



Animal Ethics Committee Operating Procedure

1. Definitions

[Australian code for the care and use of animals for scientific purposes](#) 2013 (the Code)

ACT [Animal Welfare Act](#) 1992 (the Act)

[Australian Code for the Responsible Conduct of Research, 2018](#)

2. Acronyms

AEC	Animal Ethics Committee
DVC-RI	Deputy Vice Chancellor - Research and Innovation
REO	Research Ethics Office
TCH	The Canberra Hospital

3. Purpose Statement

To ensure effective governance and operation of the AEC that will enable the AEC to meet its responsibilities under the Code and relevant institutional policies. These procedures provide operational requirements for the conduct of the responsibilities, objectives, and functions of the AEC, and the institution.

3.1 Scope of Responsibility

The University is responsible for ensuring that the operating procedures are reviewed and maintained in accordance with the Code, legislation of the relevant jurisdictions and University policies.

The AEC is responsible for ensuring it operates in accordance with these procedures and the AEC Terms of Reference.

4. Membership

4.1 Appointment of Committee Chair, members and advisors

Suitable candidates for the Chair are identified through an open and transparent process by the DVC-RI. Where possible, the Chair would hold a senior position in the institution and be independent of the care and use of animals for scientific purposes.

Suitable candidates for advisors, category A, B, C and D members (the Code 2.2.4) are identified by the REO in close consultation with the Chair. The nomination of Category C Members should be supported by an animal welfare organisation.

Once suitable candidates are identified, the Ethics Office organises the relevant documentation for agreement by the DVC-RI.

4.2 Responsibilities

4.2.1 Responsibilities of the Chair

The Chair is responsible for chairing meetings of the AEC as rostered and incorporating:

- a. Oversight of the decision-making process.
- b. Support for the Committee in a manner that encourages participation of all members.
- c. Ensuring the Committee operates in accordance with relevant legislation, codes and guidelines.
- d. Managing conflicts of interest.
- e. Maintaining confidentiality of the content of applications and the deliberations of review bodies.
- f. Ensuring the Committee operates according to its Terms of Reference and Operating Procedures.

As part of their role, they will:

- g. Contribute to discussions about policies and processes relevant to ethical research practices.
- h. Impartially guide the operation of the Committee by supporting fair and inclusive discussion that enables the AEC to make well informed decisions. This includes taking reasonable steps to resolve differences within the Committee that may impact upon consensus.
- i. Prepare correspondence on behalf of the Committee.
- j. Report Committee activities to the University's executive, including the Deputy Vice-Chancellor (Research and Innovation), and ANU governing committees as required.
- k. Work closely with the Research Ethics Office, Research Services and the ANU Animal Welfare Officers (AWOs) on the handling of serious matters involving animal welfare such as unexpected adverse events.
- l. Follow-up on matters directly concerning the Committee and animal welfare;
- m. Attend the AEC annual inspections of animal facilities and communicate and collaborate with the animal facilities as required to maintain compliance.

When the Chair is unavailable, e.g. due to absence or conflicts of interest, a Deputy Chair may be appointed from among AEC membership to temporarily assume the role.

4.2.2 Responsibilities of AEC Members

- a. Review of ethics applications, amendments, reports, policies and guidelines for research, teaching, breeding, care of animals and any other activity using animals, with a view to ensure consistency with the Code and other relevant animal welfare legislation.
- b. Undertake post-approval monitoring (PAM), either in person, or by delegating authority to an approved representative (Animal Welfare Officer).
- c. Assist with monitoring and follow-up reviews of approved projects and activities including facility inspections, annual and final reports, vet reports, external audits, and other communications.
- d. Review of unexpected adverse events and suspected instances of non-compliance.
- e. Contributing to discussions about, and approval of, policies and processes relevant to ethical research practices conducted at the University.
- f. Maintain the confidentiality of AEC deliberations and decisions, in line with the signed confidentiality agreement.

4.3 Term of appointment

Chairs, members and advisors are appointed for an initial term of six months. This allows new appointees to familiarise themselves with the role and their responsibilities. Following the initial appointment, interested members and advisors are considered for re-appointment for three-year terms in consultation with the DVC-RI, Chair and REO.

The REO will communicate the outcomes of renewals following consultation with the member, Chair and DVC-RI. Membership is managed by the REO to ensure adequate leave provisions are in place for Chair and members.

4.4 Induction of new members & advisors

Prospective members and Chairs will be required to complete the following induction processes prior to serving on a committee:

- a. Observation of a meeting.
- b. Completion of confidentiality agreement.
- c. Completion of a disclosure of interest submission in accordance with the [ANU Procedure - Disclosure of Interest](#) (the Code 2.2.21) prior to their appointment.
- d. Establishment of ANU affiliation (where applicable).
- e. Completion of mandatory training required by the University and or jurisdictional bodies. Including but not limited to ANZCCART ComPass training, Animal Welfare Victoria via the learning management system, and ANU training modules as required.
- f. Induction and training in the use of ANU ethics management system.

4.5 Professional development of members

In addition to the training requirements for induction, the University will provide support for the professional development of members. In determining the most appropriate development opportunities for AEC members, consideration will be given to the:

- a. Value to be obtained from the various training opportunities on offer and to ensure these opportunities are offered equitably to all members.
- b. Availability of funds to support proposed development opportunities
- c. Access needs of members

4.6 AEC Executive

The Executive Committee (AEC Executive) includes the Chair and at least one member from Category C or D (the Code 2.2.23). Minor amendments of approved projects or activities that are not likely to cause harm to the animals (including pain and distress) may be considered by the AEC Executive out of session.

The AEC Executive may: escalate review to the full Committee, seek additional information from the applicant, seek advice from the ANU Vet team/AWOs and/or other advisors, require administrative checks by the REO, approve subject to ratification at the next meeting, or not approve an application.

5. Applications to the AEC

5.1 Submission, receipt and processing of applications and reports to the AEC

New projects, amendment applications and reports should be submitted by investigators via the ANU online ethics system by the submission deadlines. Each new project will be allocated a unique project ID. Where possible, submissions will undergo a preliminary review by the REO and ANU Vet team, prior to submission to AEC for review.

5.2 Amendments

Minor amendments may be processed out of session by the AEC Executive. All other amendments will be reviewed in-session at a meeting of the AEC.

5.2.1 Minor amendments

Amendments to approved projects which are not likely to cause harm to animals, including pain and distress, may be considered minor amendments (the Code 2.2.23(ii)). Minor amendments may include:

- a. Minor changes to activities that have a positive welfare impact on animals or where pain/distress is minimal.
- b. Adding or removing investigators (with the exception of the Principal Investigator (PI));
- c. Requests to extend an approved project (within the maximum 3 years allowed under the Act S41), with no changes to activities/animal welfare.
- d. Addition of new strains to an approved project, provided the phenotype has been fully characterised and there are no additional monitoring or interventions due to the welfare impacts of the phenotype (if welfare impact is unknown, an amendment application will be considered 'major' and must go to an AEC meeting).
- e. Location changes (e.g. within or between approved animal facilities).

All minor amendment approvals will be presented at the next scheduled AEC meeting for ratification (the Code 2.2.23(ii)). Any amendment which does not meet the criteria for being a minor amendment, or which an AEC Executive member believes should not be considered a minor amendment, will be tabled for in-session review by the full AEC at the next appropriate meeting.

5.3 Standard operating procedures (SOPs)

The AEC may consider and approve standard operating procedures (SOPs) for use by individual research groups or for University-wide use. Any variations to approved SOPs must be detailed in project applications.

SOPs must be approved before or in conjunction with a project application and are valid for a period of three years.

5.4 AEC approved guidance

AEC members may provide advice and recommendations to the University regarding the care and use of animals for scientific purposes. The AEC will also review guidelines for activities associated with the care and use of animals to enable best practice. These will be available to investigators in a library of documents as guidance for applications and SOPs.

6. Meetings

6.1 Schedule

A schedule of meetings is provided on the ANU website. Meetings are scheduled for every five weeks, where required, between January and December (inclusive). The schedule may be changed if required to accommodate member availability or urgent business.

6.2 Conduct of meetings

AEC meetings involve the consideration and review of the following (including but not limited to):

- a. In-session applications for new and existing projects, activities, and standard operating procedures (SOPs).
- b. Ratification of out-of-session amendments.
- c. Annual and final reports.
- d. Reports from the ANU Vet team and Animal Welfare Officers (AWOs).
- e. Inspections and post-approval monitoring (PAM).
- f. UAEs and incidents.
- g. Any other matter considered relevant to the AEC.

Meeting minutes will be documented in accordance with the Code (2.2.30) including discussions, decisions, and other aspects of the AEC's operation.

6.3 Application assessment

The AEC will consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings of the AEC (i.e. a quorate of the membership present for each decision) as per Section 2.3.6 of the Code.

The AEC must discuss and decide whether the proposed use, or continued use, of animals is ethically acceptable and meets S38 of the Act. As per Section 2.3.4 of the Code, this judgement must:

- a. Be based on information provided by the applicant that demonstrates the application of the Code's governing principles.
- b. Balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

All applications (new projects, amendments, and SOPs) and annual/final reports are circulated to AEC members by the REO in a timely manner to allow sufficient time for review prior to the meeting date (the Code 2.2.26).

Each application reviewed in-session (new projects, major amendments and SOPs) will have an AEC member from each category assigned as a primary reviewer by the REO. Primary reviewers are required to provide feedback on all assigned items prior to the meeting. All AEC members are encouraged to review all applications. Where appropriate, AEC member feedback will be sent to investigators to provide an opportunity to revise their application prior to the meeting.

All items will be reviewed and discussed by the AEC at the meeting, in consultation with advisors and the Chair where appropriate.

6.4 Quorum and attendance

AEC members may attend meetings in-person, via remote attendance (e.g. videoconferencing and web-conferencing) or a hybrid of in-person and remote attendance. Members should provide the REO with adequate notice of changes to availability where possible.

The REO will oversee the calculation of quorum for AEC membership, meetings, out of session executive deliberations, and inspections to ensure they meet the requirements of the Code. For meetings, at least one member from each of the membership categories A, B, C and D must be present at for the conduct of a meeting, throughout the meeting and categories C and D together must represent at least one-third of those members present (the Code 2.2.25). At least one individual from the REO will be present at an AEC meeting to provide secretariat support.

Observers may attend an AEC meeting with the approval of the Chair providing that confidentiality requirements are met. Advisors, observers, and members of the secretariat are not included in the quorate calculation. The AEC may invite applicants to attend meetings where their submission is to be considered in order to facilitate review.

6.5 Conflicts of interest

Prior to each AEC meeting, members must declare any perceived or actual conflicts of interest (COI) relating to the items for review. Where members have a COI they will be removed from the review, discussion, and decision-making process for matters that relate to the conflict.

COIs are recorded in meeting agendas and minutes. If the meeting is no longer quorate due to removal of members, the items will be held for discussion at the next available meeting. Removal and re-entry times will be recorded in the minutes.

6.6 AEC decisions

The AEC may decide that an application to commence a project or activity, or amend an approved project or activity is:

- a. *Approved* - application is approved as written, subject to the 'standard conditions of approval'.
- b. *Approved with special conditions* - special conditions imposed by the AEC regarding the execution of the project, in addition to the 'standard conditions of approval', e.g. 'Veterinary oversight of a novel procedure'.
- c. *Approved subject to matters being addressed out of session* - application is provisionally approved but requires researchers to implement changes to the project in-line with AEC feedback. When these changes are resubmitted, they will be reviewed by the REO, Chair, and/or AEC members as dictated by the AEC to confirm that these matters have been addressed, then final approval will be granted. This final approval can be without or with special conditions.
- d. *Deferred subject to modification* - AEC feedback will be sent back to the researchers, and the application will be reviewed again at the next AEC meeting.
- e. *Not approved* - application will not be reconsidered by the AEC in its current form
- f. *Approval for the project or activity is continued, suspended, modified or discontinued* - following review of the annual report for an approved project or activity and possible consultation with the applicant.
- g. *Approval is suspended or withdrawn.*

Approval of an application by the AEC signifies that the project has been considered ethically acceptable and conforms to the requirements of the Code and S38(2) of the Act.

All approvals are granted subject to the 'standard conditions of approval' as outlined in the approval letter, such as reporting requirements, obtaining the relevant approvals, licences and training, adhering to legislation, policies and procedures, etc. Approvals are also subject to authorisation conditions as described in S39 of the Act.

Decisions should be made on the basis of consensus, as per Section 2.3.11 of the Code. Where consensus cannot be reached after reasonable efforts to resolve differences, the AEC should explore with the applicant(s), ways of modifying the project or activity 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 to review their positions, followed by further discussion.

The AEC will clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible via the ANU online ethics system.

6.7 Duration of approval

The AEC will grant approvals for projects for a period not longer than 3 years per Section 41 of the ACT Animal Welfare Act 1992. Project approval must not be given retrospectively.

If an investigator wishes to continue a project beyond the 3-year period (from the date it was originally approved), a new project application must be submitted. If continuous coverage is required for the ongoing holding of animals, a new project must be submitted with sufficient time to gain approval prior to the expiry of the existing project. The AEC may choose to pursue authorisation renewal as per S44 of the Act.

6.8 Notification of decisions

Investigators will be notified of AEC decisions regarding their application, including any standard and special conditions of approval, via the ANU online ethics system in a timely manner.

Project approval letters are provided to investigators once AEC approval is processed via the ANU online ethics system. Letters are automatically generated upon the approval of an application

and contains information including but not limited to the conditions of approval (both standard and special), commencement and expiry dates, project title, and name of PI. Standard conditions of approval are as noted in the approval letter and includes reporting requirements, obtaining the relevant approvals, licences and training, adhering to legislation, policies and procedures etc.

6.9 Special meetings

Special meetings of a quorate committee may be called at the discretion of the Chair in select, urgent circumstances. For example, a high-risk unexpected adverse event which is unable to be actioned otherwise, or an urgent project review. The procedure for special meetings otherwise aligns with scheduled meetings.

6.10 Immediate use of animals

The AEC may give approval in advance, for the immediate use of animals, should they be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people. Wherever possible this must be a decision of the full AEC. Where timing does not allow the involvement of the full Committee, the Chair or AEC Executive may approve the immediate use of animals in consultation with the ANU Vets and REO. Approval in advance of an animal ethics application is interpreted as per the Act, Division 4.2, and the Code, Section 2.1.5.

7. Reporting

7.1 Researcher reporting to the AEC

7.1.1 Annual and final reports

Annual and final report forms are developed by the REO in consultation with the AEC (2.2.32) and are submitted by investigators via ANU online ethics systems. The AEC reviews the annual progress of an ongoing project or activity, and approved projects or activities that have been completed or discontinued (2.4.34).

Annual reports are to be submitted to the AEC within four weeks of the anniversary date of the project to be reviewed at the subsequent AEC meeting. Annual reports may be used by the AEC to determine if a project may continue, be modified, suspended, or discontinued.

A final report on an approved project is submitted to the AEC as soon as practicable on completion or discontinuation of a project, to be reviewed at the subsequent AEC meeting. Failure to submit annual and final reports when required may constitute a breach of compliance and result in further investigation.

7.1.2 Notifications to the AEC

The AEC will review notifications submitted in writing by investigators for:

- a. Involvement in collaborative studies using animals at another institution.
- b. Named Investigators in an application to the AEC of another institution.
- c. Opportunistic tissue sharing.
- d. Opportunistic Collection of Biological Material from Live Animals.

7.2 AEC reporting to the Institution

An annual report to the University regarding AEC operations over the prior year will be compiled by the REO in consultation with the Chair and submitted by the AEC. Per Section 2.3.29 of the Code, this report will advise on:

- a. Numbers and types of projects and activities assessed, and approved or rejected.
- b. The physical facilities for the care and use of animals by the institution.
- c. Actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals.
- d. Administrative or other difficulties experienced.

- e. Any matters that may affect the institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.
- f. Information to fulfil licencing requirements from Australian States and Territories.

7.2.1 Chair meetings with responsible person (DVC-RI)

The Chair of the AEC will meet with the DVC-RI at least twice per calendar year to report on AEC operations (2.2.37).

8. Compliance

8.1 Inspection of sites and delegation of authority to inspect sites

The AEC undertakes annual inspections of all animal-holding facilities as per the ANU AEC Terms of Reference and Section 2.3.21 of the Code. The AEC may delegate a sub-committee of its members to inspect sites which includes one Category C or D member of the AEC. All members of the AEC are encouraged (where feasible) to attend facility inspections. Still or video images may be used in place of a physical inspection at the discretion of the AEC.

The AEC also inspects new facilities before animals are housed. Facilities must notify the AEC during the planning stages of new animal-holding facilities and consider feedback provided by the AEC, ANU Vets and the REO. The REO will organise pre-occupancy inspections of new animal facilities prior to animal occupancy.

The AEC will review desktop audits submitted by facility managers ahead of the inspections. AEC inspectors will inspect facilities in accordance with the inspection checklist within the online ethics management system and will record one of the following findings:

- a. Compliant.
- b. Complaint with mandatory actions.
- c. Compliant with recommended actions.
- d. Non-Compliant with mandatory actions.

Any actions required are recorded in addition to the names of attendees, observations, relevant still or video images, and descriptions of any issues encountered. Records of all animal facility inspections are reviewed at the subsequent AEC meeting.

8.2 Post-approval monitoring (PAM)

To facilitate the conduct of a post-approval monitoring (PAM) program, the Code allows AECs to delegate this responsibility to suitably qualified person to monitor animal care and use, including projects and activities conducted within ANU animal facilities and at sites (e.g. fieldwork). The ANU Animal Welfare Officer (AWO) role represents the AEC and is formally delegated to conduct PAM on its behalf. PAM is conducted in accordance with the [AEC approved document 036: Post Approval Monitoring](#).

All PAM reports are reviewed by the AEC at the subsequent meeting.

8.3 Unexpected Adverse Events

Unexpected adverse events (UAEs) must be reported to the AEC in accordance with the [AEC Approved Document 001: Procedure for Managing & Reporting Unexpected Adverse Events](#).

UAE reports are submitted by investigators, reviewed by the ANU Vets, then tabled at the next available AEC meeting along with associated documentation. Where matters are reported to the AEC that require immediate action, the AEC Chair will consult with the REO and ANU Vets to agree on an interim solution until a full meeting of the AEC can take place.

The AEC, via the REO, will notify investigators of the outcome of the review.

8.4 Complaints and non-compliance

Complaints and suspected non-compliance can be raised via the pathways outlined in the ANU Animal Ethics Complaints & Non-Compliance process. Matters that can be reported through this pathway may relate to:

- a. The care and use of animals.
- b. AEC processes or decisions.
- c. Independent external review processes or findings.

The AEC will investigate complaints and reports of non-compliance related to breaches of the Code and take appropriate action.

Where matters are reported to the AEC that require immediate action, the AEC Chair will consult with the REO and ANU Vets to agree on an interim solution until a full meeting of the AEC can take place. The AEC will review all incidents, including any related documents, at the next available meeting. The AEC may determine that:

- a. The incident and outcome is reviewed and no further action is required.
- b. Further information will be sought for ongoing investigation.
- c. The PI must undertake actions to ensure their project remains compliant with their approval.
- d. The incident is a minor or major breach of the Code.

After investigation, the AEC may:

- a. Direct the investigators to temporarily or permanently cease the activity or facility where continued activities have the potential to adversely affect animal wellbeing.
- b. Increase the frequency of monitoring activities.
- c. Suspend ethical approval or investigators.
- d. Withdraw ethical approval.
- e. Recommend local resolution with or without amendment to the project if the reported complaint or suspected non-compliance is not found to be a breach but requires actions to ensure compliance is maintained.
- f. Require the respondent to provide a plan for resolution of the matter including actions to prevent future occurrences.
- g. Refer the matter to HR or Research Integrity if there are concerns about the conduct of staff, students or affiliates.
- h. Refer the matter to the DVC-RI.

The AEC, via REO, will notify the PI when any further action is required and when the incident has been closed. In instances where the AEC makes a finding of non-compliance, the REO will advise relevant State and Territory authorities where required.

The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden.

9. Record Management

The following records are held in the ANU online ethics system, which is used as the primary database for:

- a. Applications (projects, SOPs, and amendments), approved or otherwise, associated information, related incidents/UAEs, AEC decisions, and correspondence.
- b. AEC facility inspections.
- c. AEC meeting agendas, minutes, and any associated documents.

Access to records held by the ANU online ethics system is restricted to approved users to ensure confidentiality. Names of AEC members are not made publicly available, and AEC deliberations are de-identified.

Documentation relating to approved projects are backed up on the ANU Electronic Records Management System (ERMS).

Version	Date	Author	Approved by	Date
1.0	19 August 2016	Research Services Division	DVC-RI	27 August 2016
2.0	31 March 2021	Research Services Division	DVC-RI	28 April 2021
3.0	16 November 2022	Research Services Division	DVC-RI	29 November 2022
4.0	27 July 2023	Research and Innovation Services	DVC-RI	10 August 2023
5.0	3 August 2026	Research Services	DVC-RI	5 August 2026