



## Animal Ethics Committee Operating Procedures

### Background

Under the *Australian Code for the Care and Use of Animals for Scientific Purposes* (the Code) institutions must establish and document procedures that will enable compliance with the provisions of the Code, and relevant policies of the institution. The Code outlines particular areas that such procedures shall cover, and these are included in the Operating Procedures overseeing the Animal Ethics Committee (AEC). The AEC is a Committee established through the Deputy Vice-Chancellor (Research & Innovation).

### Membership and Chair

#### Appointment of Committee Members & Chair

The ANU is responsible for appointing all AEC members including the Chair.

Suitable candidates for all categories are organised by the ANU Research Ethics Office in close consultation with the Chair. Once a suitable candidate is identified, the Ethics Office organises the relevant documentation for consideration by the DVC-RI, including a copy of the candidate's Curriculum Vitae and may also include referee reports. The final selection and approval of members is undertaken by the DVC-RI. Details of membership are as per the ANU AEC Terms of Reference.

The nomination of Category C Members should be supported by an animal welfare organisation.

In addition to Category A, B, C, and D members, the AEC will appoint at least one person responsible for the routine care of animals as additional members, defined at ANU as 'Category E'.

The Chair is appointed by the ANU Deputy Vice-Chancellor, Research & Innovation (DVC-RI).

Before acceptance of an appointment, the prospective member needs to read and accept in writing the AEC Terms of Reference (ToR) by completing a Confidentiality Agreement as per the Code, Section 2.2.11.

## Appointment of Advisors

Specialists, defined as 'Advisors' (non-voting), may be appointed for an advisory role deemed relevant to support the AEC. Appointments to an advisory role follow the same process outlined for members.

## Term of Appointment

Membership is for an initial term of six months, followed by an offer of three years if the member and Chair are in agreement for membership to continue. The initial six months allows new members time to familiarise themselves with the Committee's business and operations, and ensure time commitments are understood, without making a long-term commitment. It also enables the ANU to ensure new candidates are suited to the role.

If a member needs to take leave from the Committee for a period of time, a replacement member may be appointed for that timeframe.

## Induction of New Members & Advisors

Induction of new members is undertaken to ensure a smooth transition of new members to the Committee, providing the support and resources required to fulfil their new role. Induction of new members is undertaken by the Chair, Research Ethics Officers and/or the ANU Vets and includes the provision of relevant reference material.

Communication and support between members of the Committee is encouraged, in particular during the initial six months of membership for new members.

## Resolution of Conflicts of Interest

Before an appointment, prospective AEC members are required to declare interests and possible conflicts of interest as per the Code, section 2.2.21. These are reviewed by the Chair and the Ethics Office to manage any conflicts.

Conflicts of interest may also arise after an appointment when the Committee considers applications or other matters of business in which an AEC member is involved. Members must declare any perceived or actual conflicts of interest as per section 2.2.21 of the Code, and if declared interest is considered by the Chair to be a conflict, the member must remove themselves from the AEC's decision making on matters that relate to the conflict of interest. Conflicts of interest are recorded in the AEC meeting minutes.

## Reappointment

Before a member's appointment ends, the Chair, in consultation with the Ethics Office, considers the recommendation of another term of appointment. Members will be contacted by the Ethics Office, after consultation with the Chair, prior to their term's expiry to discuss and confirm membership continuation or completion. Once agreed, the final approval for continuation is by the DVC-RI. If a member is not continuing, the DVC-RI will be advised of the member's retirement. Chair reappointment will be, as noted above, by the DVC-RI with support of the Ethics Office.

## Professional Development of Members

### Purpose

The University is committed to providing equal opportunities to individuals, including Committee members, to acquire and enhance skills, knowledge and abilities through

specific development opportunities that are suitable to their AEC role. This support is provided within the limits of available opportunities and budget.

### Development Program Principles

1. In determining the most appropriate development opportunities for AEC members, consideration will be given to the value to be obtained from the various training opportunities on offer and to ensure these opportunities are offered equitably to all members.
2. Any training mandated by state or territory legislation for the Animal Ethics Committee will be arranged for members through the Ethics Office.
3. A range of appropriate development opportunities will be identified by the Ethics Office and approved by the appropriate delegate subject to the availability of funds.

## Meetings

### Schedule

The AEC will meet regularly throughout the year, with the aim to meet every 4-6 weeks.

### Quorate Meetings

AEC meetings must be quorate as required by the Code, Section 2.2.25 which requires that

- At least one member of categories A, B, C, and D must be present.
- Categories C and D together must represent at least one-third of those members present.
- To meet all state licencing requirements, the membership count includes the Chair and any Category E members.
- Advisors are not counted in the quorate calculation.

Observers may attend an AEC meeting with the approval of the Chair and providing that confidentiality requirements are met. Meetings may be face-to-face or with the use of teleconferencing.

### Chair Role

As per the Code, Section 2.2.13, the Chair is responsible for impartially guiding the operation of the AEC and resolving conflicts of interest related to the business of the AEC. The Chair also represents the AEC in any negotiations with ANU management.

The Chair at ANU, as recommended by the Code, Sections 2.2.2 & 2.2.3, is appointed from a senior position from the institution. The Chair is appointed in addition to the A-E Membership categories, and is independent of the care and use of animals for scientific purposes.

If the Chair is on leave, an Acting Chair may be appointed from the AEC Membership.

### AEC Executive and Minor Amendments

The ANU AEC has established an AEC Executive (sub-committee) as per Section 2.2.23 of the Code. This includes the Chair and at least one member from Category C or D. The ANU AEC Executive also includes a Category A member. The AEC Executive can review minor amendments out of session that are in the view of an ANU Vet or the Chair **not**

**likely to cause harm to animals or negatively change the level of the pain and distress as outlined in the original application.**

The AEC Executive may review amendments to approved protocols such as (but not limited to):

- Minor changes that do not negatively change approved welfare impact on animals or where pain/distress may be reduced.
- Extension requests (e.g. simple requests of time up to a maximum of 3 months).
- Additions of new strains that are not expected to have any adverse phenotype welfare impact. (If welfare impact is unknown, an amendment application must go to AEC meeting.)
- Location changes (e.g. within or between approved animal facilities).

Upon review of the amendment, if any member of the AEC Executive believes the application should go to the full Committee, they must declare this to the Chair and Ethics Office. It may then, upon discretion of the Chair, be transferred to the Committee for full assessment at the next appropriate meeting.

The AEC Executive must not review new protocol applications or review amendment applications that:

- Include the addition of new procedures that will likely require training of individuals on the protocol for new techniques or veterinary oversight.
- May cause harm or increase pain or distress in the animal(s).
- Are not considered a minor amendment.

All out of session amendment approvals will be provided to the AEC, at the next scheduled AEC meeting, for ratification as per Section 2.2.23 (ii) of the Code.

### Special Meetings

Special meetings of a full quorate Committee may occur if circumstances dictate, for example if an urgent high risk unexpected adverse event or an urgent protocol review requires consideration by the Committee. Special meetings are called at the discretion of the Chair.

## Reporting to the University

### Chair Meetings with Responsible Person (DVC-RI)

An annual review of AEC operations will be conducted in line with Sections 2.2.37 and 2.1.9 (ii) of the Code, *“to ensure it is effective and consistent with the Code and institutional policies. This must include an assessment of the AECs annual report and a meeting with the AEC chairperson”*.

An Annual Report to the ANU Council, of AEC activity over the prior year, will be compiled and submitted by the Ethics Office in consultation with the Chair to meet Code and State/Territory requirements.

The Chair of the AEC will meet quarterly (or more often) with the ANU Deputy Vice-Chancellor (Research & Innovation).

## Assessment of Applications

New protocol and amendment applications to be considered at a particular meeting must be submitted via the ANU approved system, by the submission deadlines. Each new protocol will be allocated a unique protocol number.

## Review and Decision Process

1. The AEC must 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 and with a quorate of the membership present for each decision (Code, Section 2.3.6, 2.3.10).
2. The AEC must discuss and decide whether the proposed use, or continued use, of animals is ethically acceptable. As per Code, Section 2.3.4, this judgement must:
  - (i) be based on information provided by the applicant (see code, Chapter 2.7) that demonstrates the application of the Codes governing principles (outlined in Section 1)
  - (ii) balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
3. New protocol applications, amendments, annual reports, final reports, meeting agendas, minutes and items of general business are circulated by the Ethics Office via ANU online Systems to AEC members in a timely manner prior to the scheduled meeting date. (Code, Section 2.2.26)
4. AEC members will review new protocol applications, amendments, annual and final reports and any circulated items of general business prior to the meeting. Upon review AEC members will be given the opportunity to ask questions or request clarification relating to applications via ANU online systems, to allow researchers to make any requested changes to their application prior to the meeting. All applications, including any changes made to an application, will be reviewed and discussed by the Committee at the meeting. Researchers may also be invited to attend a meeting to discuss their application and provide clarification for the AEC.
5. 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 effort 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 of time to review their positions, followed by further discussion. The Chairperson is responsible for impartially guiding the operation of the AEC as per Section 2.2.13 of the Code.
6. Pilot studies, as per the Code, Section 2.3.14, “...*should be regarded as integral to the overall project, especially to enable assessment of the feasibility of the project and the potential for refinement and reduction. They must be assessed by the AEC according to the criteria applied to project approval*”
7. Decisions of the AEC are to be made as promptly as possible.

8. The Committee may (as per Code, Section 2.3.9):
- Approve an application without conditions\*; or
  - Approve an application with (special) conditions; or
  - Approve an application subject to matters being addressed out of session; or
  - Defer a decision subject to modification; or
  - Not approve an application.

\* All approvals have standard conditions.

Decisions of the AEC are final. Appeals can be made via the Research Ethics Office.

All AEC approved applications must be signed off by the Chair.

Minor amendments may be reviewed by the AEC Executive out of session (see above).

### Term of Approval

The ACT Animal Welfare Act 1992 s.41 allows protocols to be approved for a maximum of three years.

Principal Investigators (PIs) may apply for a one off three-month extension of a protocol with extenuating circumstances. The extension requests are considered to be a minor amendment that can be considered out of session (OOS) by the AEC Executive. Justification for the extension request must be provided and the application must be submitted as an amendment before the protocol expiry date with sufficient time, ideally two to four weeks, for review and decision outcome by the AEC or AEC Executive. No further amendments to a protocol can be submitted during the extension period.

### Annual and Final Reports

As per Section 2.4.34 of the Code, investigators must provide an annual report for an approved project and a final report on completion or discontinuation of an approved project.

Annual Reports are to be submitted to the AEC via ANU online systems within four weeks of the anniversary date of the protocol, to be reviewed at a future AEC meeting. Annual reports may be used to determine if a protocol may continue, be modified, suspended, or discontinued.

A Final Report on an approved protocol's outcomes is submitted to the AEC via ANU online systems, as soon as practicable on completion or discontinuation of a project, to be reviewed at a future AEC meeting.

### Approval for Continuation of Projects

If a researcher wishes to continue a project after the covering protocol's approved end date, a new protocol application must be submitted for approval. If continuous coverage is required for the ongoing holding of animals, a new protocol must be submitted with sufficient time to gain approval prior to the expiry of the existing protocol. If there are no animals in care, the new protocol application submission timing is at the discretion of the researcher.

## Other Responsibilities of the Committee

### 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 to meet the Code's requirement to inspect facilities (2.3.12 & 2.3.21).

The AEC may delegate a sub-committee of its members to inspect sites which must include at least one Category C or D member of the AEC. It may also delegate a member of the Ethics Office, an ANU Vet or appointed external vet to monitor projects.

At remote sites, or where the AEC requires a report concerning a specific project, still or video images can be used (Code 2.3.23)

The AEC also inspects new facilities before animals are housed. Facilities must notify the AEC during the planning stages of new animal holding facilities to ensure input by AEC, ANU Vets and the Ethics Office as required and for inspection planning.

### Unexpected Adverse Events (UAEs)

Unexpected Adverse Events (UAE) are defined in the Code as *“any event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.”*

All UAEs involving the use of animals as part of ANU research and teaching activities must be reported to the AEC in accordance with the University's Unexpected Adverse Event Procedure on the [Managing Your Protocol - Staff Services - ANU](#) web page.

Depending on the seriousness or urgency of the event, the AEC, in consultation with the ANU Vets, may undertake one or more of the following:

- Request further information from the Primary Investigator or other staff involved.
- Request immediate veterinary intervention if this has not already occurred.
- Request that an ANU Vet or nominated person visit a specific animal holding facility or site, or animals on a project to make an assessment.
- Require that the experiment or that part of the experiment cease until the matter has been investigated further, especially where there are ongoing perceived risks to animal welfare.
- Defer the matter to the next scheduled AEC meeting.
- Call a special AEC meeting to discuss the event.
- Suspend or withdraw approval for the project or activity either temporarily or permanently as required.
- Accept with no further action required.

The AEC, via the Ethics Office, will notify the Primary Investigator when any further action is required and when the UAE has been closed. AEC instructions must be followed.

The AEC Chair is responsible for impartially guiding the operation of the AEC, which includes the handling of UAEs.

## 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. However, 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 Ethics Office. For this purpose, approval in advance is interpreted as approval in advance of an animal ethics application. (Code 2.1.5)

## Record Management

All protocols and amendments are recorded in the University's Research Ethics Management System as the primary database for ethics approvals.

All records with regards to correspondence, Unexpected Adverse Events (UAEs) and actions taken on protocols will be recorded on a University approved system that provides regular data back-up.

## Dealing with Complaints and Non-Compliance

### Suspected Non-Compliance

Concerns regarding suspected non-compliance relating to the care and use of animals for scientific purposes should be reported to the AEC for review via the Research Ethics Office or the AEC Chair.

The AEC will review the matter and may request further information to determine whether a breach of the [Australian code for the care and use of animals for scientific purposes | NHMRC](#) (the Code) has occurred. If the AEC deems that a breach has occurred, they should refer the matter to the institution for action.

The institution will report back to the AEC regarding actions taken.

Relevant State/Territory licencing authorities may also be notified by the Ethics Office as per licencing requirements.

### Complaints

Complaints relating to the care and use of animals for scientific purposes, including AEC processes for review of an application or report can be raised via the Research Ethics Office, the AEC Chair, or Chief, Office of Research and Innovation Services.

A complaint cannot result in the decision of the AEC being over-turned or amended other than by the AEC itself.

AEC Members can also raise concerns through the same avenues.

(See also the University's Web page: [Raising Concerns - Staff Services - ANU](#))



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