

# University of New England Animal Ethics Committee Operating Procedures

As an accredited user of animals for scientific purposes, the University of New England (UNE) must: ensure that the use of animals is justified, provide for the welfare of those animals and incorporate the principles of replacement, reduction and refinement into these policies for animal use.

The UNE Animal Ethics Committee (AEC) is responsible to the Vice-Chancellor (VC), through the Deputy Vice-Chancellor Research (DVCR), for assisting the University in meeting its animal ethics obligations. All communication with the DVCR, regarding the AEC, should be through the Animal Ethics Officer.

The UNE operates as an animal research establishment accredited under the following provisions:

- The NSW Animal Research Act 1985, No.123,
- The Animal Research Regulation 2010 (made under the authority of the Act).
- The Australian Code for the Care and Use of Animals for Scientific Purposes, 8<sup>th</sup> Edition 2013 (updated 2021) (made applicable by Sec. 4 of the Regulation), and
- Animal Research Review Panel Policies and Guidelines.

Central to the above governing provisions is that the University must have an Animal Ethics Committee ("the AEC"), and that no animal may be used for research or teaching without the AEC's prior approval.

These Operating Procedures are established in accordance with section 2.2.20 of the Code, which states that 'Institutions must establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use.'

These Operating Procedures:

- Come into effect upon approval by the AEC,
- Are to be reviewed at least every three years from the date of approval, and
- Are to be publicly available (2.2.1.2).

# Feedback on these Operating Procedures is welcome and should be addressed to animalethics@une.edu.au

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# **Common terms**

Accredited lands	Land designated in the Institution's Certificate of Accreditation as an Accredited Research Establishment, or on the Institution's Animal Research Authority, as the land where it intended that animal research will be carried out by that Institution. For UNE this includes all UNE Farms (Tullimba, Kirby, Laureldale, Trevanna, Tombs, Clarks, Newholme and Maxwellton) and all UNE
AEC	facilities (on and off campus)
ARRP	Animal Ethics Committee, accredited under the Act The Animal Research Review Panel is a statutory body under the Act
CART	Centre for Animal Research and Teaching
DVCR	Deputy Vice-Chancellor Research
Governing Provisions	The NSW Animal Research Act 1985, No.123; The Animal Research Regulation 2010 (made under the authority of the Act); The Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition 2013 (updated 2021) (made applicable by Sec. 4 of the Regulation); and Animal Research Review Panel Policies and Guidelines.
Person with ultimate responsibility	Person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified.
Project	The term 'project' may refer to any activity in which animals are used in research or teaching as defined by the Code and relevant legislation.
Research	The term 'research' also refers to teaching and other activities involving animals as defined in the Code and relevant legislation, where applicable
Researcher	Refers to the person named as Principal Investigator or Principal researcher in an application (whether for

	research or for teaching) which has been approved by the AEC	
The Act	NSW Animal Research Act 1985 (No 123)	
The Code	Australian Code for the Care and Use of Animals for Scientific Purposes	
UNE	University of New England	

# <u>Guidelines covering the welfare of animals used for research & teaching.</u> General Provisions

- Unless otherwise provided, the Guidelines apply to all dealings with all non-human vertebrates and cephalopods approved by the UNE AEC, including observational, nutritional, metabolic, physiological, surgical or psychological activities.
- All animal research conducted on any of the UNE accredited lands and facilities is required to have animal ethics approval from the UNE AEC.
- Applications must be submitted on the most current version of the UNE application form.
- Scientific and teaching activities must not commence until written approval has been obtained from the AEC.
- All experiments involving live animals shall be carried out by people competent for the procedures or under the direct supervision of a person competent to perform the procedures, and provisions are to be made for the education, training, and supervision of people nominated on the application, as appropriate.
- Daily animal care records must be kept, to determine the duration of problems, should they arise, concerning the animals' wellbeing, and to monitor the efficiency of husbandry practices. A daily activity log must be maintained and displayed where the animals are held. A template for the daily activity log is attached to the issued authority.
- Any unforeseen sign of pain, suffering or distress in any animal must be reported promptly to the Emergency Contact listed on the Authority, Animal Welfare Office & the AEC. See <u>standard procedure for animal</u> <u>care/animal health emergencies</u>
- Researchers in doubt as to their responsibilities should seek guidance from the AEC Chair or Secretary.
- The justification for continuing or repeating experiments must be on the basis of the results obtained as well as the potential effects on the welfare of the animals and must be constantly subject to review. See also p.7 Re-use of animals.
- Researchers should note that, apart from legal and moral considerations, activities involving the use of animals that produce undue pain, distress or discomfort may result in data that are unsatisfactory or misleading when extrapolated to normal conditions.
- On completion of experiments, researchers shall ensure that animals returned to grazing paddocks or animal houses are clearly identified and that the exact nature of the experiment is recorded on individual animal records. Individual animal records must be maintained for animals that are used for more than one research protocol.

#### **Animal Surgery**

 In these Guidelines, chronic surgical experiments are those in which a surgically manipulated animal is allowed to recover from anaesthesia, while acute experiments are those in which it is not.

- Persons undertaking chronic surgical experimentation will normally be required to have satisfactorily completed appropriate training or have an equivalent amount of practical experience in undertaking surgical techniques.
- Acute surgical experiments may be carried out by persons without surgical training provided the animal is suitably anaesthetised and the operation is supervised by a suitably qualified person.
- The AEC may on application grant exceptions to the above where it is satisfied that the reason given, and the supervision and training provided are adequate.
- Neither this Section nor the AEC Operating Procedures apply to surgical operations on university farms which are considered a normal part of routine husbandry practices.

#### **Meeting Procedures**

The AEC usually meets monthly, to examine applications for approval and to consider related matters.

The AEC operates in accordance with the University's standard procedures and guidelines. The Australian Code for the Care and Use of Animals for Scientific Purposes stipulates that at least one member must be present from each of categories A, B, C & D for a quorate meeting. Categories C and D together must represent at least one-third of those members present (2.2.25). If there is not a quorum the meeting cannot proceed.

The AEC may only approve projects that are ethically acceptable and conform to the requirements of the Code (2.3.2[i], 2.3.5).

Consideration of what is deemed to be ethically acceptable shall be guided by the Code which requires that:

- Respect for animals must underpin all decisions (1.1).
- Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented. Reasons for not wholly or partially replacing the use of animals by other methods must be provided.
- Ethical review must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits. The applicant must explain how the potential benefits, and for whom, would justify inflicting harm on the animals to be used, and how it will be minimised or mitigated.
- Ethical review must be based on information from the applicant's documentation, direct discussions with the applicant and additional information if required that demonstrates the application of the Code's governing principles (1.3, 2.3.4, 2.3.8).

A copy of each new application must be provided to all members of the AEC with sufficient notice to allow the members to consider the application in time for discussion at the next meeting of the Committee. If members have any

questions or concerns about an application they may seek clarification from the researcher, prior to the meeting, after consulting the Chair.

The AEC may only consider and approve applications for new projects at quorate meetings of the AEC (2.3.6).

The AEC must base its decisions on a thorough, fair and inclusive process of discussion and deliberation by AEC members, and decisions should be made only by those able to participate throughout the discussion (2.3.10); The AEC must provide competent, fair, consistent and timely review of applications (2.3.3, 2.3.13) and make decisions as promptly as possible (2.3.13);

The AEC should make decisions based on consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore, with the applicants, ways of modifying the project that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion (2.3.11). A majority decision shall be determined by a vote from those members of the Committee occupying Categories A, B, C, D and other but excluding the Chair; in the event that a vote is tied, the Chair shall have the casting vote. Voting may be by a show of hands or by written ballot. Abstaining members may request that their views be formally recorded in the Minutes.

#### Re-use of animals in research

When considering approval for the reuse of animals, the AEC must balance the potential effects on the welfare of animals from prolonged use and also take into account:

- The pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions.
- The time allowed for recovery of the animals between activities.
- Whether an animal has fully recovered from the previous activities.
- The pain and distress likely to be caused by the next and subsequent activities.
- The total time over which an animal will be used (2.3.15).

## **Approval Process**

The AEC approves the project and an ARA Authority is issued by the Deputy Vice-Chancellor (Research) which includes an approval number ARAxx-xxx.

Applications may be dealt with in the following ways (2.3.9.1):

- 6.1. Approved with no conditions.
- 6.2 Approved with conditions (which will remain in force for the duration of the ARA).
- 6.3 Approved but ARA temporarily withheld, pending the provision of further information/minor amendments to the satisfaction, in most cases, of the Executive. In such cases the research may not proceed until the ARA is issued.

- 6.4 Deferred, so that the application can be resubmitted to the Committee in the light of its previous comments (refer to deferral process).
- 6.5 Not Approved (refer to <u>not approved process</u>).

When pilot studies are proposed, the AEC must regard these as integral to the overall project (2.3.14).

If, during consideration of an application, the AEC identifies a point of concern, the Principal Investigator may be contacted by phone during the meeting to resolve the point of concern. This interaction and resolution are to be recorded in the minutes.

The Executive may not approve new proposals, but it may approve minor modifications to existing projects for review at the next AEC meeting. See powers of Executive.

## **Duration and completion of approvals**

Animal Ethics Committees are permitted to only provide approval for research projects for a maximum of a 12-month period. This is stated in Part 4, division 3 section 27 of the NSW Animal Research Act 'Unless sooner cancelled, an animal research authority remains in force for the period of 12 months from the date on which it was issued or, where a shorter period is specified in the authority in that regard, for the shorter period so specified'.

The UNE AEC understands that some projects may require approval for longer than 12 months, for example, teaching protocols or research projects (i.e. reproductive studies). As a result, researchers can apply for two, one year time extensions beyond the original approval. It is the researcher's responsibility to re-apply through a variation and progress report to the AEC prior to the project expiring. These documents must be submitted, tabled, and approved prior to the project lapsing. It is at the AEC's discretion should a time extension be approved (2.3.9.2).

If a variation for a time extension is not submitted and approved prior to project expiry and further time is required, a final report and a new application will need to be submitted. There are no exceptions to this rule. To assist with this, the AEC will send a minimum of one reminder as projects approach expiry.

This process can be repeated one more additional time, meaning the project will be approved for three years total. After the three-year period has lapsed, the researchers will need to submit a new application and a final report to close off the previous approved project.

A final report must be submitted on completion of each project. See <u>Animal</u> use reporting requirements.

## **Responsibilities of members**

Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (1.3) and meets the requirements of the Code (2.2.14). A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1 of the Code and must balance whether the potential effects on the wellbeing of the animals involved are justified by the potential benefits (1.3).

To fulfil this responsibility, members should:

- All new members must complete the Animal Ethics Course. All existing members have to complete external training or the MyLearn course every 5 years,
- Be familiar with the Code and other policies and guidelines relevant to the business of the AEC, and
- Provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC (2.2.15).

Procedures must include the declaration of interests by prospective members and the management of conflicts of interest in making appointments (2.2.10).

During their appointment to the AEC, and before any deliberations of the AEC, members and prospective members must declare any interest that could influence the objectivity of their decision-making (2.2.16)

Members and others who attend meetings or who are privy to material relating to the activities of the AEC must maintain confidentiality regarding the content of applications and the Committee's deliberations, in accordance with institutional requirements (2.2.17). Content of applications or other matters subject to the AEC's deliberations must not be discussed with anyone other than members of the Committee and the Secretary without the permission of the researcher.

Members are required to attend at least 75% of the meetings held during each year of their appointment. Members will be expected to participate in inspections of animal facilities.

If there are concerns that a member of the AEC is failing to meet their obligations to the work of the Committee and/or its role in ensuring compliance with the Code, the matter shall be referred to the Chair and the Secretary for consideration. If the concerns are deemed to have substance, the matter shall be raised with the member who will be given reasonable opportunity to respond. Should the matter remain unresolved, independent assistance may be sought through channels such as mediation or the NSW Animal Welfare Unit. Strict confidentiality must be observed throughout all such proceedings and rights of appeal must be available.

The Chair may ask a member to resign from the AEC, by providing not less than 24 hours' notice in writing, if the Chair deems this course of action to

be in the best interests of ensuring that the AEC is able to perform its functions effectively. If the member does not accede to the Chair's request, the Vice-Chancellor may initiate action through the DVCR to retire the member. The Vice-Chancellor may retire members at any time by providing not less than 24 hours' notice in writing. Such decisions may be appealed by the AEC member being retired, in accordance with the grievance procedures.

#### **Powers of the Executive**

In accordance with the governing provisions, the AEC may delegate certain powers to its Executive.

The AEC Executive must include the Chair, the Secretary and one C or D member. Categories C and D together must represent at least one-third of the Executive.

The Executive has the Authority to:

- Discuss with researchers the issues related to the outcome of their application,
- Approve minor modifications to projects for ratification at the next AEC meeting,
- Approve, in advance, the immediate use of animals should that be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people,
- Draft and recommend changes to forms/policies/procedures of the AEC,
- Halt or suspend a project, and
- Formally withdraw approval for any project or authorise the treatment or humane killing of any animal.

The Executive does not have the Authority to approve new proposals (2.2.23).

Those AEC members participating in the AEC Executive may change depending on availability, provided that the above requirements for membership are met.

#### Management of conflicts of interest

All members will be asked to declare any conflicts of interest at the beginning of each meeting, as a standing item of the Agenda.

Members are required to disclose the nature of their interest and conflict as soon as practicable after they become aware of anything that may be reasonably considered to be a conflict of interest.

Persons with a conflict of interest must remove themselves from the AEC's decision-making on matters that relate to the conflict of interest (2.2.21). Any such absence shall be recorded in the Minutes of the meeting. Once such members have withdrawn, the remaining members must constitute a quorum (2.3.12).

No member shall provide written or verbal comment on any application for which they have a conflict of interest unless requested by the AEC and their interest has been declared.

If a researcher has consulted a Committee member about their application prior to the application being discussed at the meeting, the Committee member must disclose this communication to the Committee.

The AEC Chair is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC (2.2.13).

The Chair is responsible for considering and responding to any concern raised by a researcher that an AEC member has an interest that may have influenced the objectivity of an AEC decision. In this instance, the Chair must advise the complainant, in writing, of the AEC's response. If the complainant is not satisfied with the AEC's response, a grievance may be lodged, in accordance with the UNE complaints relating to AEC process.

## **Confidentiality**

AEC members, UNE staff and others privy to the content of applications and the deliberations of the AEC shall observe the confidential nature of those documents and discussions.

Members wishing to seek advice on confidential matters may approach the Chair for assistance (2.2.22).

## Person with ultimate responsibility

UNE is obligated to identify a person with ultimate responsibility for the care and use of animals in a project (2.4.5). This person must:

- 1. Ensure that all people involved in the project understand and accept their roles and responsibilities,
- 2. Ensure that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities, including their education, training and supervision, as appropriate, and
- 3. Be competent with respect to the wellbeing of animals used in the project.

This person does not relieve the individual responsibility of each investigator working with animals in the project.

At UNE the person with ultimate responsibility is always the Principal Researcher (first named researcher on the application).

The conduct of research on animals is bound by the provisions of the <u>UNE Code</u> of <u>Conduct for Research</u>.

#### Student researchers

Postgraduate or other students involved in animal research may not be listed as a Principal Investigator on an application submitted to the AEC, they must be declared as students in the application.

## The use of animals in teaching

Section 4 of the Australian Code focuses specifically on the use of animals for the achievement of educational outcomes in science. The Code states 'Institutions must ensure that animals are used for teaching only when their use is essential to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements, and suitable alternatives to replace the use of animals to achieve the educational outcome are not available' (4.3).

The Code also requires that students are given an opportunity to discuss the ethical, social, and scientific issues involved in the use of animals for research or teaching. When students use animals as part of their professional training, curricula in the academic discipline should include material on such aforementioned issues (4.12). Students should also be given the opportunity to conscientiously object, without penalty, and alternatives discussed with the student to ensure their progress will not be compromised.

In accordance with the Code UNE has an obligation to identify the person with ultimate responsibility for the case and use of animals in teaching activities (4.4). At UNE this person is the Principal Investigator. This person, however, does not relieve the individual responsibility of those named on the project. Teachers have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry, and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use (4.11).

When using animals for teaching purposes at UNE, teachers are required to follow UNE AEC procedures when submitting an application. The same application form is used for both teaching and research.

Examples of teaching activities involving animals may include, but are not limited to:

- Undergraduate teaching activities (such as observational wildlife surveys and dissections),
- Engagement activities with industry partners, and
- Field days.

As stated in section 4.17 of the Code, AEC approval is not required for the training and application of agricultural extension work practices, or the training of students in veterinary science, veterinary nursing, or animal

technology to achieve competency-based outcomes in routine procedures if all of the following apply:

- The animals are at their home property, or a premises licensed by a state or territory Veterinary Surgeons Board,
- The procedures would normally occur as part of routine,
- Management or veterinary clinical management of the animal,
- The animals are not subjected to anything additional to routine management or veterinary clinical management of the animal, and
- The teacher is competent to carry out the procedure.

## Animal use reporting requirements

Under the Animal Research Regulation 2010 (clause 24), accredited research establishments are required to report animal usage to the NSW ARRP yearly by the 31<sup>st</sup> of March. The information the UNE AEC is required to report on is derived from the progress/final reports submitted by researchers. Researchers will start receiving automated reminders two months prior to the end date of their project that progress/final reports are required. The Animal Ethics Committee encourages researchers to submit progress/final reports as soon as the animal use component of the project is finished.

Should researchers fail to submit progress/final reports within two months of the project end date, the researchers will be in breach and no further projects will be approved for the offending researchers until the reports have been submitted and approved by the AEC.

Victoria, Queensland, South Australia, Western Australia, and Tasmania all hold similar reporting requirements.

## Closing dates, late applications, and out-of-session meetings.

Committee meetings are typically held on the last Friday of each month. Applications for each month's agenda close 14 days prior to the meeting, i.e., 12pm on the Friday. Due to the tight time frame, no late applications will be added to the agenda once it has closed.

Late applications submitted either by an outside organisation or by an internal UNE researcher, which require the AEC to be convened outside its set meeting schedule, will attract a fee of \$1000 inclusive of GST for both internal UNE researchers and outside organisations.

Fees are based on a full cost recovery basis.

A maximum of four Extraordinary Meetings are available for all researchers and only under exceptional circumstances when the researchers can provide a strong justification for consideration at an out-of-session meeting (justification to be reviewed by the Chair each time). A minimum turnaround time of five working days will be met if a quorum can be achieved.

#### **External Applications**

Applications may be considered for approval from researchers who are not UNE employees or those who do not have an Agreement with UNE to act as their AEC upon the approval from the DVCR, if:

- (i) The applicants intend to operate on University property, or
- (ii) They wish to undertake research off-campus at a location which the AEC judges to be reasonably accessible for the purposes of a site inspection.

The AEC reserves the right to refuse to accept any such application.

If the application is assessed, it attracts the following fee structure:

An application fee of \$1000 plus \$100 GST. It may also attract monitoring fees based on the following, subject to variation:

- (i) Initial inspection fee for off-campus facilities prior to approval,
- (ii) Complexity of the project (combined with the duration of the project will determine the degree and regularity of supervision, visits and/or inspections),
- (iii) Duration of the project (combined with the complexity of the project will determine the degree and regularity of supervision, visits and/or inspections), and
- (iv) Travel costs.

Fees are based on a full cost recovery basis.

#### **Deferral process**

The Animal Ethics Committee will automatically deem projects as requiring a deferral if any of the queries the AEC holds to have significant implications on grounds of ethical concerns, integrity, or animal welfare.

Additional reasons why a project may be deferred include, but are not limited to:

- Application not written in plain English.
- Excessive administrative issues (e.g. not answering questions).
- Out of date application forms.
- Inadequate or insufficient information, especially with respect to procedures, dose rates and monitoring.
- Inconsistency throughout the application.

Should an application be deemed a deferral, the AEC Chair and Secretary will arrange a meeting with the researchers to discuss the project and what changes need to be made prior to resubmission to the full Committee.

## Not approved projects

Reasons why a project may not be approved include, but are not limited to:

- Use of animals not adequately justified.
- Severity of procedures not adequately justified.
- The use of non-animal alternatives not adequately addressed.

Should an application not be approved, the AEC Chair and Secretary will arrange a meeting with the researchers to discuss the project.

#### **Animal Ethics Course**

It is mandatory that anyone who is working on animals at the University of New England complete the Animal Ethics Course. This is in accordance with section 2.4.4.5 of the <u>code</u> which states 'Investigators must undertake education and training, competency assessment, in accordance with the institutional and AEC policies and procedures'.

The UNE has a comprehensive ethics course available on MyLearn to all animal users (internal and external). Users will be required to obtain a grade of 80% or higher in each of the module quizzes (nine total). Once users have completed the course a four-digit number will be provided (which must be included on ethics applications) as well as a certificate that is valid for five years from the date of completion.

The AEC may recommend that any person named on an application complete the UNE Animal Ethics Course, unless the person can demonstrate that they have attended or completed equivalent training by providing the AEC with one of the following:

- Successful completion of an Animal Ethics Course at another institution (certification of this must be provided), or
- Provide a statutory declaration. This will only be accepted if it is clear that previous training in animal ethics has been obtained.

The UNE requires that all animal users complete a refresher course every five years. Upon completion of the refresher users will be issued with a six-digit number which will be valid for five years from the date of completion of the refresher.

## Amendments to approved projects (Variations)

Amendments are classified as either minor amendments or major amendments.

A minor amendment would be a change that, in comparison to what has already been approved, has a minor or positive impact on:

- Animal welfare; and
- The anticipated scientific or educational value and the likelihood of meeting the project's objectives.

Examples of minor amendments may include:

- Changes in staff where they are appropriately qualified or supervised.
- Changes in numbers of animals used below a certain percentage of the number originally approved (e.g. 5-10%).
- Addition of a new research location but using the same project methodology.

Major amendments are those with the potential to have an adverse effect on animal wellbeing. All amendments (minor and major) must be tabled, assessed, and approved at the next available AEC meeting. Approval must be granted prior to the amendments taking place. It is at the AEC's discretion should a variation be approved or not approved.

#### **Out-of-session amendments**

Minor amendments may be approved out-of-session, at request, by email consultation with the AEC Executive and ratified at the next AEC meeting. Out-of-session amendments incur a fee.

The fee schedule is as follows:

Personnel Change - \$100

All other minor amendments (e.g., procedural changes, additional animals) - \$200

The different fees are deemed appropriate as, at times, change of personnel might be unavoidable and to ensure that animal welfare is not compromised the AEC deems it appropriate to charge a lesser fee.

Out-of-session fees can be reviewed and changed by the DVCR at any time, giving one month's notice.

Major amendments cannot be assessed by the Executive.

#### Monitoring animal care and use

The AEC must monitor the use of animals, housing conditions and the care of animals in facilities (2.3.2.4).

## Monitoring shall include:

- Monitoring of the acquisition, transport, breeding, housing and care of animals and relevant procedures in projects approved by the AEC.
- Assessment of compliance with the Code and decisions of the AEC.
- Inspection of animals, animal housing, the conduct of procedures, records, and reports (2.3.17).

#### The AEC shall conduct monitoring through:

- Review of reports and other relevant documents at scheduled meetings.
- Delegation of monitoring to the Animal Welfare Officer when required and to help ensure that monitoring is regular and ongoing (2.3.18).
- Site inspections of each animal facility operated by UNE (see below).

Monitoring of project compliance in accordance with the ARA.

The Code states that each individual AEC must determine the frequency and timing of inspections (2.3.21).

- The UNE AEC aims to conduct four site inspections per calendar year, with the intention of inspecting all UNE's accredited sites during this time
- The AEC will aim to inspect sites that hold research animals on a regular basis during all inspections.
- All AEC members are invited to attend the inspection, and a Category C or D member of the AEC is to participate in the inspections (2.3.20).
- The UNE AEC will conduct announced and unannounced inspections. Announced inspections will allow researchers to meet Committee members and discuss the progress of their project at length.
- Procedures that are likely to cause pain or distress should be inspected by the AEC at an early phase of the project.
- The AEC may also require that an AEC representative be present during certain procedures being undertaken as part of an AEC approved research protocol.
- Any new facilities must be inspected by the AEC, the AEC Executive or a representative of the AEC prior to the animals being housed in the facilities.

Inspections are designed to ensure all housing and research facilities are of a high standard and animals are being cared for in accordance with the Australian Code of Practice for the Care and use of Animals for Scientific Purposes.

In accordance with the Code, once an animal is allocated to a project, the person with ultimate responsibility is responsible for the day-to-day monitoring of its well-being. Prior to this allocation, day-to-day monitoring is the responsibility of the Centre for Animal Research and Training (CART) or UNE SMART Farms, where appropriate. The AEC monitors these activities during inspections and in the review of reports, unless otherwise determined by the Committee.

The Secretary will maintain records and take minutes (including the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30, 2.3.22) of all inspections. Minutes are to be tabled at the closest AEC meeting for approval. Identified problems must receive appropriate follow-up and the AEC must be advised and given opportunity for input. Outcomes of follow-up and related discussions by the Committee must be recorded in the minutes of meetings.

## Monitoring animals at remote sites

The Australian Code for the Care and Use of Animals for Scientific Purposes states that 'AEC procedures should cover the delegation of authority to suitably qualified people to monitor animal care and use, including projects and activities conducted at remote sites (e.g. fieldwork). Procedures should include how reports of such monitoring are to be provided to the AEC (e.g. using still or video images) (2.3.23).

As such, the UNE AEC will request photographs of the remote research sites that will be used and, in most cases, will request that the researchers nominate an external monitor who can provide the AEC with a report of the facilities and communicate with the AEC about any problems.

## Research conducted overseas

Where a research project involving animals is to be conducted overseas and the personnel responsible is an UNE researcher (student or staff), UNE AEC review and approval is required. In addition, approval may be required from an overseas ethics committee or equivalent body where appropriate or available. At a minimum it is expected that the governing principles of the Code are met when conducting research overseas, taking into account compliance with local requirements. The AEC also requires assurances that animal facilities meet the standard expected of UNE animal facilities.

UNE reserves the right to request that the requirements of the Code and local compliance are met and that any tensions with overseas legal or other processes are resolved as set out in the Code.

#### **Unexpected Adverse Events**

The <u>Australian Code</u> defines an <u>Adverse Event</u> as: any event that has negative impact on the wellbeing of an animal.

It defines an <u>Unexpected Adverse Event</u> as: an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

An unexpected adverse event may result from different causes, including but not limited to:

- Death of an animal, or group of animals, that was not expected,
- Adverse effects following a procedure or treatment that was not expected,
- Adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study,
- A greater level of pain or distress than was predicated in the planning of the project or activity, and

 Power failures, inclement weather, emergency situation or other factors external to the project or activity that have a negative impact on the welfare of the animals.

It must be assumed that circumstances that would cause pain and distress in humans would also cause pain and distress in animals (1.10).

Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress, in accordance with institutional and AEC policies and procedures regarding <u>animal health</u> <u>emergencies</u>. Alleviation of pain and distress of a severity that was not anticipated in an approved project must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity. If necessary, animals must be humanely killed without delay (3.1.24).

When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person (3.1.25).

The Australian Code also states in part that: "Investigators must provide to the AEC...prompt notification of any unexpected adverse events" (2.4.34).

It is the policy of the University of New England's (UNE) Animal Ethics Committee (AEC) that all unexpected adverse events must be reported to the AEC in writing, via the Animal Ethics Officer, within 24 hours and a formal unexpected adverse event report form submitted within 72 hours of the event. Additionally, if the unexpected adverse event resulted in the death of a research or teaching animal, a postmortem report must also be completed and submitted with the unexpected adverse event report form.

When reviewing an Unexpected Adverse Event, the AEC must ensure that:

- Animal wellbeing is not further compromised.
- The matter is addressed promptly.
- Activities that unexpectedly have the potential to adversely affect animal wellbeing cease immediately.
- Determine what further action (if any) is necessary.

Reviewing an Unexpected Adverse Event may include consulting with relevant people, insisting on appropriate amendments, or suspending or withdrawing approval for the project (2.3.24). When approval is to be suspended or withdrawn, care must be taken to make provision for all animals committed to the study, including any that were not affected by the Unexpected Adverse Event.

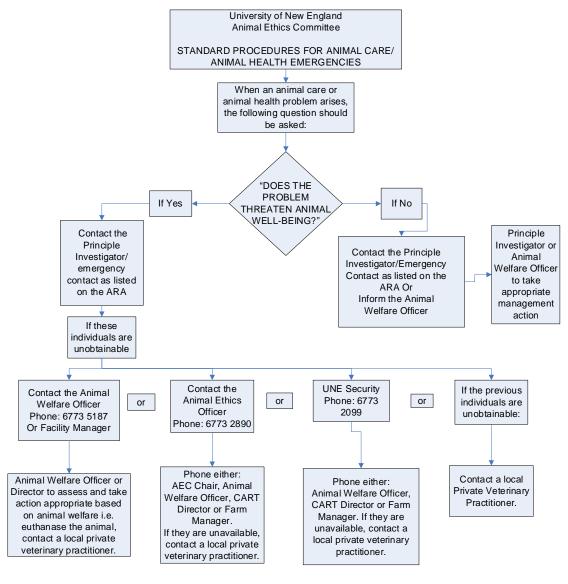
If the circumstances of an incident are so urgent that consultation with the full AEC would delay action that needs to be taken for animal welfare concerns, the project may be suspended by the AEC Chair or, if unavailable, the Animal Welfare Officer. If the Chair or the Animal Welfare Officer are

unavailable a project may be suspended by a quorum of AEC members consisting of one member each from Categories A, B, C and D if they have reached consensus.

When a decision is taken to suspend or withdraw an approval, the Principal Investigator must be notified as soon as possible, and clear reasons given.

The Committee will deem the event either compliant or non-compliant. Refer to the <u>non-compliant</u> section of procedure.

## Standard procedures for animal care/animal health emergencies



#### Complaints relating to animal research

Enquiries and concerns about the care, health or welfare of an animal involved in a protocol being conducted by UNE researchers or teachers can be raised at any time with the AEC Chair or Secretary. Concerns may be raised by any party including investigators, animal carers, the AEC, individual AEC members, students, employees, and members of the public (5).

If any person involved is dissatisfied with the outcome or process involved in dealing with an enquiry or concern that has been properly raised, they may lodge a formal complaint with the UNE AEC. Complaints may relate to alleged breaches of the Code, relevant legislation, or institutional policies (5.1).

The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes specifies that institutions must establish mechanisms to respond to complaints concerning the use of animals within the institution (i.e., Grievance Procedures).

Consistent with the Animal Research Review Panel Policy #8 Establishment of protocols for grievance procedures has been set up to handle the following situations:

- (a) A formal complaint from a person not satisfied with the outcome or process following an enquiry or concern properly expressed (Refer to Procedures for handling enquiries and concerns).
- (b) Complaints from independent people who are not associated with the University with respect to the use of animals in research or teaching.
- (c) Disputes between researchers or teachers and the AEC with respect to the use of animals in research or teaching.
- (d) Disputes between members of the AEC.

It is the University's policy that complaints made by staff or students will not jeopardise their employment or entitlements for voicing concern or initiating an enquiry or complaint concerning the use of animals within the University.

The handling of complaints shall (5.2):

- Ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers (5.2.5),
- Observe relevant UNE policies and procedures,
- Ensure appropriate reporting to, and consultation with, the institution, the AEC, government authorities, and any other relevant bodies (5.2.6), and
- Ensure that access to relevant procedures is available to complainants and all other stakeholders (5.2.7).

Complaints will be received on the understanding that complainants will comply with all reasonable requests to assist in the investigation of their complaint and that, should a complainant choose not to comply with such requests, further investigation or resolution of their concerns may be delayed or may not be possible.

#### 23.1 Making a complaint.

- A complaint must be in writing and signed.
- The complaint must be lodged with the Animal Ethics Secretary.
- Receipt of a complaint must be acknowledged immediately in writing.
- Complaints must be passed promptly to the AEC Chair.

 In situations where it is not appropriate to notify the AEC directly, matters may be referred to the DVCR or their delegate. If the matter relates directly to an Animal Welfare issue, the AEC Chair must be advised.

Complaints may be made anonymously, although it must be recognised that anonymity can hinder the investigation of complaints in some situations.

Anonymous complaints can be made through:

- Sending a written complaint by mail to Research Services, Care of Animal Ethics Secretary, T.C Lamble Building, UNE, NSW, 2351, or
- Sending an email to <u>animalethics@une.edu.au</u> from an email address that does not contain a name or any other obvious identifier.

## Investigation of complaints/grievance

The responsibility for investigating a complaint lies with the AEC Chair, who will advise the complainant on a proposed course of action within two working days of receiving the complaint.

If the complainant is dissatisfied with the proposed course of action, an alternative approach may be negotiated. If an agreement on a course of action cannot be reached, the complainant may take the matter to the DVCR or their Delegate.

The investigation of complaints must give priority to the wellbeing of the animals and ensure that activities with the potential to adversely affect animal wellbeing cease immediately (5.2.1, 5.4.1). The AEC Chair must decide whether there is immediate danger of animal pain or distress. If so, the AEC Standard Procedures for <u>Animal Care/Animal Health Emergencies</u> apply. Where necessary, the powers given by the AEC to the Executive to halt or suspend a project will also apply.

Complaints relating to activities that would normally require AEC approval must be referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval (5.4.2);

Complaints that raise the possibility of a breach of UNE Research Policy or the *Australian Code for the Responsible Conduct of Research* must be handled in accordance with the UNE procedures specified (5.4.2). Where complaints allege misconduct that falls outside the range of this, the complaint must be handled in accordance with UNE processes for dealing with other forms of misconduct (5.4.4) See Research Integrity;

The AEC Chair shall investigate complaints in the manner provided below.

- The AEC Chair may delegate the investigation, in whole or in part, to other appropriate persons, including member(s) of the UNE AEC, or other University staff. The AEC Chair remains responsible for the investigation.
- If the complaint is made against the AEC Chair, or involves potential conflict of interest for the Chair, the AEC Chair must immediately

inform the DVCR who will appoint someone else to conduct the investigation. This person will have the same powers as the AEC Chair.

Any person acting under this section is called a "Complaints Investigator."

The Complaints Investigator may, where possible, try to resolve the complaint informally. Where formal processes apply, the Complaints Investigator must notify in writing all parties judged to be affected by the complaint.

The AEC and the DVCR must be notified of the complaint as soon as practicable.

The Complaints Investigator may investigate by making all enquiries deemed relevant, including, but not limited to, unannounced inspection of facilities, examination of records, discussion with appropriate individuals, inviting any person with an interest in the proceedings to attend a meeting of the AEC for discussions and seeking any further relevant expert advice.

Investigation may involve consultation with other parties if deemed necessary to establish facts or obtain input considered likely to assist in reaching a fair resolution. Such consultation will be with the approval of the complainant and confidentiality will be observed wherever possible. Steps may be taken to establish that the complaint is not without genuine foundation. Complaints deemed to be without genuine foundation will not be investigated further.

The Complaints Investigator shall keep an adequate record of the progress of the investigation.

Where projects involve more than one institution and/or AEC there must be prompt communication with the other institution(s)/committee(s) on all relevant matters (5.3).

In the event that a complaint cannot be resolved by internal processes, UNE should identify an external party through whom the complainant can pursue their concerns (5.8). The complainant should also be advised that they can report alleged breaches to the Department of Primary Industries (5.11).

When the investigation of a complaint finds that activities have been conducted in accordance with an AEC approval, the activities must be reviewed to ensure that the reason for the complaint is addressed. The AEC may decide that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn (5.5.1).

The Research Services Office must maintain records of complaints (5.10). Records may be in the form of Minutes of AEC meetings and should include the identity of the complainant (if known), details of the complaint, copies of correspondence and meeting notes, and outcomes.

## 23.2 Outcomes of the Investigation

The Complaints Investigator shall prepare a written report for presentation to the AEC as soon as practicable. If a complaint has been resolved informally, the report may simply state that fact. In other cases, the report shall set out the enquiries undertaken, and contain the Complaints Investigator's recommendations on all the issues raised. These may include whether any project or procedure should be modified, whether any person was at fault and any further action that might be suggested.

The AEC shall consider the report and may accept, modify or reject any of the recommendations.

A member of the AEC referred to in the recommendations may present their views when the report is discussed but must withdraw during the determination of the AEC decisions.

The AEC shall provide a report to the complainant and all interested parties, detailing the procedures undertaken and the outcomes from the investigation and the decisions and/or recommendations of the AEC on the matter. People provided with a copy of the report will be given the opportunity to make comments back to the AEC.

Upon receipt of relevant comments from all interested parties, the AEC will proceed to reach and implement its decisions on the report as it finds appropriate.

#### 23.3 Appeals against AEC decisions

Any person objecting to an AEC decision may request that the DVCR or their delegate review the decision. Such a request must be made in writing, be made as soon as practicable after the AEC's decision is handed down and must set out in detail the reasons for dissatisfaction.

On receipt of such a request, the DVCR or their delegate may review the decision in any way seen fit. All available documentation on the investigation and the AEC deliberations will be available to the DVCR. Following this review, the AEC may need to review its process in reaching its decision regarding the application or report and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden (5.6).

## Complaints relating to the AEC process.

Complaints about the AEC process may relate to the Committee's review of an application or report, or attempts to resolve disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution (5.1.2).

Complaints about the AEC process must be in writing and must include the name and contact details of the complainant; anonymous complaints will not be investigated. In situations where it is not appropriate to notify the AEC Chair and/or Secretary directly, matters may be referred to the DVCR or their

delegate. Upon receipt of a complaint, the AEC Chair and Secretary shall be informed and shall work together to propose a course of action. The course of action may involve referral of the matter to senior management or independent parties within UNE upon mutual agreement by the parties concerned.

Within the constraints imposed by privacy regulations and respect for confidentiality, the AEC should be informed of the complaint and may provide input if the matter relates to its responsibilities as defined by the Code.

Steps may be taken to establish the validity of the complaint.

If a resolution cannot be reached through internal processes, the complaint may be referred to an appropriate regulatory body or independent mediator upon mutual agreement by the parties concerned.

Following determination of a complaint about AEC process, the AEC should review the relevant procedures and re-evaluate any decisions in light of the reviewed process. However, the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden (2.2.29, 5.6).

#### Research Integrity

In accordance with the UNE <u>Code of Conduct for Research Rule (CCR)</u> and the UNE <u>Procedures for Investigating Research Conduct Breaches or related complaints</u> where breaches, complaints and allegations are made which relate to animal welfare, animal ethics or an AEC Authority, those matters must be referred in the first instance to the Chair of the AEC.

Researchers are encouraged to contact the <u>UNE Research Integrity Office</u> for any questions or more information.

## Regulatory breaches - non-compliance

A regulatory breach is a failure to comply with the Code or other regulations relating to animal use. A regulatory breach may involve any party involved in the use of animals including investigators, animal carers, the AEC, governance officials, and external parties involved in animal use approved by the UNE AEC (5.1.4).

When a regulatory breach is detected, the AEC must ensure that:

- Activities that have the potential to adversely affect animal welfare cease immediately.
- The issue is addressed promptly in consultation with the Principal Investigator.

In situations where urgent action is required to minimise the impact on animal welfare, responsibility for ensuring an appropriate response may be taken by the AEC Chair or the Animal Welfare Officer until such time as the matter can be considered by the full Committee.

Further action to be taken by the AEC to address regulatory breaches (2.3.2.4) may include:

- Suspending or withdrawing approval for the project.
- Referral to UNE management (2.3.25, 5.5.2) via six monthly Chair report at the University Research Committee.
- Requirement of additional training and competency assessment.
- Referral to the Research Integrity office of UNE.
- Other measures determined by the AEC to encourage compliance and reinforce an understanding that behaviours that compromise compliance are not tolerated (5.9).
- Notification of regulatory authorities in cases where there has been a significant impact on animal welfare (5.12).

The AEC Chair shall inform the Principal Researcher in writing of the nature of the breach, the basis of the Committee's decision and any action to be taken.

The Research Services Office must maintain records of regulatory breaches (5.10). Records may be in the form of Minutes from AEC meetings and should include details of the breach, copies of correspondence and meeting notes, and outcomes.

Regulatory breaches may include, but are not limited to:

- Carrying out animal research without an active animal research authority.
- Non-approved personnel working on a project.
- Non-submission of progress/final reports. See <u>Animal use reporting</u> requirements.
- Carrying out procedures not approved by the AEC for a specific project.
- Failure to inform the AEC of unexpected adverse events and complete post mortems within the specified time frame (72 hours).

In most instances, offending researchers involved in the matter of non-compliance will be required to re-sit the UNE animal ethics course. As a result, those researchers will not be able to be listed on any new projects until the ethics course has been completed.

Non-compliance may be outside the jurisdiction of the Animal Research Act and, therefore, researchers should be aware of the following relevant legislation as this may also result in prosecution:

- Prevention of Cruelty to Animals Act (1979)
- The Veterinary Surgeon's Act (2003)
- Poisons and Therapeutic Goods Act 1966
- National Parks and Wildlife Act (1974)

If you are working in other states or territories, you will need to be aware of relevant state specific legislation.

Non-compliance also poses a risk at an institutional level and may result in the loss of licence for UNE as a registered research facility.

## **Cancellation procedures (suspension or withdrawal)**

At any stage during the research/project the AEC may be required to suspend, withdraw or cancel a project. This may be due to, but is not limited to, matters of regulatory breach/non-compliance, animal welfare concerns or unexpected adverse events.

When a decision is taken to suspend or withdraw an approval, the Principal Investigator must be notified as soon as possible by the AEC Chair and will be required to cease all activities immediately. If the project is conducted on UNE accredited lands the animals will be taken into the care of CART until a determination can be made regarding the fate of the project.

The Chair of the AEC is responsible for determining how swiftly a suspension, withdrawal or cancellation must be made in relation to a project. A quorum of the AEC must be formed in response to this. The AEC will at its discretion involve third parties, such as the ARRP, when making its determination.

The welfare of the animal is of the utmost priority, and it is to take precedence over all activities and processes.

If any researcher has had their project cancelled this must be disclosed on all future AEC applications.

## **Standard Operating Procedures**

Standard Operating Procedures (SOPs) are technical internal documents designed and written as instructions for researchers carrying out a routine procedure. The instructions are designed to standardise activities. SOPs are detailed in section 2.2.33 of the Code and a register of the UNE SOPs can be found on the AEC webpage.

Reference to SOPs can help researchers prepare applications to the AEC. Researchers must explain the procedure in brief in the application and provide reference to the relevant SOP. The Code states that an SOP can only be referenced in an application should the following conditions be met:

- The SOP must have current approval from the AEC,
- The SOP must include in its title the date of approval or last review by the AEC,
- Investigators named in the application must be competent to implement the SOP, and
- Any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP by the researchers.

When writing a new SOP to be approved by the UNE AEC the following steps must be followed. See SOP writing procedure.

- 1. Review the UNE SOP for 'writing an SOP' (found in the SOP register).
- 2. Download the UNE SOP template.
- 3. Write SOP It is important to remember that all information contained must be precise.
- 4. SOP must then be reviewed by a subject matter expert; this person does not have to be internal to UNE.
- 5. SOP reviewed by the UNE Animal Welfare Officer.
- 6. SOP submitted to the UNE AEC for review.
- 7. Once approved, an SOP number will be allocated by the Secretary and the SOP uploaded to the AEC webpage.

New SOPs must not be used until approved by the AEC (2.2.34).

All SOPs must be reviewed every three years (2.2.35), a register of this will be kept by the AEC. The researcher who submitted the SOP will be required to perform the review, and it will need to be signed-off on from a subject matter expert. The SOP will then require re-approval from the AEC. Should the SOP be over three years old it will have lapsed and be removed from the register.

All SOPs must be made available to all relevant people, including AEC members. (2.2.36)

#### State/Territory licences & additional permits

UNE holds the following licences with state regulatory bodies.

State/Territory	Licence Type	Licence Number and expiry date
NSW	Operate as an Animal	53143
	Research Establishment	1st February 2025
QLD	Registration as a Scientific	SUR000227
	User	21st August 2027
VIC	Scientific Procedures	SPFL20058
	Fieldwork Licence	7 <sup>th</sup> August 2027
TAS	Animal Research Licence	30 <sup>th</sup> April 2025
WA	Licence to use animals for	U24 /2023 -2025
	scientific purposes	31 <sup>st</sup> December 2025
SA	Licence for teaching,	263
	research or experimentation	13 <sup>th</sup> July 2025
	involving animals	

UNE does not hold an active research licence for the Northern Territory or Australian Capital Territory, as such researchers will be required to obtain their own.

Researchers conducting projects which involve native animals or an animal that is a threatened species or part of an endangered population or a threatened ecological community will need to obtain permits from the Office of Environment and Heritage, or relevant state body.

Research conducted in a National Park may need relevant permits from National Parks & Wildlife Services, or equivalent. Similarly, research conducted on fish may require licences from Department of Primary Industries – Fisheries, or equivalent.

Research conducted using birds may also need a Banding authority obtained through the Australian Bird and Bat Banding scheme.

It is the researchers' responsibility to ensure that the necessary permits/scientific licences are obtained prior to conducting research.

In most cases the above permits/scientific licences will only be valid once ethical approval is provided. In this circumstance ethics approval will be granted on the condition that relevant permits/licences are obtained prior to the commencement of the research activity.

#### **Data Management**

All UNE researchers, including HDR candidates, have responsibilities when it comes to ensuring the value and integrity of research data. The UNE Library's Academic Services and Outreach team is the point of contact for questions regarding managing, storing, sharing, and publishing research data. Researchers are encouraged to access and complete the Research Data Management Plan Template and to contact librarians@une.edu.au for general enquiries. The application form also provides prompts to ensure data management plans are in place.

#### **3Rs Award**

As part of UNE's commitment to the ethical principles of the Code, UNE offers an annual 3Rs Award to reward and promote the implementation, discovery, or development of methodologies and/or technologies that enhance the 3Rs principles.

- Replacement of animals with alternative methods,
- Reduction of number of animals used, and
- Refinement of techniques to minimise the potential impact on animals.

<u>Terms of reference</u> and <u>application forms</u> are located on the AEC webpage.

#### **Honorary Titles**

UNE Emeritus title holders can continue to use the UNE AEC and be listed as a Principal Investigator on any animal ethics project, with agreement from the relevant Head of school. Honorary Titles and awards rule (8.f.iii),

UNE adjunct title holders may be granted access to utilise the UNE AEC if the relevant Head of School deems it appropriate. <u>Honorary Titles and awards rule</u> (18.a.vi)

## **Collaborative Agreements**

UNE holds Collaborative Agreements with the following institutions, to regulate procedures for animal ethics applications (2.6.6):

- New South Wales Department of Primary Industries Orange Animal Ethics Committee (NSW DPI OAEC)
- Commonwealth Scientific and Industrial Research Organisation Armidale (CSIRO Armidale)
- Rivalea
- University of Queensland (UQ)

In accordance with the requirement of the Code that 'each AEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts' (clause 2.6.4.ii), proposals for animal work at UNE properties and facilities (Accredited lands) shall be submitted to the UNE AEC, and proposals for animal work at the abovementioned institutions properties and facilities (Accredited lands) shall be submitted to their relevant AEC.

If animal research involves locations at both UNE and an abovementioned institution, each AEC shall approve the research located at their institution to enable monitoring of all phases of the project [clause 2.6.4 (iv)], and each AEC must be informed of the extent of the entire project, in accordance with clause 2.6.4 (iii). In such a case, the project shall not commence until each AEC approves the activities at its institution [clause 2.6.4 (ii)].

A Collaborative Research Agreement between Accredited Animal Research Establishments pro forma (Appendix A) will be used for each project involving staff and/or students from the abovementioned institutions. To be completed by the AEC issuing approval and provided to the other AEC.

All investigators are required to notify the AEC of their employer institution in writing if they are involved in studies using animals at another institution, or if they are named in an application to the AEC of another institution, in accordance with clauses 2.4.9 and 2.6.8.

If you are collaborating with an Australian research institution (in the capacity of Principal Investigator) *not* listed above, contact <a href="mailto:animalethics@une.edu.au">animalethics@une.edu.au</a> so that a formal agreement can be arranged.

Projects involving staff or students of UNE (in a capacity other than Principal Investigator) approved by an external Australian-accredited animals ethics committee are required to submit the *notification to the UNE AEC of work conducted at an external organisation*.

#### Communication

These Operating Procedures shall be implemented in a manner to ensure that applications and reports are assessed in a manner that is fair to applicants and acceptable to all AEC members and that ensures AEC members are provided with the necessary information in a timely manner (2.3.7).

The AEC shall clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible (2.2.27).

The AEC shall consider face-to-face meetings with applicants to resolve issues (2.2.28).

#### The Institution

UNE must seek advice from the AEC on matters relating to the use of animals to ensure that the requirements of the Code are met (2.3.27).

The AEC must be consulted during the planning of new animal facilities or refurbishment or modification of existing facilities (2.1.6.5). New, refurbished, or modified facilities must be inspected and approved for use by the AEC prior to housing animals, to establish that the facility meets the Code's requirements (2.1.6.5, 3.2.14, 3.2.17-20) and environmental conditions (3.2.17.1).

#### Records

Records of the AEC's business must be maintained by the Research Services Office.

Records must include:

- A register of all applications (including amendments) to the AEC, including the outcomes of deliberations (2.2.30.1),
- Minutes that record decisions and other aspects of the AEC's operation (2.2.30.2),
- Records of inspections conducted by the AEC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30 and 2.3.22),
- Details of applications to be maintained in records include:
  - o Name of responsible institution.
  - Project identification number.
  - o Principal investigator (person with ultimate responsibility).
  - Title of project.
  - o Ethical approval or non-approval with date.
  - o Date(s) designated for review.
  - Details of monitoring procedures.
  - Animal species and numbers used.
  - Details of intended site for the holding of, and research on, animals.
  - Comments made by Committee members about protocols.
  - Investigators' responses to comments by AEC members.

Relevant correspondence.

Animal care staff shall have access to records of approved projects and reports where appropriate and in consultation with the AEC (2.2.31).

#### Reporting on AEC operations

The AEC must report on its operations to the senior management of UNE (2.3.2.9).

The AEC must submit a written report on its operations annually to the governing body through the Deputy Vice-Chancellor Research (2.3.28).

The annual report should include (2.3.29):

- The number of meetings held,
- Numbers and types of projects and activities assessed, and approved or rejected,
- The physical facilities for the care and use of animals by the institution,
- Actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals.
- · Administrative or other difficulties experienced,
- Outcomes or initiatives that have helped advance the 3Rs,
- Reports of any formal complaints received whether relating to animal wellbeing or AEC processes, and whether originating from within or outside UNE, and
- Matters that may affect the Institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.

As part of the AEC accreditation licence, an annual report to the Animal Research Review Panel (ARRP) must be submitted by 31st March each year.

The AEC Chair should meet, at a minimum, once yearly with the DVCR to discuss the activities of the AEC (2.2.37).

The Chair may directly notify or meet with the DVCR on matters relating to the AEC at other times at their discretion.

#### **Document management**

Administration changes (i.e. change in membership, re-appointment of membership, increase of application or variation costs, contact details) to the document are to be made by the Secretary as they occur and be approved by the AEC Chair.

Contextual changes (i.e. new operating procedures or amendment to procedures) must be approved by the Animal Ethics Committee and the DVCR.

#### **Document modification history**

Version	Description	Description of	Date	Provided To
Number	of Version	changes	Completed	

1	Supersede UNE AEC Constitution	New document	11/11/2020	UNE AEC (endorsed), UNE Research Committee (endorsed), UNE Academic Board (endorsed)
2	Updated Operating Procedures	Changes made following external audit review 2021	30/07/2021	UNE AEC (approved)
3	Update of AEC membership	Update of AEC membership	19/08/2022	Appendix - no need for approval
4	Update of AEC membership	Update of AEC membership	18/01/2023	Appendix - no need for approval
5	Update of AEC membership & licence approvals	Update of AEC membership & licence approvals	20/09/2023	Administration changes & appendix - no need for approval
6	Removed appendix, removed reference to Moodle throughout and replaced with MyLearn	Removed appendix, removed reference to Moodle throughout and replaced with MyLearn	13/10/2023	Administration changes & appendix - no need for approval
7	Invited changes from AEC members and other stakeholders finalised	Minor amendments to terminology, updates to outdated links, improvements to Research Integrity sections	08/12/2023	UNE AEC (approved) UNE Research Committee (pending), UNE Academic Board (pending)

# **Document Approval**

Approved by	Date
(Name & Position, where relevant)	
UNE Animal Ethics Committee	27.11.2020
UNE Animal Ethics Committee	30.07.2021
UNE Animal Ethics Committee	08.12.2023

Date of next review: 8th December 2026