review includes assessment of:

a. justification for animal use;
b. welfare impacts;
c. monitoring and intervention strategies;
d. investigator competency; and
e. compliance with legislation and the Code.

(55) Research / teaching activities involving the use of these animals will only be approved when the use of animals is justified by the potential benefits to:

a. the animal;
b. human health;
c. increasing knowledge gained in a particular area of research;
d. meeting relevant learning outcomes from teaching activities;
e. the environment; and
f. where there is strong evidence that the wellbeing of the animals will be supported at all times.

(56) Research projects using animals can only commence after the required approvals, ARAs, and any scientific licences (where applicable) are in place.

(57) All personnel must treat animals with respect and care, recognising their sentience and intrinsic value.

(58) Investigators must avoid or minimise harm (including pain and distress) to animals involved in research and training. by:

a. clearly defining and implementing humane endpoints;
b. ensuring only trained and competent personnel conduct animal protocols. The Lead Animal Investigator is responsible for ensuring all team members meet competency requirements, as per Part A of the Animal Research Procedure (Section 7 of this Manual).

(59) Approved projects are subject to ongoing review, including annual progress reports, inspections, and monitoring of adverse events. The AEC may suspend or withdraw ethics approval if ethical standards are not maintained.

(60) Animal use in teaching must be pedagogically justified, and alternatives must be considered. Student involvement must be supervised, and learning objectives must be clearly defined and evaluated.

(61) Research involving wildlife or culturally significant species must consider community values, conservation status, and Indigenous perspectives.

(62) The University recognises the Code requirement for the immediate use of animals in the event of unexplained and severe disease outbreaks, or morbidity/mortality in animals or people. In such circumstances, Investigators should contact the Animal Ethics Office to request expedited review. This clause applies to circumstances where animal research activities must be initiated or modified urgently in response to external, unforeseen, or time-critical events (e.g. emerging disase, biosecurity threats, or urgent public or animal health issues), rather than routine or project specific animal welfare incidents within a approved protocol. It does not apply to the management of adverse events, unexpected outcomes or disease incidents wihtin an existing approved animal research project.

Funding and Ethics Approval Alignment

(63) Where research funding supports activities involving the use of animals, the funding must be transparently linked to an approved animal ethics protocol.

(64) The Chief Investigator is responsible for ensuring that all funding sources supporting animal research activities are declared to the AEC. Funding sources may be declared at the time of initial application and updated throughout the life of the project as additional funding is obtained. Updates to funding sources may be provided through variations or annual progress reports, depending on the timeing and intended use of the funding.

(65) Investigators who hold, administer, or expend research funds that support animal research must be named on the animal ethics protocol in an appropriate role, but are not required to hold a Chief Investigator role unless they meet the eligibility requirements specified in this Manual.

(66) Funding held by students or other non-staff investigators may only be used for animal-based activities where those activities are conducted under an approved animal ethics protocol with an eligible Chief Investigator and an appropriately nominated Lead Animal Investigator.

Animal Ethics Committee

(67) The University maintains an Animal Ethics Committee (AEC) in accordance with the Animal Research Act 1985 (NSW), Animal Research Regulation 2021 (NSW) and the Code.

(68) The AEC is responsible for reviewing, approving, and monitoring all research and teaching activities involving animals to safeguard animal welfare and uphold ethical standards and compliance with legislation.

(69) The AEC serves as the institutional animal ethics committee and is accountable to the University Council via Academic Senate, and the Deputy Vice-Chancellor (Research and Innovation) operates under the Animal Ethics Committee Procedure Manual and Terms of Reference.

(70) Investigators are encouraged to engage with the AEC throughout the lifecycle of their project. This includes:

a. seeking guidance from Research Ethics Advisors (REA), Animal Welfare Officer, or the Animal Ethics Office during application preparation;
b. submitting applications in accordance with the AEC Procedure, which outlines submission, review, approval, and monitoring processes;
c. attending AEC meetings to discuss applications when invited;
d. responding to AEC feedback and conditions in a timely and comprehensive manner.

(71) Investigators must refer to the following documents for detailed information on AEC processes and expectations:

a. Animal Ethics Committee Procedure Manual;
b. Animal Ethics Committee Terms of Reference;
c. Research Peer Review Procedure for Ethics Applications;
d. Research Data and Primary Materials Management Procedure.

Animal Care

(72) The University is responsible for ensuring that animals used in research and teaching are housed, cared for, and monitored in accordance with current best practice and legislative requirements.

(73) The University will:

a. maintain accredited breeding and holding facilities for research animals where applicable;
b. employ appropriately qualified and competent personnel to provide routine animal care and husbandry within University-managed animal facilities;
c. support access to veterinary and diagnostic services; and
d. maintain the role of the Animal Welfare Officer (AWO) to oversee animal wellbeing and biosecurity.

(74) The Operations Manager, BioResearch Facilities is responsible for the day-to-day management of breeding and holding facilities, including:

a. implementation of Standard Operating Procedure's (SOP's) approved by the AEC for animal care during supply, animal husbandry, and breeding and holding;
b. oversight of routine monitoring and early identification of animal health concerns; and
c. maintenance of facility biosecurity, including pathogen surveillance and response protocols; and
d. coordination with the AWO and AEC to ensure compliance with approved protocols.

(75) All personnel involved in animal care must be trained and competent in their assigned duties.

(76) Competency development and assessment must be guided by the principles of Replacement, Reduction, and Refinement and must prioritise the protection of animal welfare. Competency requirements are outlined in the Animal Research Competency Procedures (see Section 7), Part A.

Monitoring and Welfare

(77) The AEC has authority to define, approve, and enforce minimum institutional standards for the monitoring of animals used in research and teaching. These standards apply across species, housing types, and research settings and are established to ensure consistent, effective assessment of animal wellbeing and timely intervention.

(78) Compliance with approved monitoring standards is a condition of animal ethics approval. The AEC may specify monitoring requirements through the ethics review process, and as conditions of approval. The AEC may require amendments where monitoring arrangements are inadequate to safeguard animal welfare.

(79) All personnel involved in animal research must ensure that animals are monitored in accordance with an approved strategy that supports animal wellbeing and complies with ethical and legislative requirements.

(80) Monitoring must be conducted by competent personnel or under the direct supervision of a competent person in accordance with Section 7, Part A (Animal Research Competency Procedure).

(81) Animals used for Research and teaching must be monitored at a frequency sufficient to ensure their wellbeing, and to detect adverse events at an early stage, in accordance with Animal Research Review Panel (ARRP) Guideline 29. This requirement applies to all animals, regardless of housing type or research phase. Monitoring frequency must increase during periods of potential impairment or vulnerability (e.g. post-procedural recovery, illness, or high- risk interventions).

(82) As a general minimum standard, animals should be visually checked at least once daily; however, monitoring frequency and methods must be appropriate to the nature of the procedures and the risks to animal welfare;

(83) The AEC may approve alternative monitoring strategies where justified and where animal welfare will not be compromised. In such cases, Researchers must adhere to the monitoring requirements specified in the approved protocol.

(84) Responsibility for monitoring animals in accordance with the approved protocol rests with the research team. Routine husbandry obsevations by animal care staff do not replace or fulfil these monitoring requirements.

(85) Detailed guidance on the implementation of monitoring requirements is provided in Section 7, Part C.

(86) All monitoring must be documented in accordance with the University's Records Governance Policy, and records must be available for review by the AEC and regulatory bodies.

(87) Detailed procedural requirements for monitoring during specific study phases, including documentation formats and escalation pathways, are outlined in Section 7, Part C of this Manual and the Animal Ethics Committee Procedure Manual.

(88) The Animal Welfare Officer (AWO) and BioResearch Facilities staff may conduct inspections and initiate emergency interventions where animal welfare is compromised. Investigators must cooperate fully with these processes.

(89) The University recognises the Code's requirement for animals in social isolation or separation from a group. For mice and rats, a maximum duration of 4 weeks is permitted unless otherwise approved by the AEC.

(90) Procedures for pilot studies, animal monitoring, and management and reporting of adverse events are detailed in Section 7, Parts B-D of this Manual and the Animal Ethics Committee Procedure Manual.

Adverse Events

(91) All staff involved in the care and use of animals for research or teaching purposes must report all adverse events involving animals, including both predicted and unexpected adverse events. Reporting must be timely, accurate, and in accordance with the Animal Ethics Committee Procedure Manual and Section 7, Part D of this Manual.

(92) Assessment and response to adverse events must be in accordance with the Animal Ethics Committee Procedure Manual.

(93) The AEC may impose conditions, suspend approval, or withdraw approval where adverse events indicate a risk to animal welfare or non-compliance with approved protocols.

(94) Investigators must cooperate fully with investigations into adverse events and provide all requested documentation, including monitoring records, treatment logs, and post-mortem findings where applicable.

(95) The University may initiate inspections or emergency interventions in response to adverse events. These actions may be taken without prior notice where animal welfare is compromised.

(96) Procedures for reporting, review, and resolution of adverse events are detailed in the Procedure Section of this Manual and the Animal Ethics Committee Procedure Manual.

External and Multi-Centre Animal Research

(97) Collaborative animal research involving external institutions must be conducted in accordance with the University's Collaborative Research Procedure, and the requirements of the Code.

(98) Where research involves animals held or used at another institution, Investigators must ensure that:

a. the external institution is accredited under the Animal Research Act 1985 (NSW), or equivalent legislation;
b. the project has been approved by an AEC recognised under the relevant jurisdiction;
c. a formal agreement is in place outlining responsibilities for animal care, monitoring, reporting, and adverse event management.
d. the University's AEC is notified of the collaboration and provided with relevant documentation, including ethics approvals, copies of ARAs and ethics applications.

(99) If any component of the live animal work is to be conducted at the University of Newcastle, a separate ethics application must be submitted to the University's AEC for that component.

(100) Where the University's AEC is the reviewing committee for a multi-centre project, Investigators must ensure that:

a. all participating institutions are listed in the ethics application;
b. animal use across sites is clearly described and justified;
c. monitoring and reporting responsibilities are clearly defined;
d. any site-specific risks or welfare considerations are addressed; and
e. a collaborative agreement is signed by all participating institutions.

(101) The AEC may request additional documentation or impose conditions to ensure that collaborative projects meet ethical and legislative requirements.

Research Conducted Overseas

(102) Research involving animals conducted overseas must comply with the ethical standards and legal requirements of the host country, and must be reviewed by the University's AEC prior to commencement.

(103) Investigators must provide:

a. evidence of local ethics approval (where applicable);
b. a description of local animal welfare standards and how they compare to the Code;
c. justification for conducting the research overseas; and
d. a plan for monitoring and reporting adverse events.

(104) The AEC will assess whether the proposed research meets the principles of ethical animal use as outlined in the Code. Where local standards are inconsistent with the Code, the AEC may impose additional conditions or decline to approve the research.

(105) Overseas research involving live animals or field work must be included in ethics applications. Where the University is not the primary institution, Investigators must still seek AEC review for any component conducted under the University's auspices.

(106) The University may require formal agreements with overseas institutions to clarify responsibilities for animal care, compliance, and reporting.

(107) Where tissues or samples are collected under an approved protocol at an overseas institution and provided to University Investigators – refer to Clause 109-114 of this document.

Use of Animal Tissues Sourced from External Providers

(108) Animal tissues or samples obtained from sources external to the University to be used in University approved animal research projects must be declared to the Animal Ethics Committee via a Registration of Animal Tissue Use where the University has not previously reviewed the ethical sourcing and intended use of the material. External sources may include, but are not limited to, abattoirs, veterinary clinics, farms, government agencies, other research institutions, and archived or stored collections. This requirement applies:

a. to all intended uses of such materials under the auspices of the University, including research teaching and commercial activities;
b. tissues obtained from external institutions (Australian or international) where:

i. the tissues were generated under a non-University animal ethics approval; and
ii. University Researchers receiving the tissues are not listed on that approval.

(109) Registration is not required to:

a. commercial purchased animal-derived materials (e.g. cell lines, foetal bovine serum, antibodies, or commercial supplied reagents);
b. tissues generated and shared wihtin the University under an AEC approved animal research project; or
c. tissues used as part of an approved collaborative research project where University Researchers are formally included on the relevant animal ethics approval, or where ethical review responsibilities are clearly defined and recognised by the AEC.

(110) The purpose of Registration is to ensure that externally sourced animal-derived materials used under the auspices of the University have been ethically and lawfully obtained, and that their use is consistent with institutional and regulatory expectations. Registration does not involve re-assessment of the original animal ethics approval.

(111) A Registration of Animal Tissue use must include:

a. details of the source (e.g. provider type, institution, location);
b. documentation confirming lawful acquisition (e.g. supplier declaration, Material Transfer Agreement, or equivalent);
c. confirmation that the material was obtained under appropriate ethical approval or lawful process; and
d. intended use of the tissue (e.g. research, teaching, or commercial use).

(112) Registration of Animal Tissue Use must be submitted via the University's Animal Ethics eForm system, in accordance with guidance available on the Animal Ethics Resources page.

(113) The notification must include:

a. details of the source (e.g. provider type, institution, location);
b. documentation confirming lawful acquisition (e.g. supplier declaration, Material Transfer Agreement); and
c. intended use of the tissue (research, teaching, commercial).

Non-Compliance

(114) The University is committed to maintaining high standards of animal welfare and research integrity. All personnel involved in animal research must comply with approved protocols, relevant legislation, and the Code.

(115) Non-compliance includes any activity that deviates from approved protocols, breaches of legislative or Code requirements, or compromises animal welfare. Examples of common non-compliance events are available in the Non-Compliance Grading Reference Table on ResearchHub.

(116) The University has established procedures for identifying, assessing, and managing non-compliance events. These procedures are detailed in Section 8 of the Animal Ethics Committee Procedure Manual.

(117) Investigators must report any suspected or actual non-compliance to the Animal Ethics Office via animal-ethics@newcastle.edu.au as soon as possible. Alternatively, reports can be submitted via ServiceNow, which allows for anonymous reporting if required.

(118) Reports should include, where available:

a. a description of the incident or concern;

b. the approximate timing or sequence of a timeline of events;
c. any actions taken to address the issue; and
d. any supporting documentation (e.g. monitoring records, communications, photos).

(119) If urgent animal welfare concerns are involved, Investigators must immediately contact:

a. the Animal Welfare Officer (AWO);
b. the Animal Ethics Office;
c. the Operations Manager, BioResearch Facilities (for facility-related issues).

(120) The Animal Ethics Office will assess the report and determine the appropriate management pathway, as per the Animal Ethics Committee Procedure Manual. This may include:

a. administrative resolution;
b. review by the AEC;
c. referral to the Research Integrity Unit for investigation under the Research Breach Investigation Procedure.

(121) Investigators must cooperate fully with any investigation and provide requested documentation or attend meetings as required.

(122) Where non-compliance is substantiated, the University may impose corrective actions, suspend or withdraw ethics approval or refer matters for institutional investigation. Actions will be proportionate to the nature, severity, and context of the non-compliance and may include measures to support compliance, address system issues or prevent recurrence.

(123) Corrective actions may include training, protocol amendments, enhanced monitoring, or suspension of activities.

Section 7 - Animal Research Procedures

Part A - Animal Research Competency Procedure

(124) This part outlines the mandatory institutional requirements for establishing, demonstrating, and maintaining competency in new, significantly modified, or infrequently performed animal protocols. It applies to all personnel named on an Animal Research Authority (ARA) and must be read in conjunction with the Code, the Act, the Regulation, and relevant ARRP guidelines.

(125) Animal protocols are assigned to one of three risk classes: low, moderate or high—based on invasiveness, welfare impact, and complexity.

Minimum Competency Requirements

(126) All personnel involved in animal research must meet the minimum competency requirements as specified in Table 1 prior to commencing any activities involving animals.

(127) No person shall be permitted to participate in animal research activities, including practical training involving live animals, without completing the mandatory training requirements outlined in Table 1.

(128) Personnel who do not meet the competency requirements for specific animal protocols must work under a supervisor until such competency is achieved and documented.

(129) Compliance with minimum competency requirements shall be monitored through the ethics application process

and may be subject to audit during project reviews for inspections.

Table 1. Competency Requirements

Role	Competency Requirements
Animal based Investigators, and Teachers including Chief Investigator	All persons listed on animal research projects will: 1. complete modules A and B of the University's Code and Animal Research Ethics (CARE) prior to being named on an animal ethics protocol, and must recertify this once every three years; 2. University staff or students who are new to animal research at the University must complete ComPass Phase 1 (nationally available training provided by ANZCCART); 3. complete additional CARE modules as required by the AEC for specific animal protocols or activities associated with increased animal welfare impact (e.g. anaesthesia, surgery); 4. receive instruction in a scientific discipline relevant to the experimental work being undertaken; 5. demonstrate appropriate competency for their assigned role through the application process, including: a. classification of each proposed animal protocol by complexity level (basic, intermediate or advanced) to reflect the level of technical skills, experience and supervision required; b. assessment of the individual's experience for each technique and species combination, including frequency, recency and nature of prior training; c. identification of the individuals current competency status (for each animal protocol (e.g. competency, requires supervision, requires training); and d. documentation of how competency has been achieved or will be achieved, including supervision and training arrangements where applicable; 6. Work under a Supervisor where they are assessed as not fully competent, with clear training and supervision plans specified.
Lead Animal Investigator	In accordance with the Code (clause 2.4.5), Lead Animal Investigators must: 1. be competent (or gain competency before project commencement) in monitoring the welfare of the species/strain to be used; 2. be able to assess animal wellbeing, identify signs of pain, distress, or illness; 3. be able to make timely decisions regarding intervention, treatment, or euthanasia in accordance with approved protocols and monitoring criteria.
Operations Manager, BioResearch Facilities	In accordance with the Code (clause 2.5.14), the Operations Manager, BioResearch Facilities is responsible for the overall management of research animal breeding and holding facilities at the University, and is appointed on the basis of appropriate animal care or veterinary qualifications, or experience.
BioResearch Facilities Staff	The Code (clause 2.4.2), requires that, within the scope of their responsibilities, animal carers and veterinary staff must ensure that their duties are performed competently. The University supports BioResearch Facilities staff in gaining formal animal care qualifications and accepts, as evidence of competency, completion of a suitable competency-based animal care course.
Animal Welfare Officer	The Animal Welfare Officer (AWO): 1. is appointed on the basis of appropriate veterinary qualifications, eligible for full registration as a veterinarian in New South Wales; and 2. has extensive practical experience and familiarity with animal research; 3. is expected to comply with the requirement for demonstrated continuing professional education to maintain registration.

Pathways to Competency

(130) The University operates on the presumption that competency in animal protocols is ordinarily developed through existing expertise within the research team or broader institution, whereby a competent member of the team provides training and supervision to less experienced personnel.

(131) Internal training must follow a staged process in which the trainee first observes the animal protocol, then performs it under direct supervision, and progresses to independent performance only once the required standard of competency has been demonstrated and documented.

(132) Where appropriate expertise is not available within the immediate research team, competency may be

developed through supervised external training. This may include collaboration with another accredited institution, temporary placement or secondment to an external facility for hands on instruction, or completion of an externally provided training course that delivers practical, assessed procedural training. In all such cases, the external trainer or institution must be appropriately qualified, and where relevant, may be listed on the Animal Research Authority as a Supervisor for the purposes of training and initial oversight.

(133) In circumstances where neither internal nor external expertise is reasonably available, or where the animal protocol represents genuine method development, competency must be developed within a pilot study framework. In such cases, training and skill acquisition must occur under enhanced welfare oversight, with staged progression and explicit approval from the AEC, as set out in Part B of this Section.

Supervision Requirements

(134) Lead Animal Investigators must:

a. provide oversight of investigator competency and ensure appropriate training/supervision arrangements for animal protocols where they lack high personal experience;
b. take responsibility for ensuring all named Investigators achieve required competency levels before performing assigned animal protocols.

(135) Training and supervision plans must be documented and approved for all personnel classified as requiring development in any animal protocol or species.

(136) Supervision arrangements must specify the supervising personnel, duration of supervision, and criteria for achieving independent competency.

(137) High-risk animal protocols must be performed under a Supervisor. Where a Supervisor is available within the research team or through an approved collaboration, that individual must be physically present for initial performance of the animal protocol and available to intervene as required.

(138) All method-development work, and any high-risk animal protocol for which no competent procedural Supervisor is available other than the AWO, must be performed initially in the physical presence of the AWO.

(139) Where procedural timing or location prevents direct attendance by the AWO or a Supervisor, the performance of the animal protocol must be video recorded at a resolution sufficient to allow assessment of technique and animal welfare, including the recovery period.

(140) In such cases, the next attempt must not occur until the AWO or Supervisor has reviewed the video recording and provided feedback.

(141) The number of supervised attempts required for a trainee to progress varies by risk class but will ordinarily consist of one to five supervised attempts for low-risk animal protocols, 5 to 10 supervised attempts for moderate-risk animal protocols, and 10 to 20 supervised attempts, with additional welfare review, for high-risk or surgical animal protocols. The Supervisor must be available to intervene at any point and must not be responsible for more trainees than can be safely supervised.

(142) Where surgical animal protocols are undertaken for the purpose of skills development, the requirements articulated in ARRP Guideline 4, including justification of educational value and consideration of alternatives, must be addressed.

(143) A training log must be maintained, detailing all supervised attempts, feedback provided, and any corrective actions implemented.

Assessment and Certification of Competency

(144) Competency shall be assessed on an animal protocol-specific and species-specific basis, recognising that competency levels may vary according to the protocol complexity and individual learning.

(145) Assessment must occur through direct observation and must include evaluation of technical performance, adherence to welfare requirements, and accurate application of monitoring and humane endpoints.

(146) Individual competency status must be documented as Competent, Requires Supervision, or Requires Training for each animal protocol and species combination.

(147) Competency assessments must be documented and retained in project files.

(148) External training or qualifications may be accepted as evidence of competency where relevant and appropriate.

(149) Personnel acquiring new competencies during a project must be updated on the approved protocol through variation application or annual progress reporting.

(150) Skills requiring regular practice to maintain proficiency (including but not limited to microsurgery, complex behavioural assessments, and advanced imaging techniques) may require more frequent competency verification than basic animal protocols.

(151) Failure to maintain required competency levels may result in suspension from animal research activities.

(152) The AEC may require demonstration of maintained competency for critical, high-risk, or infrequently performed animal protocols at any time during project ethics approval periods.

(153) The AEC may review competency documentation and classifications at any time throughout the life of a project where concerns are raised about personnel performance and may direct additional training, impose further supervision or restrict animal protocol performance where necessary to maintain compliance with welfare and legislative requirements.

(154) If any adverse event, deviation from an approved animal protocol, or welfare concern arises during competency development, an individual’s independent practice of that protocol may be suspended immediately. In the event of suspension, further attempts may only proceed following review by the AWO and, where required, notification to or approval from the AEC.

(155) All assessments, training records, monitoring sheets, and video files (where applicable) must be maintained in accordance with the University's Records Governance Policy and be made available to the AEC, AWO and regulatory authorities upon request.

Part B - Pilot Study Procedure for Animal Research

(156) Pilot studies are used to assess the feasibility, welfare impacts, and procedural competency of new or substantially modified, or otherwise uncertain animal research methods before full-scale implementation.

(157) Investigators must consider the use of pilot studies where:

a. the effects of the treatment are unknown;
b. a new species or strain is being used;
c. the intervention is complex or high-risk;
d. the animal protocol is novel or significantly modified;
e. personnel competency requires development but appropriate expertise is not otherwise available.

(158) In all cases, pilot studies provide a structured framework for assessing animal welfare impacts and ensuring that subsequent research is scientifically justified, ethically sound, and appropriately designed before implementation at scale.

(159) Where pilot studies are used as an escalation pathway for competency development, this must occur in accordance with the principles and pathways outlined in Part A of this Section.

Design of Pilot Studies

(160) Pilot studies must be submitted as new Initial Applications for ethics approval, except where their completion is a requirement of approval of a new Initial Application from the AEC. This ensures appropriate ethical review and oversight.

(161) Pilot study applications must include:

a. detailed methodology and welfare monitoring protocols;
b. a description of alternatives considered, including simulation-based approaches, in vitro techniques and use of cadaveric material;
c. justification for animal numbers (typically minimal);
d. clear success/failure criteria and stopping rules;
e. adverse event management strategies; and
f. timeline for completion and reporting.

(162) Where surgical skills training is proposed, the criteria outlined in ARRP Guideline 4 must be satisfied, including a clear demonstration of educational necessity.

(163) The AWO must attend initial pilot animal protocols wherever practicable.

(164) Where attendance is impossible due to operational constraints, the performance of the animal protocol must be recorded in high-resolution video, capturing all critical stages including recovery.

(165) No subsequent animal protocols may occur until the AWO has reviewed the video recording and communicated feedback to the research team. This requirement ensures close welfare oversight and supports safe incremental progression.

Pilot Study Monitoring and Reporting Requirements

(166) Monitoring and reporting requirements for pilot studies must be proportionate to the complexity, duration, and potential welfare impacts of the proposed work.

(167) Where required by the AEC, completed monitoring documentation must be provided to the AWO within the timeframe specified by the AEC, having regard to the nature and risk profile of the pilot study.

(168) The AEC may require interim reports at specified milestones for pilot studies involving higher levels of uncertainty, complexity, or potential welfare impact. To support transparent and consistent study design, the AEC may identify stop/go decision points appropriate to the pilot's aims and risk profile. The following are illustrative examples only (not exhaustive or prescriptive), and the AEC may adapt or combine them as proportionate to the pilot:

a. technical feasibility gates – e.g. successful completion of a defined number of animal protocols without critical deviations from the Standard Operating Procedure (SOP); acceptable procedural time, anaesthesia stability, or device performance;
b. animal welfare gates – e.g. adverse events not exceeding a pre-specified incidence or severity; pain scores

staying within expected ranges with planned analgesia; recovery to predefined clinical criteria within a set timeframe;

c. scientific information gates – e.g. dose finding data that identifies a tolerable dose range; demonstration that the primary outcome is measurable and biologically variable as anticipated; confirmation that sampling yields adequate signal to noise for downstream analyses;
d. operational gates – e.g. confirmation that required personnel, equipment, and monitoring systems function as intended; verification that record keeping and sample tracking meet data integrity requirements.

(169) Where such decision points are required, progression must not occur until the relevant criteria have been satisfied and any AEC specified feedback has been addressed. For lower risk or straightforward pilot studies, the AEC may determine that formal decision points are unnecessary.

(170) Upon completion, Investigators must submit a pilot study report to the Animal Ethics Office. The report must demonstrate:

a. technical competency;
b. the technique and/or research has been demonstrated to be feasible and ethically justified;
c. assessment of animal welfare outcomes;
d. any refinements to animal protocols as a result of the pilot study;
e. compliance with approved monitoring and intervention protocols.

(171) Research activities beyond the pilot phase must not commence until the AEC has reviewed the pilot study report, provided ethics approval and an ARA has been issued. The AEC may:

a. approve progression to full research;
b. require additional pilot work or protocol modifications; and/or
c. impose specific conditions for the main study.

(172) The Animal Ethics Committee Procedure outlines how pilot study reports are reviewed and ratified. Investigators should refer to that document for AEC processes and timelines.

Part C - Monitoring Procedure for Animals Used in Research and Teaching

(173) The University has established monitoring standards for animals used in research and teaching. These standards define the minimum requirements for welfare assessment, documentation, categorisation of clinical signs, escalation actions, and humane endpoints.

(174) Unless otherwise approved by the AEC, Investigators must conduct animal monitoring in accordance with the applicable University monitoring standard relevant to the species and research context.

(175) Where an Investigator proposes an alternative monitoring approach that does not follow the University monitoring standard, a detailed justification must be provided in the ethics application, demonstrating that the proposed alternative approach provides an equivalent or higher level of animal welfare protection. Approval of alternative monitoring arrangements is at the discretion of the AEC.

(176) Exceptions to University monitoring standards may be approved by the AEC where standard monitoring is impracticable or inappropriate (e.g. biosecurity constraints, fragile nests, sensitive wildlife, or safety considerations).

(177) Approved exceptions must:

a. be explicitly justified in the ethics application;
b. be approved by the AEC prior to implementation; and
c. be clearly documented in the approved monitoring strategy and monitoring records.

(178) In the absence of an approved exception, the following University monitoring standards apply.

University Monitoring Standards

Minimum Requirements for a Monitoring Event

(179) As a minimum, each monitoring event must:

a. confirm the presence and number of animals for which the Investigator is responsible;
b. involve observation conducted in a manner sufficient to assess the welfare status of each animal, including where animals are not immediately visible;
c. assess animals against the monitoring standard approved by the AEC, and any project-specific criteria;
d. include appropriate inspection of the housing, enclosure, or environment where this may affect animal welfare;
e. be documented accurately and contemporaneously.

(180) Where animals cannot be adequately assessed without additional access (e.g. removing a cage from a rack, opening an enclosure, entering a paddock, or temporarily displacing shelters), this must be done unless an AEC approved exception applies.

(181) Monitoring that does not meet these minimum requirements does not constitute acceptable monitoring.

Use and Completion of Monitoring Records

(182) Monitoring records are a formal record of animal welfare assessment and must accurately reflect the condition and presence of animals at the time monitoring is performed.

(183) Monitoring records must not be completed or signed unless the monitoring has been conducted in accordance with the approved monitoring strategy and approved monitoring standard.

(184) Completion of monitoring records where animals have not been adequately assessed, or where records are inconsistent with observed animal condition, constitutes non compliance.

Project-Specific Monitoring Content

(185) Investigators remain responsible for identifying project specific welfare risks, animal protocol related impacts, and species specific indicators that must be incorporated into monitoring under the approved monitoring standard.

(186) Project specific additions may be required by the AEC where necessary to safeguard animal welfare.

Monitoring Strategy and Checklist Development

(187) Investigators must ensure that animals are monitored in accordance with the monitoring strategy approved by the AEC. The strategy must be documented in the ethics application and reflect the applicable University monitoring standard and any approved exceptions.

(188) Monitoring must begin when animals are allocated to a research project and continue until the project concludes.

(189) Monitoring strategies must include, at minimum:

a. Use of Monitoring Checklists, and, where relevant Close Monitoring Cards.
b. Intervention points and humane endpoints.
c. Planned actions for abnormalities and the escalation pathway.
d. Observation frequency across study phases.
e. Roles and responsibilities for monitoring and escalation (including out of hours coverage).

(190) Investigators must use the Monitoring Checklist for Impacts of Research Protocols on Animal Welfare to identify relevant signs, animal protocols, and welfare risks when developing their monitoring strategy. This supports the ethical justification of animal use and must be used to inform the content of monitoring checklists submitted with ethics applications.

(191) Monitoring checklists must:

a. be relevant to the species and animal protocols;
b. be focused on animal welfare (not experimental outcomes);
c. support early detection of welfare concerns;
d. be clear and unambiguous;
e. be understandable by all personnel involved in animal care (e.g. AWO, technicians);
f. include only signs that can be observed or assessed at the time of monitoring (e.g. not lab-based metrics like blood cell counts);
g. include a “No Abnormalities Detected (NAD)” option for efficiency.

(192) All monitoring checklists to be used must be submitted with the ethics application and approved by the AEC. Where an alternative to the University monitoring standard is proposed, the justification must be included for AEC consideration.

(193) Monitoring checklists must include clear categorisation of observed signs linked to defined escalation actions. The following standard categories apply unless otherwise approved by the AEC:

a. NAD (No Abnormalities Detected): no action required
b. Category 1 – Mild Signs: Monitor again in 4 hours. If not improved, seek advice from the Lead Animal Investigator and AWO/veterinarian for advice and intervention. If the same sign persists for more than three consecutive days, contact the AWO/veterinarian for reassessment and advice.
c. Category 2 – Moderate Signs: Contact the Lead Animal Investigator and AWO/veterinarian for advice and intervention.
d. Category 3 – Severe Signs: Euthanase immediately. If the event represents an unexpected adverse event as defined in this Manual — for example, if it occurs earlier than predicted or at a higher incidence than approved, inform the AWO, ensure a post-mortem examination is completed, and submit an Adverse Event Report to the AEC.
e. Weight Loss ≥20%: Euthanase immediately, regardless of other signs.
f. Combination of Signs: If more than two signs are present within any one category, escalate to the next highest category.
g. If signs are present across multiple categories, treat according to the highest category observed.

(194) Investigators may adjust standard categories (e.g. weight loss thresholds or escalation timeframes) to suit specific species or animal protocols, provided the proposed categorisation and justification is submitted with the ethics application and approved by the AEC.

(195) Checklist criteria should be phrased so that boxes are only marked when an abnormality is present. Each

category must be explicitly linked to defined actions and escalation pathways to ensure timely and appropriate responses.

Receipting and Acclimatisation

(196) Animals must be monitored from the time of arrival at the University in accordance with Clause 81. As a general minimum standard, animals should be visually checked at least once daily; however, observtions during this period should be conducted in a manner that minimises disturbance and avoids unnecessary handling. Alternative monitoring frequencies may be approved by the AEC where justified and where animal welfare will not be compromised.

(197) Upon receipt of animals into a faciliy (Day 0), BioResearch Facilities staff will undertake initial handling and placement of animals, including observation for any obvious signs of illness, injury, or transport-related stress.

(198) The Lead Animal Investigator must ensure that monitoring of animals in accordance with Clause 81 commences from Day 1.

(199) Where animals are identified as potentially unsuitable for research use at any stage, the Animal Welfare Officer must be contacted promptly for assessment and advice.

(200) The acclimatisation period allows animals to recover from transport and adjust to their new environment. During this time, animals may not dispaly typical physiological or behavioural patterns.

(201) The minimum acclimatisation period is 5 days, unless otehrwise approved by the AEC. Variations to this period must be justified in the approved protocol.

(202) Animals must be assessed and confirmed as suitable for the intended research purpose prior to the commencement of experimental procedures. To facilitate this, a detailed physical assessment (e.g. weighing, body condition scoring, or examination for specific conditions such as malocclusion) should be performed at an appropriate stage following acclimatisation, or when animals are first handled as part of approved procedures, unless earlier assessment is required for welfare reasons.

(203) Where early assessment of animals is required to confirm fitness for purpose)including for supplier notification or replacement purposes), handling and more detailed examination may be performed during receipting. Such assessments should be conducted in a manner that minimises stress and disturbance, and only to the extent necessary to confirm animal suitability.

(204) Routine identification procedures (e.g. ear notching, tattooing) may be undertaken during or following acclimatisation where required for animal management or experimental purposes. These procedures are considered low impact and do not, in themselves, require additional monitoring beyond routine requirements, unless otherwise specified in the approved protocol.

Monitoring Requirements Across Study Phases

Naïve Phase Monitoring

(205) The naïve phase begins after the acclimitisation period ends and continues until experimental interventions commence. Observation during the naive phase allows Researchers to establish a baseline understanding of normal behaviour, appearance, and physiological condition for the species, strain, and individual animals. This baseline is important for identifying adverse effects during subsequent experimental procedures.

(206) Animals must be monitored during the naïve phase in accordance with Clause 81. As a general minimum standard, animals should be visually checked at least once daily. Daily monitoring does not require routine handling of animals unless indicated by observations or specified in the approved protocol.

(207) Where appropriate for confirmation of ongoing health and suitability for research use, animals should under periodic physical assessment, such as weighing or body condition scoring, at a frequency appropriate to the species, strain, and project requirements, and at least once weekly unless otherwise specified in the approved protocol.

(208) Alternative monitoring frequencies may be approved by the AEC where justified and where animal welfare will not be compromised. Where an alternative monitoring strategy is approved, Researchers must adhere to the requirements specified in the approved protocol.

(209) Monitoring during the naïve phase must be documented in accordance with University Monitoring Standards, approved by the AEC. Investigators may use the same monitoring records developed for the active phase of their project where appropriate.

Active Research Phase Monitoring (Interventions Started)

(210) From the commencement of the approved project, animals must be monitored daily, including weekends, in accordance with ARRP Guideline 29. Exceptions must be approved by the AEC and clearly justified in the ethics application.

(211) Monitoring during the research phase must be documented using formal monitoring sheets, based on the University Monitoring Standards, approved by the AEC.

(212) Monitoring frequency must increase during periods of potential impairment or vulnerability (e.g. post-procedural recovery, illness, or high-risk interventions).

(213) Where possible, critical procedures should be scheduled during periods where appropriate personnel and facility support are available (e.g. standard working hours) to ensure timely monitoring and response to animal welfare concerns.

(214) In planning such activities, Investigators must consider the availability of support services (e.g. Animal Welfare Officer, BioResearch Facilities staff) recognising that while some services may be availalbe on-call outside standard hours, on-site support may be limited.

(215) Where critical periods extend beyond or occur outside standard working hours, including post-procedure recovery periods, appropriate arrangements must be in place to ensure adequate monitoring of animals and timely response to any adverse events.

Part D - Adverse Event Procedure

(216) The University, in accordance with the Code requires comprehensive management and reporting of all adverse events to ensure animal welfare remains paramount and research integrity is maintained.

(217) Adverse events should be classified as either predicted or unexpected.

(218) Predicted adverse events:

a. are events where the event aligns with the outcomes described in the approved Animal Research Authority or supply unit procedures, and
b. the incidence and severity is consistent with that in the approved protocol. For example, sickness or mortality rates that fall within the range approved by the AEC.

(219) Unexpected adverse events:

a. are events that may have a negative impact on the wellbeing of animals and that was not predicted in the

approved project or activity; or

b. occur much earlier than predicted (e.g. significant weight loss predicted after 2 months on diet, but observed after 2 weeks); or
c. has an incidence rate that is higher than what was predicted in the approved project. Examples of unexpected adverse events are included in Table 3 and example scenarios are available on ResearchHub.

(220) All adverse events must be documented and reported as follows:

a. predicted adverse events must be managed according to the ethics approval and Clause 194, documented and reported in the Annual Progress Report, which is submitted to the AEC at the end of the project approval year;
b. for unexpected adverse events, immediate action must be taken to safeguard the welfare of affected animals. Specific obligations for responding to such events are outlined in "Immediate Response Obligations" below. All unexpected adverse events must be reported through formal channels. See "Reporting Unexpected Adverse Events".
c. if an Investigator is unsure whether an event is predicted or unexpected, the Animal Welfare Officer (AWO) or Ethics Officer (Animal) should be consulted to determine classification and appropriate reporting requirements.

Table 3 - Unexpected Adverse Event Examples

Animal related adverse events	Environmental/husbandry-related adverse events (potential effect on animal welfare)
Death	Air-conditioning problems
Sickness	Lighting problems
Pain	Access to food/water affected in some manner
Distress	Flooding of cage
Injury	Emergency situation
Abnormal behaviour	Power failure

Immediate Response Obligations

(221) The immediate welfare of research animals is paramount. When animal wellbeing is no longer consistent with AEC approval, immediate action must be taken by the person who first notices the problem, including but not limited to:

a. address immediate welfare needs:
    i. provide veterinary care or carry out humane intervention for affected animals;
    ii. remove immediate hazards (e.g. faulty equipment or hazardous environment factors);
    iii. implement emergency protocols outlined in approved monitoring checklists.
b. inform relevant staff:
    i. contact the Lead Animal Investigator (if not present) and the Animal Welfare Officer promptly. In emergency cases where the Animal Welfare Officer is unavailable, contact the Ethics Officer (Animal);
    ii. for facility-related issues (e.g. environmental failures), promptly inform the Operations Manager, BioResearch Facilities.
c. record and document:
    i. maintain detailed monitoring records for all affected animals;
    ii. keep detailed records of immediate actions, timeframes, and personnel involved;

iii. take photographs of environmental conditions or adverse situations, if appropriate;
iv. secure any equipment or environmental samples relevant to determining the cause of the event.

(222) Table 4 outlines the actions required and their timeframes for unexpected adverse events.

Table 4. Actions Required for Unexpected Adverse Events

Action	Details	Timeframe	Responsibility
Act Immediately (within minutes):	Address immediate animal welfare needs through appropriate veterinary care or humane intervention. Remove obvious hazards while responding to affected animals. Implement emergency protocols as outlined in the approved monitoring checklists. Contact emergency veterinary services if required.	Immediate	Investigator / Lead Animal Investigator / BioResearch Facilities staff
Inform:	The Lead Animal Investigator is to promptly contact the Animal Welfare Officer following an unexpected adverse event. If the Lead Animal Investigator is unavailable, the Animal Welfare Officer may be contacted by another member of the research team. Should the Animal Welfare Officer be unavailable, contact the Ethics Officer(Animal).	Follow Animal Research Authority Specific Monitoring Sheets for specific guidance regarding timelines and actions.	Lead Animal investigator or Investigator
	The Senior Manager, BioResearch Services must be advised when an adverse event involves facilities, a disease outbreak, emergency, or environmental issue.	Promptly (within hours)	Researcher / Chief Investigator / BioResearch Facilities staff / Animal Welfare Officer
Report:	All adverse events involving animals must be reported to the AEC by email or phone. This obligation can be met by ensuring the AWO is informed about the adverse event promptly per the ARA-specific monitoring sheet instructions. The AWO must then inform the AEC Chair on the Researcher's behalf.	Within 48 hours	Animal Welfare Officer / Ethics Officer (Animal)
Report:	All unexpected adverse events involving animals must be reported to the AEC via the Unexpected Adverse Event Report. N.B. Each adverse event must be documented in a separate report. Multiple incidents must not be combined in a single report, except when a single incident involves more than one animal.	Within 14 days.	Lead Animal Investigator
Report:	All predicted adverse events involving animals must be reported to the AEC via the Annual Progress Report.	Annually.	Lead Animal Investigator

Reporting Unexpected Adverse Events

(223) Reporting unexpected adverse events involving research animals:

a. is an ethical obligation;
b. is mandatory in accordance with the Code, Clause 2.4.34 (ii); and
c. enables timely investigation of the cause/s of the event, and the establishment of prevention strategies to

improve animal welfare and research activity outcomes across the University.

(224) The Animal Welfare Officer, or Ethics Officer (Animal) must be notified of an unexpected adverse event promptly (within hours) via phone or email. Animal Research Authority Specific Monitoring Sheets should be followed for specific guidance regarding timelines and actions.

(225) Upon notification the Animal Welfare Officer or Ethics Officer (Animal) will promptly provide the AEC Chair with the details of an unexpected adverse event. In the absence of the Committee Chair, the Deputy Chair or Animal Ethics Executive Committee will be informed.

(226) All unexpected adverse events require submission of a detailed Unexpected Adverse Event Report within 14 calendar days.

(227) Each unexpected adverse event must be documented in a separate Unexpected Adverse Event Report. Multiple incidents must not be combined in single report, except where a single incident involves more than one animal.

(228) This report constitutes a formal submission to the AEC and must include:

a. complete description of circumstances leading to the unexpected adverse event;
b. timeline of events and immediate responses undertaken;
c. monitoring records and treatment logs;
d. post-mortem findings where applicable, including photographic documentation;
e. analysis of contributing factors and potential preventive measures;
f. assessment of impacts on other animals within the research program;
g. recommended modifications to monitoring protocols or research procedures (if applicable).

(229) When information is not available at the time of submission of the report (such as results of pathology tests) an interim report must be submitted within the 14-day time requirement, with a final version of the report submitted on receipt of all information. Delays in post-mortem results do not extend initial reporting deadlines.

(230) The final version of the report must include a copy of the post-mortem where applicable, and completed monitoring checklists associated with the incident.

(231) Where a post-mortem or facility report has been supplied in support of an unexpected adverse event report, it may not be altered in any way by the research team without the express permission of the author of the original report.

(232) All unexpected adverse event records must be maintained in accordance with the University's Records Governance Policy and be available for inspection.

(233) A Variation Application is not required where the unexpected adverse event results in the need for activities within the approved protocol to be repeated. In these instances, a request for replacement animals to meet research goals must be included in the Unexpected Adverse Event Report.

(234) Where ethics approval for additional animals is granted, the Animal Ethics Office may adjust approved numbers and issue an amended Animal Research Authority once the amendment of the ARA is approved by an appropriate delegate.

(235) Studies must not be repeated until the AEC has approved the Unexpected Adverse Event Report and an amended Animal Research Authority has been issued.

(236) AEC handling of submitted Unexpected Adverse Reports is detailed in the Animal Ethics Committee Procedure

Manual.

Post-Mortem Examinations

(237) A post-mortem examination is required if an animal has died or has been euthanased due to its condition, and the:

a. cause of the problem is not defined; or
b. incidence and severity of the problem is not as expected.

(238) If the above circumstances are met, the AWO must be contacted to determine whether a post mortem is required. The AWO's decision to proceed with a post-mortem is final.

(239) The AEC requires that post-mortems are conducted by a Veterinarian or person approved as competent to do so by the AEC.

(240) Where gross examination does not reveal the cause of death, further pathological testing may be required as determined by the AWO to maximise the chance of identifying the cause of the unexpected adverse event. Unless otherwise agreed, the costs associated with additional testing are the responsibility of the Chief Investigator or research team.

Part E - Schedule 4D, 8 and 9 Drug Usage and Compliance

(241) The use of Schedule 4 (S4), Schedule 8 (S8) and Schedule 9 (S9) substances in animal research must be approved by the AEC as part of the ethics application. Investigators must comply with all relevant legislation, including:

a. Animal Research Act 1985 (NSW);
b. Poisons and Therapeutic Goods Act 1966 (NSW);
c. Poisons and Therapeutic Goods Regulation (2008);
d. Medicines, Poisons and Therapetuic Goods Act 2022 (NSW);
e. Animal Research Review Panel Policy 14: The use of scheduled substances in animal research.

(242) Ethics applications must include:

a. justification for drug use;
b. dosage, route of administration, and frequency;
c. welfare monitoring protocols;
d. secure storage and handling arrangements.

(243) S4 drugs (“restricted substances”) may be ordered from a licensed wholesaler. Orders must comply with the Poisons and Therapeutic Goods Regulation 2008 and include:

a. the name of the Chief Investigator; and
b. the animal ethics approval number.

(244) S8 and S9 drugs (“drugs of addiction” and “prohibited substances”) require:

a. a NSW Health Authority to Possess or Supply Schedule 8 or 9 substances;
b. a copy of the authority to accompany the initial order;
c. secure storage and record-keeping in accordance with Section 65 of the Poisons and Therapeutic Goods

Regulation 2008;

d. inclusion of the NSW Health authority number on all orders.

(245) The AWO must be consulted regarding the use of scheduled substances and may provide advice on veterinary protocols and compliance.

(246) The AEC may impose conditions on the use of scheduled substances, including pilot studies, enhanced monitoring, or reporting requirements.

(247) Records of acquisition, use, and disposal must be maintained in accordance with the University's Records Governance Policy and made available for inspection by authorised personnel.

(248) The prescribing of scheduled substances for animals is restricted to registered veterinarians. Where a veterinarian prescribes a substance outside the approved protocol to safeguard animal welfare, the AEC must be notified of the event via the Animal Ethics Office.

(249) Where the Animal Welfare Officer is the prescribing veterinarian, they are responsible for both the clinical decision and notification to the AEC.

(250) Where an external veterinarian is engaged, the Lead Animal Investigator may facilitate communication with the Animal Ethics Office; however, the prescribing veterinarian must provide sufficient information to ensure that the AEC is informed of the substance administered, the clinical rationale, and the authority under which the decision was made.

Section 8 - Complaints

(251) Any person, including University staff, students, affiliates, collaborators, or members of the public may raise concerns or complaints regarding the ethical conduct of animal research or teaching, the welfare of animals, or compliance with approved protocols. This includes concerns about:

a. animal care and use practices;
b. monitoring and welfare assessments;
c. facility conditions;
d. investigator conduct;
e. breaches of approved protocols;
f. non-compliance with legislation or institutional policy.

(252) Complaints may be raised directly with the Animal Ethics Office, the Animal Welfare Officer, or the Chair of the AEC. Alternatively, concerns may be submitted via the “Submit a Research Integrity Concern or Complaint” form available on the University's ServiceNow portal. This form allows for anonymous reporting and may be used by internal or external parties.

(253) Complaints will be managed in accordance with the University's Research Breach Investigation Procedure and the AEC Non-Compliance Management Procedure as per the Animal Ethics Committee Procedure Manual. All complaints will be treated seriously and confidentially, and appropriate action will be taken to investigate and resolve the matter.

(254) Students who hold a conscientious objection to participating in teaching activities involving animals may raise their concerns via the “Submit a Research Integrity Concern or Complaint” form in ServiceNow. This form allows for anonymous submission and ensures that concerns are directed to the appropriate University staff for review.

(255) The University will make reasonable efforts to accommodate conscientious objections, including offering alternative learning activities where feasible. Students are encouraged to raise concerns early to allow sufficient time for review and planning.

Status and Details

Status	Current
Effective Date	14th September 2026
Review Date	14th September 2029
Approval Authority	Academic Senate
Approval Date	11th August 2026
Expiry Date	Not Applicable
Responsible Executive	Rohan Walker Pro Vice-Chancellor (Research)
Enquiries Contact	Rebecca Dyson Senior Manager, Research Integrity 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.

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

"Commercial activities" - As defined in the University of Newcastle Act 1989.

"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.

"Learning outcome" - In accordance with the AQF definitions, the expression of a set of knowledge, skills and the application of the knowledge and skills a person has acquired and is able to demonstrate as a result of learning.

"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.

"Affiliate" - A person or organisation legally obligated to, or informally associated with the University. Categories of affiliates are outlined on the University website.

"Delegate" - (noun) refers to a person occupying a position that has been granted or sub-delegated a delegation of authority, or a committee or body that has been granted or sub-delegated a delegation of authority.