

Operating Procedures

Background

The Animal Ethics Committee (AEC) is an executive committee of the Southern Cross University (SCU) Vice Chancellor (VC) and reports to the Senior Deputy Vice-Chancellor (SDVC), as a delegated representative of the VC, for assisting the University in meeting its animal ethics obligations.

As an accredited user of animals for scientific purposes, the University of Southern Cross University (SCU) must ensure that the use of animals is justified, provide for their welfare, and incorporate the principles of replacement, reduction, and refinement into its policies for animal use. All communication with the SDVC regarding the AEC should be directed through the Animal Ethics Officer.

SCU 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, 8th Edition 2013 (updated 2021) (made applicable by Sec. 4 of the Regulation) [The Animal Code]
- Animal Research Review Panel Policies and Guidelines

Central to these governing provisions is the requirement for SCU to have an AEC, with these Operating Procedures established in line with section 2.2.20 of The Animal Code, which mandates that institutions must set up procedures for the effective governance and operation of the AEC to ensure compliance and promote competent and timely ethical review of animal care and use. These Operating Procedures are established in accordance with section 2.2.20 of The Animal Code, enabling the AEC to comply with The Animal Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use.

The SCU AEC Operating Procedures come into effect upon approval by the SDVC and the AEC, are to be reviewed at least every 3 years from the date of approval and are to be publicly available as per clause 2.2.1.2.

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Reference Table for 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, is intended for animal research or teaching by that Institution.
ARRP	The Animal Research Review Panel – Statutory body under the Animal Research Act 1985 (NSW)
Governing Provisions	The Animal Research Act 1985 (NSW), 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 the Animal Research Review Panel Policies and Guidelines.
Primary Investigator – Person with the 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	An activity in which animals are used in Research or teaching as defined by governing provisions.
Researcher	Refers to the individual named as the Principal Investigator in an application for teaching or Research.

Introduction – Guidelines Welfare of Animals used for Research and Teaching

Scope and Application of Guidelines

- i. For the purposes of these guidelines, an *animal* is defined in accordance with the Animal Code as all live non-human vertebrates, including cephalopods.
- ii. Unless otherwise specified, these guidelines apply to all activities involving animals approved by the SCU Animal Ethics Committee (AEC), including but not limited to observational, nutritional, metabolic, physiological, surgical, and psychological activities.

- iii. All animal research and teaching conducted on SCU-accredited lands and facilities must have prior ethics approval from the SCU AEC.
- iv. Applications for ethics approval must be submitted via IRMA, accessible through the AEC Webpage. Investigators are encouraged to consult with the AEC prior to submitting an application to discuss their proposed project.
- v. No scientific or teaching activity involving animals may commence until written approval has been obtained from the AEC.
- vi. All procedures involving live animals must be conducted by individuals who are competent in the relevant techniques, or under the direct supervision of a competent person. Appropriate education, training, and supervision must be provided for all individuals listed on the application.
- vii. Daily animal care records must be maintained to monitor animal wellbeing and assess the effectiveness of husbandry practices. A daily activity log must be kept and displayed at the location where animals are housed. A template for this log is available in the Resources section of the AEC Webpage.
- viii. Any unforeseen signs of pain, suffering, or distress in animals must be reported immediately to the Emergency Contact listed on the Authority, the Animal Welfare Office, and the AEC. Refer to the Standard Procedure for Animal Care/Animal Health Emergencies.
- ix. Researchers uncertain about their responsibilities should seek guidance from the AEC Chair or Secretary.
- x. The justification for continuing or repeating experiments must be based on previously obtained results and the potential impact on animal welfare. This justification must be continually reviewed. Refer also to the section on Re-use of Animals.
- xi. Researchers should be aware that, beyond legal and ethical considerations, activities causing undue pain, distress, or discomfort may compromise the validity of data and its applicability to normal conditions.
- xii. Upon completion of experiments, individual animal records must be maintained for any animals used in multiple research protocols.

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.

- i. Persons undertaking chronic surgical experimentation will be required to have satisfactorily completed appropriate training or have an equivalent amount of practical experience in undertaking surgical techniques.
- ii. 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.
- iii. 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.
- iv. This section of the guidelines and the AEC Operating Procedures exclude surgical operations conducted at university facilities, which are considered part of routine husbandry practices.

Meeting Procedures

The AEC meets monthly to review applications for approval and to consider related matters. The AEC operates in accordance with the University's standard procedures and guidelines. The Animal Code states that at least one member must be present from each of Category's A, B, C, and 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 Animal Code (2.3.2[i], 2.3.5). Consideration of what is deemed to be ethically acceptable must be guided by The Animal 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 are 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 Animal Code's governing principles (1.3, 2.3.4, 2.3.8).

All members are provided online access to the AEC Agenda with sufficient notice (minimum of 10 days) to allow the members to consider the application in time for discussion at the next Committee meeting. If members have any questions or concerns about an application, they may seek clarification from the Chair prior to the meeting.

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

The AEC should 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 should 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 should have the casting vote. Voting can be conducted by a show of hands or through a 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

After the AEC approves the project, an ARA Authority is issued by the SDVC, which includes an approval number generated by IRMA ARAXX-XXX.

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

- Approved with no conditions.
- Approved with conditions (which will remain in force for the duration of the ARA).
- Approved but ARA temporarily withheld, pending the provision of further information/minor amendments to the satisfaction, in most cases, of the Executive. Minor administrative issues may be approved by the secretary. In such cases, the Research may not proceed until the ARA is issued.
- Deferred - resubmitted to the AEC meeting in light of its previous comments. Refer to deferral process
- Resubmission- resubmitted with major amendments to the next AEC Meeting. Refer to resubmission process
- Not approved - Refer to not approved process

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 Executive Committee.

Duration and Completion of Approvals

AECs are permitted to 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."

SCU AEC understands that some projects may require approval for longer than 12 months, such as teaching protocols or research projects. As a result, investigators of teaching protocols can apply for four one-year extensions beyond the original approval and investigators of research protocols can apply for two one-year time extensions beyond the original approval, unless, in exceptional circumstances the Chair approves a total of five years. It is the researcher's responsibility to re-apply through an annual progress report and variation to the AEC prior to the project expiring. These documents must be submitted through IRMA, tabled, and approved prior to the project lapsing. It is at the AEC's discretion whether a time extension is approved (2.3.9.2).

If an annual progress report and variation for an extension of time is not 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.

A final report must be submitted upon completion of each project. See Animal Use Reporting Requirements. If a Primary investigator wants to continue with the Research or Teaching project, they will need to submit a new application and a final report to close off the previously approved project.

Responsibilities of Members

Each member is responsible for determining, based on their own judgment, whether an application or other matter under consideration by the AEC is ethically acceptable (1.3) and meets the requirements of The Animal Code (2.2.14). A judgment regarding the ethical acceptability of a proposed use of animals must be based on information that demonstrates the principles outlined in Clause 1.1 of The Animal Code and must balance the potential effects on the wellbeing of the animals involved against the potential benefits (1.3). To fulfill this responsibility, members are required to:

- Complete the ANZCCART ComPass Animal Ethics Course upon recruitment and every 5 years.
- Complete Victorian Licencing training within the first 6 months of recruitment.
- Be familiar with The Animal Code and other policies and guidelines relevant to the business of the AEC.
- 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) and institutional policies including the [SCU Code of Conduct](#) and the [SCU Volunteer Policy](#). 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.

Animal Ethics Committee

Members are required to attend at least 75% of the meetings held during each year of their appointment. Members have the option 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 Animal Code, the matter should be referred to the Chair and the Secretary for consideration. If the concerns are deemed to have substance, the matter should be raised with the member, who will be given a 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 VC may initiate action through the SDVC to retire the member. The VC 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.

Executive Committee

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, and procedures of the AEC.
- Halt or suspend a project.
- 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 Interests

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 leave the AEC meeting during the consideration of the project and may only return once all decisions related to the conflict of interest have been finalised. Any such absence must be recorded in the Minutes of the meeting. Once such members have withdrawn, the remaining members must constitute a quorum (2.3.12).

A member must not 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 and 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 complaint may be lodged in accordance with the SCU complaints relating to the AEC process.

Confidentiality

- AEC members, SCU staff, and others privy to the content of applications and the deliberations of the AEC must observe the confidential nature of those documents and discussions.
- SCU [Code of Conduct](#) outlines the policy on the use of confidential information by employees and affiliates of the University.
- SCU [Volunteer Policy](#) outlines the policy on the use of confidential for volunteers.

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

Primary Investigator – Who can be the person with the Ultimate Responsibility

SCU 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:

- i. Ensure that all people involved in the project understand and accept their roles and responsibilities.
- ii. 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.
- iii. 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 SCU, the person with ultimate responsibility is always the Principal Investigator (the first named researcher on the application).

Students

Postgraduate or other students involved in animal research cannot be listed as a Principal Investigator on an application submitted to the AEC, they must be declared as students in the application if they are conducting this Research as part of their studies. Undergraduate students enrolled in a teaching unit do not need to be listed.

Adjuncts

Principal Investigators on Animal Ethics applications must hold a substantive appointment with Southern Cross University. Adjunct and honorary appointees may participate as co-investigators but cannot be listed as the sole Principal Investigator.

The Use of Animals in Teaching

Section 4 of The Animal Code focuses specifically on the use of animals for achieving educational outcomes in science, stating: "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 Animal Code also requires that researchers must ensure that students have the opportunity to discuss the ethical and social issues, and legal responsibilities, involved in the care and use of animals for scientific purposes, at a level appropriate to their learning ability and comprehension, and before the use of animals commences. (4.12).

In accordance with The Animal Code, SCU has an obligation to identify the person with ultimate responsibility for the care and use of animals in teaching activities (4.4). At SCU, this person is the Principal Investigator. However, this person does not relieve the individual responsibility of those named on the project. Researchers have personal responsibility for all matters that relate to the wellbeing of animals 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 SCU, instructors must adhere to SCU AEC procedures when completing an online application via IRMA. The application for Research and teaching includes a specific section for teaching that must be completed. 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
- Field days

Annual and Final Reporting

Reporting to the AEC

Researchers will receive automated reminders for three months, two months, and six weeks before their project's end date, notifying them that progress or final reports are required. The AEC encourages researchers to submit these reports as soon as the animal use component of the project is completed.

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

Office Reporting to the NSW and other state Governments

In accordance with the Animal Research Regulation 2010 (clause 24), accredited research establishments must report their animal usage to the NSW Animal Research Review Panel (ARRP) annually by the 31st of March. Researchers will receive an email at the beginning of the first quarter, prompting them to submit their animal usage numbers through the Animal Usage tile in IRMA by the 1st of February.

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

Application Submission Dates and Out-of-Session Meetings

Committee meetings are held 11 times a year on a Monday. Applications for each month's agenda close 14 days prior to the meeting to allow the AEC members a minimum of 10 days to review the applications. Due to the tight time frame, no late applications will be included in the agenda after the deadline.

Late applications submitted by an outside organisation or by an internal SCU 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 SCU researchers and outside organisations. Fees are based on a full cost recovery basis.

A maximum of one out of session meeting per year is 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 ten working days will be met if a quorum can be achieved.

External Applications

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

- The applicants intend to operate on university property, or

- They wish to undertake research/teaching off-campus at a location which the AEC judges to be 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:
 - Initial inspection fee for off-campus facilities prior to approval.
 - Complexity of the project (combined with the duration of the project will determine the degree and regularity of supervision, visits, and/or inspections).
 - Duration of the project (combined with the complexity of the project will determine the degree and regularity of supervision, visits, and/or inspections).
 - Travel costs.

Fees are based on a full cost recovery basis.

Resubmission, Deferral or Rejected application process

Resubmission and Deferral

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

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

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

Should an application be deemed a resubmission to the next meeting, 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.

Reasons Why a Project May be Rejected

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

Should an application be rejected by the AEC, the Chair and Secretary will arrange a meeting with the researchers to discuss the project.

Amendments to approved Projects (variations major and minor)

Amendments are classified as either minor amendments or major amendments.

Minor Amendment (Variation)

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.

Minor amendments may be approved out-of-session by email consultation with the AEC Executive and ratified at the next AEC meeting.

Major Amendment (Variation)

Major amendments are those with the potential to have an adverse effect on animal wellbeing. All major amendments 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 whether a variation is approved or not approved.

Major amendments cannot be assessed by the Executive.

Mandatory Courses

It is mandatory that anyone working with animals at SCU complete an Animal Ethics Course. This is in accordance with section 2.4.4.5 of The Animal Code, which states: "Investigators must undertake education and training, competency assessment, in accordance with the institutional and AEC policies and procedures."

All investigators have access to the animal ethics course via [ANZCCART ComPass](#). After completing the course investigators submit their certificates with their Animal Ethics Application through IRMA. The competency will then be approved for five years under their name.

The AEC may recommend that any person named on an application complete an 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 submitted through IRMA with the application), or
- A statutory declaration. This will only be accepted if previous training in animal ethics has been obtained.

SCU requires that all animal users complete a refresher course every five years.

Monitoring animal care and use including remote sites

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

- Monitoring the acquisition, transport, breeding, housing, and care of animals, as well as relevant procedures in projects approved by the AEC.
- Assessing compliance with The Animal Code and decisions of the AEC.
- Inspecting animals, animal housing, the conduct of procedures, records, and reports (2.3.17).

The AEC must conduct monitoring through:

- Reviewing reports and other relevant documents at scheduled meetings.
- Delegating monitoring to the Animal Welfare Officer when required, to help ensure that monitoring is regular and ongoing (2.3.18).
- Monitoring project compliance must be conducted in accordance with the ARA.
- Conducting site inspections of each animal facility operated by SCU (see below).

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

- The SCU AEC aims to conduct one site inspections per calendar year, with the intention of inspecting all SCU'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 should participate in the inspections (2.3.20).
- The SCU 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 that animals are being cared for in accordance with The Animal Code.

In accordance with The Animal Code, once an animal is allocated to a project, the person with ultimate responsibility is responsible for the day-to-day monitoring of its wellbeing. 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 next AEC meeting for approval. Identified problems must receive appropriate follow-up, and the AEC must be advised and given the 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 Animal Code 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 SCU 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

When a research project involving animals is to be conducted overseas, and the personnel responsible is an SCU researcher (student or staff), SCU AEC review and approval are required. Additionally, 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 Animal Code are met when conducting Research overseas, taking into account compliance with local requirements. The AEC also requires assurances that animal facilities meet the standards expected of SCU animal facilities.

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

Unexpected Adverse Events

The Australian Code defines an Adverse Event as any event that has a negative impact on the wellbeing of an animal.

It defines an Unexpected Adverse Event 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

Animal Ethics Committee

- Adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals used, not the number approved for the study
- A greater level of pain or distress than was predicted in the planning of the project or activity
- Power failures, inclement weather, emergency situations, 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 animal health emergencies. 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 SCU 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, the project may be suspended by a quorum of AEC members consisting of one member from each category A, B, C, and D if they reach 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 non-compliant section of the procedure.

Procedures for Animal Care and Health Emergencies

When an animal care or health problem arises, if it is not life threatening, the Primary Investigator should be notified immediately. If they are unavailable the emergency contacts listed on the Authority or Animal Welfare Officer must be notified. Appropriate management action should be taken.

In a situation where the **problem is threatening animal wellbeing**, the following applies:

- i. **Initial Contact:**
 - In the event of animal wellbeing problem, immediately contact the **Principal Investigator** or the **emergency contacts** listed on the authority.
- ii. **Secondary Contact:**
 - If the Principal Investigator or emergency contacts are unavailable, proceed to contact the following individuals in order:
 - Animal Welfare Officer
 - Facility Manager
 - Animal Ethics Officer
 - Chair

Complaints and Non-Compliance (Regulatory Breaches)

Concerns or enquiries regarding the care, health, or welfare of animals involved in research or teaching protocols conducted by SCU staff, as well as matters related to the operations of the AEC, may be raised at any time with the AEC Chair or Secretary. These concerns can be submitted by any individual or group, including investigators, animal carers, AEC members, students, staff, or members of the public.

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 SCU AEC. Complaints may relate to alleged breaches of The Animal Code, relevant legislation, or institutional policies (5.1).

The Animal Code 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](#), protocols for grievance procedures have been established to handle the following situations:

- 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).

Animal Ethics Committee

- Complaints from independent people who are not associated with the University with respect to the use of animals in Research or teaching.
- Disputes between researchers and the AEC with respect to the use of animals in research or teaching.
- 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 must (5.2):

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

Making a complaint

- The complaint must be lodged with the Animal Ethics Secretary.
- A complaint must be in writing.
- Receipt of a complaint must be acknowledged within 48 hours in writing.
- Complaints must be passed promptly to the Office of the SDVC, or the AEC Chair depending on the nature of the complaint.
- In situations where it is not appropriate to notify the AEC directly, matters may be referred to the SDVC or their delegate. If the matter relates directly to an Animal Welfare issue, the AEC Chair must be advised.

Anonymous Complaints

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:

- Email to animal.ethics@scu.edu.au from an email address that does not contain a name or any other obvious identifier.

Investigating a Complaint

The AEC Chair is responsible for investigating complaints and must propose a course of action to the complainant within five working days. If the complainant is dissatisfied, an alternative approach can be negotiated. If no agreement is reached, the matter can be escalated to the SDVC or their delegate. The investigation must prioritise animal wellbeing, ensuring that any activities potentially harming animals cease immediately (5.2.1, 5.4.1). The AEC Chair must assess if there is immediate danger of animal pain or distress, in which case the AEC Standard Procedures for Animal Care/Animal Health Emergencies apply. Where necessary, the powers given by the AEC to the Executive to halt or suspend a project will also apply. Complaints about activities requiring AEC approval must be referred to the AEC to ensure compliance with their approval (5.4.2).

The AEC Chair must 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 SCU AEC, or other University staff. The AEC Chair remains responsible for the investigation.
- If the complaint is made against the AEC Chair or involves a potential conflict of interest for the Chair, the Secretary must immediately inform the Director, who will appoint someone else to conduct the investigation. This person will have the same powers as the AEC Chair.

The investigator acting on behalf of the Chair may, where possible, try to resolve the complaint informally. Where formal processes apply, the investigator must notify in writing all parties judged to be affected by the complaint. The AEC and the SDVC must be notified of the complaint as soon as practicable.

The Investigator may conduct investigations through various means, including unannounced facility inspections, record examinations, discussions with relevant individuals, and seeking expert advice. Consultations with other parties may occur, if necessary, with the complainant's approval and confidentiality maintained where possible. Steps will be taken to ensure the complaint has a genuine foundation; complaints without genuine foundation will not be investigated further.

The Investigator must 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, SCU 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 Office of the SDVC 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.

Outcomes of the Investigation

The Investigator must 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 must set out the enquiries undertaken and contain the 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 must 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 should provide a report to the complainant and all interested parties, detailing the procedures undertaken, 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.

Appeals against the AEC Decision

Any person objecting to an AEC decision may request that the SDVC or their delegate review the decision. Such a request must be made in writing within 10 days of receiving, in writing the AEC's decision.

On receipt of such a request, the SDVC or their delegate may review the decision and all available documentation on the investigation and AEC decisions. After this review, the AEC may need to reassess its decision-making process for the application or report and re-evaluate its decision based on the reviewed process. The final decision on the ethical acceptability of an activity rests with the AEC and must not be overridden (5.6).

Complaints about AEC Processes

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 Director, SDVC or their delegate. Upon receipt of a complaint, the AEC Chair and Secretary must be informed and 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 SCU 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 Animal 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).

Regulatory Breach – Non-Compliance

A regulatory breach is a failure to comply with The Animal 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 SCU 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 SCU 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 Office of the SDVC.
- 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 must 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 Office of The SDVC 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 all correspondence on the matter, and the determination letter.

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 Animal use reporting requirements.
- Carrying out procedures not approved by the AEC for a specific project.

- Failure to inform the AEC of unexpected adverse events and complete postmortems 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 ANZCCART 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 SCU as a registered research facility.

Withdrawal or Suspension of a project

At any stage during the 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.

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 takes 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 routine procedures. The instructions are designed to standardise activities. SOPs are detailed in section 2.2.33 of The Animal Code, and a register of the SCU SOPs can be found on the AEC webpage.

Reference to SOPs can help researchers prepare applications to the AEC. Researchers must explain the procedure briefly in the application and provide reference to the relevant SOP. The Animal Code states that an SOP can only be referenced in an application if the following conditions are 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 demonstrate the competency to implement the SOP.
- 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 SCU AEC, the following steps must be followed. See SOP writing procedure:

1. Download the SCU SOP template on the webpage.
2. Write the SOP – It is important to remember that all information contained must be precise.
3. The SOP must then be reviewed by a subject matter expert; this person does not have to be internal to SCU.
4. The SOP is reviewed by the SCU Animal Welfare Officer.
5. The SOP is submitted to the SCU AEC for review.
6. Once approved, an SOP identifier will be allocated by the Secretary, and the SOP will be 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). The researcher who submitted the SOP will be required to perform the review, and it will need to be signed off by 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 system.

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

Interstate Licencing and Permits

SCU currently holds the following licences with regulatory state bodies

State	Licence Type	Licence Number & Expiry Date
NSW	Operate as an Animal Research Establishment	2028
QLD	Registration as a Scientific User	2026
VIC	Scientific Procedures Fieldwork Licence	2026

SCU does not currently hold active research licences with the following states: WA, SA and TAS. Researcher are required to obtain their own licence for the Territories (NT & ACT).

Permits

Researchers conducting projects involving native animals, threatened species, endangered populations, or threatened ecological communities must obtain permits from the Office of Environment and Heritage or the relevant state body. Research conducted in a National Park may require permits from National Parks & Wildlife Services or an equivalent authority. Similarly, Research involving fish may require licences from the Department of Primary Industries – Fisheries or an equivalent body. Research involving birds may also require a Banding authority obtained through the Australian Bird and Bat Banding Scheme.

It is the researchers' responsibility to ensure that the necessary permits and scientific licenses are obtained prior to conducting Research. In most cases, these permits and licences will only be valid once ethical approval is provided. Ethical approval will be granted on the condition that the relevant permits and licenses are obtained before the commencement of the research activity.

Collaborative Agreements

In accordance with the requirement of The Animal Code that "each AEC should be responsible for the 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 SCU properties and facilities (Accredited lands) must be submitted to the SCU AEC. Proposals for animal work at the properties and facilities of the aforementioned institutions (Accredited lands) must be submitted to their relevant AEC.

If animal research involves locations at both SCU and another institution, each AEC must approve the Research conducted at their respective institution to enable monitoring of all phases of the project (clause 2.6.4.iv). Additionally, each AEC must be informed of the entire project's extent, in accordance with clause 2.6.4.iii. The project must 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 (Appendix A) will be used for each project involving staff and/or students from the aforementioned institutions. This agreement must 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 animal.ethics@scu.edu.au to arrange a formal agreement.

Projects involving staff or students of SCU (in a capacity other than Principal Investigator) and approved by an external Australian-accredited AEC, the application titled 'Notification of Work Conducted at an External Organisation' must be submitted.

Communication

Communication with Investigators

These Operating Procedures must be implemented to ensure that applications and reports are assessed fairly for applicants and acceptable to all AEC members, ensuring that AEC members are provided with the necessary information in a timely manner (2.3.7).

The AEC should 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 should consider meetings with applicants to resolve issues (2.2.28).

Communication with the Institution

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

The AEC must be consulted during the planning of new animal facilities or the 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 Animal Code's requirements (2.1.6.5, 3.2.14, 3.2.17-20) and environmental conditions (3.2.17.1).

Document management

Documentation

Records of the AEC's business must be maintained by the Office of the SDVC. 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:

- Name of responsible institution.
- Project identification number.
- Principal investigator (person with ultimate responsibility).
- Title of project.
- Ethical approval or non-approval with date.
- 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.

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 AEC and the SDVC.

The Institutional reporting requirements

Reporting on AEC Operations

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

The AEC must submit a written report on its operations annually to the governing body through the SDVC (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 SCU
- Matters that may affect the institution's ability to maintain compliance with The Animal 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 SDVC to discuss the activities of the AEC (2.2.37).

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

Document Approval

Date	Approved by	Version
26 May 2025	AEC	v0.1
24 July 2025	SDVC	v0.1
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