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;
f. Poisons and Therapeutic Goods Regulation 2008;
g. Drug Misuse and Trafficking Act 1985;

University Policies 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

(4) This Manual applies to the breeding, holding, and use of all animals at the University for the purposes of research, as defined by the Animal Research Act 1985 No 123. In this context 'research' includes teaching.

Section 3 - Intent

(5) This Manual and its associated documents are designed to ensure that animal research at the University is conducted in an ethical manner and in accordance with legislation.

Section 4 - Audience

(6) This Manual must be read and complied with by all personnel involved in research, animal care and use, including but not limited to Chief Investigators, Investigators (teachers and Researchers, including students), veterinary staff, Research Ethics and Integrity Unit staff, BioResearch Facilities staff, and the Animal Care and Ethics Committee.

Section 5 - Document Specific Definitions

(7) 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. This period is a minimum of 5 days and is routinely between 5 and 7 days, unless otherwise approved by the ACEC.
b. "Animal" means any live non-human vertebrate (that is, fish, amphibians, reptiles, birds, and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.
c. "Animal husbandry check" means the daily process conducted by BioResearch Facilities staff to ensure animals have food, water, and an appropriate environment. Animal husbandry checks do not include monitoring for predicted adverse effects or completing a Monitoring Checklist.
d. "Animal Research Authority" 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.
e. "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.
f. "Investigator" means any person who uses animals for scientific purposes. It includes Researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

Section 6 - Animal Research Policy

Part A - The Animal Care and Ethics Committee

(8) The University:

a. has established the Animal Care and Ethics Committee (ACEC), which is directly responsible to the Vice-Chancellor;
b. ensures, through the ACEC, that all animal research conducted at the University complies with relevant legislation, national guidelines, and codes;
c. provides the ACEC with the resources and authority to fulfill its terms of reference and operate as set out in the legislation; and
d. accepts the responsibility to respond effectively to recommendations made by the ACEC to ensure that all animal research within the University remains in accordance with the legislation, national guidelines, and codes.

(9) The ACEC Terms of Reference are outlined in the ACEC Constitution.

(10) All animal research at the University must be approved by the ACEC prior to the research commencing. In accordance with the governing principles of the Code, the ACEC will only approve those research projects for which animals are essential, justified, and which conform to the requirements of the Code.

(11) In accordance with the Code and the Animal Care and Ethics Committee Procedure, the content of ACEC applications and deliberations remain confidential unless required to be shared under a collaborative agreement.

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

Part B - Investigators

(13) Investigators must:

a. be aware of their responsibilities in the Code Chapter 2.4;
b. fully disclose and discuss ethical issues in research project applications;
c. address the 3Rs in applications to the ACEC, and report any methods used to implement the 3Rs to the ACEC;
d. be knowledgeable about the species to be used in their research project;
e. justify the choice of species to the ACEC in terms of current knowledge about the species and its applicability to the proposed research methods and required outcomes;
f. use quality design, statistical, and procedural methods of research practice as prescribed in Best Practice Methodology in the Use of Animals for Scientific Purposes 2018; and
g. prior to applying for an Animal Research Authority, have completed animal research training required by the University or the ACEC, including modules of the in-house the Code and Animal Research Ethics (CARE) training suite as described in clause 19.

Chief Investigators

(14) Chief Investigators are ultimately responsible for the conduct of their animal research projects and Researchers under their supervision, and must be aware of their particular responsibilities in the Code clause 2.4.5 in addition to the requirements listed in Clause 19.

Part C - The Care and Use of Animals

Accountability and Responsibility

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

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

a. ensure that practices and procedures for the care and management of animals are developed and reviewed on a regular basis so as to encompass current best practice;
b. ensure that adequate numbers of competent people are employed to provide care for animals;
c. maintain the role of the Animal Welfare Officer as the role responsible for the direction of competent animal care; and
d. support availability and access to appropriate veterinary and diagnostic services.

Competency of People Involved in Animal Care and Use

(17) The University and the ACEC recognise that animal research involves a broad range of duties and procedures, some simple and some very complex, and that Investigators competent in a particular procedure are the best personnel to supervise, train, and assess competency in others for that procedure.

(18) Persons carrying out animal research who are considered 'yet to be competent' must be under the direct supervision of a person who is competent, and a monitoring strategy must be in place until competency is attained.

(19) The minimum level of competency for Investigators at the University is completion of the CARE 1+2 module prior to joining an animal ethics protocol, and re-completion again once every three years thereafter. Further competency requirements for Investigators, BioResearch Facilities staff, and the ACEC are described in the University's Animal Research Competency Procedures as outlined in this Manual (Section 7, Part E).

(20) Chief Investigators must ensure that all persons responsible for making observations of animals from which an intervention point or an endpoint will be determined, are trained in and competent in evaluating the normal physiology, behaviour, and body condition of the animals under observation, and the anticipated specific changes from what is considered to be normal.

Animal Care, Animal Husbandry and Breeding and Holding Facilities

(21) The Senior Manager, BioResearch Services is responsible for ensuring Standard Operating Procedures are current, effective, and approved by the ACEC for:

a. animal care during supply;
b. animal husbandry; and
c. breeding and holding facilities.

Monitoring and Adverse Events

(22) The University will ensure adequate monitoring of animals and prompt and appropriate response to all adverse events where animal wellbeing may be compromised. All staff involved in the care and wellbeing of animals are required to comply with the Animal Research Monitoring and Adverse Events Procedures as outlined in this Manual (Section 7, Part G).

(23) BioResearch Facilities staff required to undertake any special responsibilities for monitoring animals, in addition to routine husbandry, must become part of the research team.

(24) The University recognises the Code (Clause 3.1.12) requirement for animals in social isolation or separation from a group. The ACEC allows a maximum duration of such housing conditions of up to 4 weeks for mice or rats only. Timeframes beyond 4 weeks require ACEC approval.

The Use of S4 and S8 Drugs

(25) The use of S4 and S8 drugs in animal research is restricted and must be in accordance with the S4 and S8 Drug Use Procedure in this Manual (Section 7, Part H).

(26) The use of restricted substances (Schedule 4 “S4" drugs) and drugs of addiction (Schedule 8 "S8" drugs) in animals used for research and teaching purposes is controlled under the following legislation:

a. Animal Research Act 1985 No 123;
b. Poisons and Therapeutic Goods Act 1966;
c. Poisons and Therapeutic Goods Regulation 2008;
d. Drug Misuse and Trafficking Act 1985.

(27) Additionally, the Animal Research Review Panel, the statutory body under the Animal Research Act, has issued the following policy: The use of restricted drugs and the conduct of restricted acts of veterinary science in animal research (ARRP policy 14, revised 27 February 2014).

Quarantining and handling animals that pose risk to other animals and humans

(28) Investigators and BioResearch Facilities staff are required to comply with the University's Animal Hazards Procedure.

The Immediate Use of Animals

(29) 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.

(30) The Animal Care and Ethics Committee Procedure must be referred to when the immediate use of animals, as outlined in the Code, becomes necessary.

Part D - Collaborative Animal Research

(31) Investigators must comply with the Collaborative Research Procedure and associated documents.

Section 7 - Animal Research Procedures

Part E - Animal Research Competency Procedures

Intent

(32) Clause 2.1.2 of the Code requires that institutions ensure that all people involved in the care and use of animals:

a. understand their responsibilities and the requirements of the Code; and
b. have the necessary skills and knowledge and have access to appropriate educational programs and resources.

(33) These procedures outline how the University will assess and ensure the competence of people involved in the care and use of animals at the University.

Assessing Competency

(34) The Chief Investigator is responsible for conducting an assessment of competency for each person involved in their particular research project that involves the care and use of animals. Standard Operating Procedures (SOP)

approved by the ACEC, must be used to determine competency in a particular procedure where an SOP for that procedure exists.

(35) In submitting an ethics application to the ACEC, the Chief Investigator will notify the ACEC whether all persons are competent for the procedures to be carried out in the research project, or whether supervision will be required. When supervision is required, the Chief Investigator will nominate a person who is competent in the procedure to be the supervisor.

(36) The Chief Investigator must notify the ACEC of any investigators who have attained competence in a particular procedure in the Annual Progress Report/Renewal application to the ACEC.

(37) The ACEC may require an assessment of competency in routine or specific activities. Such an assessment will be performed by a person or group nominated by the ACEC who holds suitable qualifications against an agreed competency standard (which may be an ACEC approved SOP).

Competency Requirements

(38) Table 1 outlines the competency requirements of personnel involved in animal research.

Table 1. Competency Requirements

Role	Competency Requirements
Animal based researchers, Investigators, and Teachers	All persons listed on animal research projects will: 1. complete CARE 1+2 module of the University's Code and Animal Research Ethics (CARE) training course before joining an animal ethics protocol and recomplete this once every three years thereafter; 2. receive instruction in a scientific discipline relevant to the experimental work being undertaken; and 3. have satisfied the ACEC that they have attained a level of training sufficient for carrying out their tasks. Training may be formal or based on past or present knowledge using the same or a similar species or procedure/s; or 4. be working under supervision and follow instructions given by a competent supervisor.
Chief Investigators	In accordance with the Code (clause 2.4.5), Chief Investigators must: 1. ensure that procedures and resources are in place so that all people involved in the care and use of animals in their research project/s can meet their responsibilities, including their education, training, and supervision as appropriate; and 2. be competent with respect to the wellbeing of animals used in their research project/s.
Senior Manager, BioResearch Services	In accordance with the Code (clause 2.5.14), the Senior Manager, BioResearch Services 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. The Senior Manager, BioResearch Services will ensure that: 1. the practices and procedures for the care and management of animals are based on current best practice; 2. animal wellbeing is monitored by competent BioResearch Facilities staff who are knowledgeable about animal behaviour, and signs and sites of pain and distress for the species at all stages of animal care and use; and 3. routine monitoring by BioResearch Facilities staff occurs frequently enough to ensure that sick or injured animals are promptly identified, and appropriate action is taken. The Senior Manager, BioResearch Services is responsible for providing details of the training and experience of BioResearch Facilities staff to the ACEC, and for giving information about how inexperienced staff will be supervised until they are considered competent for the procedures they perform in the following circumstances: 1. on a 6 monthly basis when reporting on research projects to the ACEC; and 2. when new persons are added to a research project. 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.

Role	Competency Requirements
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.
Veterinary 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.
Animal Welfare Officer	The Animal Welfare Officer (AWO): 1. provides oversight of the care, husbandry and health of animals, and the biosecurity of facilities; 2. is appointed on the basis of appropriate veterinary qualifications, eligible for registration as a veterinarian in New South Wales; and 3. has extensive practical experience and familiarity with animal research; 4. develops and coordinates orientation and training programs for staff and students working with animals in University of Newcastle animal facilities and in the field to ensure that a high standard of animal care and welfare is practiced on all sites and that staff are aware of their obligations in terms of animal ethics and animal welfare. The Animal Welfare Officer is expected to comply with the requirement for demonstrated continuing professional education to maintain registration.
Animal Care and Ethics Committee (ACEC)	Where the composition of the ACEC meets the requirements of the Code, the ACEC is considered competent in undertaking ethical reviews and providing fair, consistent, and timely review of applications and reports related to the care and use of animals. The University provides an induction for new ACEC members which includes legislative and committee documentation; makes available appropriate periodicals via the University Library access; and will endeavor to support the attendance of ACEC members at appropriate seminars, conferences, and workshops.

Part F - Submission, Receipt and Processing of Applications to the ACEC

(39) Submissions for approval from the ACEC must undergo peer review in accordance with Research Peer Review Procedure for Ethics Applications prior to submission for approval to the ACEC.

(40) The Animal Ethics website "Obtaining approval for animal research" provides resources to assist with the submission process.

Part G - Animal Research Monitoring and Adverse Events Procedures

Purpose

(41) The Code, enacted under the Act and the Regulation, requires that institutions develop procedures to ensure animal wellbeing is monitored by competent people, and that appropriate action is taken when unexpected adverse events occur.

(42) These procedures assist University Investigators, as defined in the Animal Research Regulatory Manual, to make decisions regarding animal monitoring and adverse events related to animal research, and in doing so meet legislative requirements.

Monitoring of Animals

(43) If an animal research project requires BioResearch Facilities staff to conduct monitoring duties outside of the standard animal husbandry checks, BioResearch Facilities staff details must be included on the Animal Research Authority for that research project, via the New Project Application, or via a Variation Application. The addition of BioResearch Facilities staff to the research project must be approved by the Chief Investigator of the research project and the Senior Manager, BioResearch Services, and agreed to by the BioResearch Facilities staff member/s involved.

(44) The ACEC requires that all animal ethics applications include information on the monitoring strategy to be used to

ensure the wellbeing of animals, including the use of Monitoring Checklist(s).

(45) The ACEC expects that a monitoring strategy will be developed to ensure that abnormalities are detected and acted upon before they result in significant pain, distress, or the death of an animal. The frequency of observations must be:

a. increased when animals are in periods of potential impairment; and
b. such that areas of concern and potential problems can be detected and acted upon as early as possible.

(46) All monitoring of animals must be conducted in accordance with the strategy approved by the ACEC. ACEC approval is required for any changes to an approved monitoring strategy and must be obtained before implementing any changes.

BioResearch Facilities Staff Monitoring Responsibilities

(47) BioResearch Facilities staff will perform daily animal husbandry checks as defined in Clause (7.c).

(48) BioResearch Facilities staff will notify the research project Chief Investigator and a nominated contact person if an animal is found to be unwell during the daily animal husbandry checks. A veterinarian may be contacted by BioResearch Facilities staff where the Chief Investigator and nominated contact person are not able to be contacted. Any subsequent treatment of research animals will be recorded in the Procedures Record/Treatment folder for the research project.

Investigator Monitoring Responsibilities

(49) Chief Investigators are ultimately responsible for the monitoring of animal's wellbeing once it is allocated to the research project and enters the acclimatisation period, and until the animal is no longer required and subsequent provisions are made.

(50) During the acclimatisation period the Chief Investigator is responsible for ensuring that the animals are monitored by a research project team member at least twice, with the first monitoring event to occur 1-2 days post-delivery to ensure that the animals are appropriate for the research project as per clause 2.4.15 (i) of the Code. The animal's delivery date is counted as Day 1 of the acclimatisation period.

(51) If approved by the ACEC, animals are considered to be in a waiting period after the acclimatisation period has ended and prior to commencement of the research project procedures. Animals without known vulnerabilities must be monitored by a research project team member at least twice per week during the waiting period. Animals with known vulnerabilities may require more frequent monitoring, which will be considered by the ACEC as part of the initial research project application.

(52) Table 2 provides a summary of Investigator responsibilities for monitoring animals.

Table 2. Summary – Investigator Responsibilities for Monitoring Animals in Holding

Period	Period Duration	Monitoring Frequency
Acclimatisation	5-7 days unless approved otherwise by the ACEC.	At least twice during the period with the first monitoring event at least 1-2 days post-delivery.
Waiting period for animals without known vulnerabilities.	As approved by the ACEC.	At least twice per week.
Waiting period for animals with known vulnerabilities.	As approved by the ACEC.	As approved by the ACEC in the research project application.

Period	Period Duration	Monitoring Frequency
Procedures (research project has commenced).	As approved by the ACEC.	Daily unless approved otherwise by the ACEC

Monitoring Records

(53) The Code requires records of the monitoring of animals to be maintained. Standard ACEC approval requires that monitoring records begin at the time that an animal is allocated to an approved research project.

(54) The documentation of a monitoring strategy may involve the use of simple checklists for periods when an animal's welfare is less likely to be impacted (e.g. during the acclimatisation period), and more detailed checklists for periods when an animal's welfare is more likely to be impacted (e.g. following an intervention).

(55) Monitoring checklists must be:

a. specifically designed for each procedure and species. Clinical signs will differ according to the type of research, as well as between species and individual animals. For some research projects, several different Monitoring Checklists will be necessary to cover different phases of the work; and
b. developed with input from research project members involved with the monitoring of animals. Input may also be sought from the Animal Welfare Officer, Ethics Officer (Animal), or members of the ACEC.

(56) Animals may be monitored individually or in a group. If group monitoring is used and a problem is identified with an individual animal, the monitoring of that animal must be moved to an individual Monitoring Checklist and the original Monitoring Checklist annotated to indicate that this animal is now being individually monitored.

(57) For animals requiring close monitoring, the cages must have a Close Monitoring Card to ensure that the need for closer monitoring is readily apparent to BioResearch Facilities staff and Investigators.

(58) Monitoring of animals by BioResearch Facilities staff will be recorded on a University Procedures Record/Treatment Sheet.

(59) Investigators must use a University Procedures Record/Treatment sheet in the following situations:

a. when an animal has been allocated to a research project but has yet to enter the research phase;
b. during the research phase if a Specific Monitoring Checklist is not required by the ACEC;
c. during a research project when an animal has recovered from a procedure, or when close specific monitoring is no longer necessary; or
d. recording of procedures that are performed, with the clinical record then continuing on a specific Monitoring Checklist.

(60) Investigators must use a Specific Monitoring Checklist(s), developed for the research project and approved by the ACEC, in the following situations:

a. during the period following an intervention; or
b. when monitoring an animal for specific problems associated with an inherent condition that affects its health or welfare.

(61) Records associated with the monitoring of an animal's wellbeing must remain with the animal at all times (usually in the red folder provided by BioResearch Facilities). Specific monitoring records for particular animals may accompany those animals to the laboratory or other examination/ procedure area/s.

(62) Monitoring records must:

a. be a true and accurate reflection of the monitoring that has occurred. Falsification such as, but not limited to, pre- or post-dating records is unacceptable;
b. be completed and signed by the person who has conducted the monitoring;
c. be legible and completed in ink;
d. only be altered to correct genuine errors by striking through the incorrect information, adding the correct information and including an explanation for the alteration; and
e. be maintained in accordance with the University's Records Governance Policy.

(63) The use and effectiveness of Monitoring Checklists will be reviewed during inspections of research projects. All monitoring records must be available to members of the ACEC and the Animal Research Review Panel (or by an independent external reviewer as required – see Clause 92) during inspections.

Developing Monitoring Checklists

(64) Examples of Monitoring Checklists are available on the Animal Ethics website.

(65) The effectiveness and relevance of monitoring checklists for specific research projects must be reviewed regularly by the Investigator, with a view to improvement.

Use of Pilot Studies

(66) Consideration must be given to the use of preliminary or pilot studies to determine endpoints, particularly when the effects of the treatment are unknown.

(67) Pilot studies using a small number of animals can:

a. help determine the morbidity, time course of effects, and frequency of observations required to set an endpoint;
b. provide an indication of the variance of responses between treatment groups, which can then be used to estimate future group sizes more accurately; and
c. provide the opportunity for research project members to become experienced with the procedure and the expected signs and symptoms.

Adverse Events

(68) The immediate welfare of research animals is paramount. If it is discovered that a problem affects the wellbeing of an animal or animals beyond what is planned for in the approved research project, quick actions must occur to remove obvious causes. The reporting of such events is mandatory in accordance with the Code clause 2.4.34 (ii).

(69) Adverse events can be a single or cumulative event and may be unexpected or predicted.

(70) Examples of adverse events are included in Table 3 and example scenarios of adverse events are available on the Animal Ethics website.

Table 3. Adverse Event Examples

Animal related events	Environmental/husbandry-related events (potential effect on animal welfare)
Death	Air-conditioning problems
Sickness	Lighting problems

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

Unexpected Adverse Events

(71) Unexpected adverse events are those that have a negative impact on animal wellbeing and:

a. are not predicted events in the approved research project; or
b. have an incidence rate that is higher than what was predicted in the approved research project.

Predicted Adverse Events

(72) Predicted adverse events are those events which are adverse, but where the cause is known and the level of incidence/severity is as described in the approved research project or supply unit procedures.

Research Related Events

(73) Research related events may impact on research results or the progress of a research project, but have no impact on animal wellbeing.

Post Mortem Examinations

(74) 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.

(75) If circumstances in Clause (74) are met, the Animal Welfare Officer must be contacted to determine whether a post-mortem is required. The Animal Welfare Officer's decision to proceed with a post-mortem is final.

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

(77) Where the gross examination does not reveal the cause of death, further pathological testing should be undertaken to maximise the chance of determining the cause of the unexpected adverse event.

(78) Table 4 outlines the actions required for adverse events.

Table 4. Actions Required for Adverse Events

Action	Details	Timeframe	Responsibility
Act Immediately:	Determine and remove any obvious hazards while responding to the immediate needs of sick or at-risk animals.	Immediate	Researcher / Chief Investigator / BioResearch Facilities staff

Action	Details	Timeframe	Responsibility
Inform:	The Chief Investigator is to promptly contact the Animal Welfare Officer following an unexpected adverse event. If the Chief 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.	Chief Investigator or Researcher
Inform:	The Senior Manager, BioResearch Services must be advised when an adverse event involves facilities, a disease outbreak, emergency, or environmental issue.	Promptly	Researcher / Chief Investigator / BioResearch Facilities staff / Animal Welfare Officer
Report:	All adverse events involving animals must be reported to the ACEC by email or phone.	Within 48 hours	Animal Welfare Officer / Ethics Officer (Animal)
Report:	All unexpected adverse events involving animals must be reported to the ACEC via the Adverse Event Report.	Within 14 days.	Chief Investigator
Report:	All expected adverse events involving animals must be reported to the ACEC via the Annual Progress Report.	Annually.	Chief Investigator

Reporting Adverse Events

(79) Reporting adverse events involving research animals:

a. is an ethical obligation;
b. is mandatory in accordance with the Code; 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.

(80) The Animal Welfare Officer, or Ethics Officer (Animal) must be notified of an unexpected adverse event promptly via phone or email. Animal Research Authority Specific Monitoring Sheets should be followed for specific guidance regarding timelines and actions. Where it is determined that animal health or welfare is at risk, preliminary written advice must be submitted within 48 hours so that appropriate action can be taken to remove or minimise the risk. Contact the Animal Welfare Officer for further information if required.

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

(82) All reports must be submitted to the ACEC in accordance with Animal Ethics application procedures. Table 5 outlines the reporting responsibilities for adverse events.

Reporting Responsibilities

Table 5. Responsibilities for Reporting Adverse Events

Adverse Event Situation	Responsibility for Reporting
Breeding colony	Chief Investigator or their nominee
Stock animals prior to allocation to a project	Chief Investigator or their nominee

Adverse Event Situation	Responsibility for Reporting
Research breeding colony	Chief Investigator or their nominee
Animal supplied or allocated to a research project, but experiments have not yet commenced	Chief Investigator or their nominee
Animal supplied or allocated to a research project, and experimental intervention has commenced	Chief Investigator or their nominee

Reporting Unexpected Adverse Events

(83) Adverse Event Reports must be submitted within 14 calendar days of the occurrence of the unexpected adverse event.

(84) Where submissions are incomplete (e.g. post mortem results are not yet available), the completed Adverse Event Report must be re-submitted once results are known or the cause has been identified.

(85) A Variation Application is not required where the adverse event consequently requires currently approved studies to be repeated, and this is detailed in the Adverse Event Report. Studies must not be repeated until the ACEC has approved the Adverse Event Report and an amended Animal Research Authority has been issued.

Reporting Predicted Adverse Events

(86) Predicted adverse events are reported in the Annual Progress Report.

Reporting Research Related Events

(87) Research related events are reported via:

a. a Variation Application to request the use of additional animals if repetition of experiments is required; or
b. the Progress Report/Renewal application for a research project, Annual Report for an animal supply unit, or a Specific Report, which can be submitted anytime.

Part H - S4 and S8 Drug Use Procedures

S4 Drugs

(88) Researchers can use S4 drugs (“restricted substances”) for animals in approved research projects provided that:

a. the ACEC has approved the use of the drug in that research project;
b. the drug is ordered in accordance with the provisions of the Poisons and Therapeutic Goods Regulation 2008 from the holder of a wholesaler’s licence or wholesaler’s authority. Such an order must be in writing and include the name of the Chief Investigator and the Animal Ethics Approval Number; and
c. additional guidelines established by the Animal Research Review Panel (ARRP Policy on the Use of Restricted Drugs in Animal Research) are followed.

S8 Drugs

(89) Researchers can use S8 drugs (“drugs of addiction”) for animals in approved research projects provided that:

a. the ACEC has approved the use of the drug in that research project;
b. a NSW Health “Application for Authority to Possess or Supply Schedule 8 or Schedule 9 Substances, Prohibited Drugs/Plants for the Purpose of Research, Instruction, Analysis or Treatment of Animals” has been completed

and approved;

c. the drug is ordered from the holder of a wholesaler's licence or wholesaler's authority. Such an order must be in writing and include:
    i. the name of the Chief Investigator;
    ii. the Animal Ethics Approval Number; and
    iii. the NSW Health authority number. The initial order must be accompanied by a copy of the authority from NSW Health;
d. the drug is handled and held as required by the New South Wales Poisons and Therapeutic Goods Act 1966, and its Regulation 2008; and
e. additional guidelines established by the Animal Research Review Panel (ARRP Policy on the Use of Restricted Drugs in Animal Research) are followed.

Section 8 - Complaints and Non-Compliance

(90) Please refer to the Animal Care and Ethics Committee Procedure.

Section 9 - External review

(91) The University will ensure that an independent external review of its compliance with the Code is carried out at least every four years. Generally, the triennial accreditation inspection that is carried out by the Animal Research Review Panel (ARRP) will satisfy this requirement.

(92) The University may make arrangements for a review to be conducted in accordance with the Code where the ARRP is unable to inspect within four years of the previous external inspection, or where the University considers an additional external review is required.

Status and Details

Status	Current
Effective Date	14th November 2023
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Approval Authority	Academic Senate
Approval Date	1st November 2023
Expiry Date	Not Applicable
Responsible Executive	Juanita Todd Pro Vice-Chancellor (Research)
Enquiries Contact	Rebecca Dyson Senior Manager, Research Ethics and 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.

"Calendar days" - All days in a month including weekends and public holidays.

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

"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.