FREQUENTLY ASKED QUESTIONS

ANU’s Animal Experimentation Ethics Committee & Animal Ethics Processes

The purpose of this document is to provide a clear set of responses to frequently asked questions. The aim has been to render the document without resorting to ‘legal speak’. However, it must be recognised that this area is subject to and governed by regulation and in certain places the Australian Code for the care and use of animals for scientific purposes, 8th edition 2013 (the Code) has been quoted to avoid erroneous interpretations. Anyone undertaking animal research is expected to acquaint themselves with the Code, a copy can be found at The Code.

The animal welfare legislation in each Australian State and Territory includes this document as a mandatory Code. Other animal welfare regulations apply across different states and territories. It is the responsibility of the individual to ensure they are familiar with the regulations in the locations where they are undertaking animal based research.

1. HOW IS THE COMMITTEE STRUCTURED?

The membership of the Committee is comprised of volunteers. The Code sets out mandatory membership. The members fall into 4 categories.

**Category A**—a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution’s activities or the ability to acquire relevant knowledge.

**Category B**—a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must include possession of a higher degree in research or equivalent experience.

**Category C**—a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.
Category D—a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEEC, and must not fit the requirements of any other category.

Institutions should consider appointing a chairperson who is independent of the care and use of animals for scientific purposes. The ANU has appointed an independent Chair person.

Institutions should appoint to the AEEC a person responsible for the routine care of animals within the institution. Since 2004, the AEEC has always appointed two animal care technicians as full voting members.

Institutions may appoint additional members with skills and background of value to the AEEC. The AEEC has appointed a number of non-voting advisors.

The membership must comply not simply with the national code (The Australian Code for the Care and Use of Animals for Scientific Purposes) but with the animal welfare regulations of each of the Australian State. Members are appointed by the DVC-R.

2. HOW MANY MEMBERS DOES THE COMMITTEE HAVE?

The Committee has 14 members and 3 advisors. In accordance with the Code, Categories C and D must comprise at least one third of the voting membership.

The ANU appoints more than one mandatory member to each category to support the quorum required at meetings for the Committee to be able to make decisions. Without multiple members in each category researchers would have to wait longer to have their application reviewed.

3. WHY IS THE COMMITTEE THE SIZE IT IS?

As the Committee comprises volunteers and there is a heavy workload, it is essential that the Committee can be quorate when it meets in order to expedite the progress of proposal review.

4. WHO CHAIRS THE COMMITTEE?

The Chair should be independent of those involved in the care and use of animals. The ANU Committee is chaired by a senior researcher in the School of Philosophy.
The Chair’s field of expertise includes applied ethics. The Chair is appointed by the DVC-R.

5. HOW OFTEN DOES THE COMMITTEE MEET?

The Committee meets 11 times a year (every month excluding December) but also undertakes some straightforward activities (as permitted by the Code) out of session. Sometimes extra meetings are called to deal with serious matters involving animal welfare.

6. IS THE COMMITTEE SUBJECT TO EXTERNAL REVIEW?

The animal ethics activity of the University is subject to a four yearly cycle of review by independent experts. Annually the committee and University’s activities are audited by each state and territory Government where the ANU holds a licence to approved animal based research (ACT, VIC, NSW, TAS, QLD, WA).

7. WHEN IS THE COMMITTEE QUORATE?

At least one member of each mandatory category A, B, C and D must be present.

8. HOW DOES THE COMMITTEE REACH DECISIONS?

As required by the Code the Committee aims to achieve decisions by consensus. Where consensus cannot be reached, and in line with the Code, discussion should take place with the Investigator to attempt to achieve consensus by the Committee, failing which, the Chair may decide to move to a decision by majority voting. This is exceptionally rare and advisors to the AEEC are not able to vote in these instances.

9. WHO SERVICES AND SUPPORTS THE COMMITTEE?

The Committee is serviced by staff in the Research Services Division (RSD). RSD provides advice and guidance to assist investigators with the ethics process. Responsibility for the protocol rests with the Chief Investigators. RSD makes no decisions with regard to review of proposals this all falls to the Committee.

10. DOES THE UNIVERSITY EMPLOY A VET?

There is a formal position of University Veterinarian. This position resides within RSD. The Vet provides advice to the Committee but is not a member and takes executive decisions where animal welfare is prejudiced and during any activity
classed as an unexpected adverse event (see later). There are also other members of University staff who have veterinary qualifications and their expertise is drawn on as required.

11. WHAT VOLUME OF ACTIVITY IS UNDERTAKEN BY THE COMMITTEE?

The Committee reviews around 80 new proposals and 180 amendments every year, as well as annual reviews for all active projects (approx. 200). The Committee also undertakes facility inspections and reviews unexpected adverse events and responses.

12. ARE AEEC MEETINGS MINUTED?

All AEEC meetings are formally minuted and confirmed minutes are provided to the DVC-R on a monthly basis. Minutes from AEEC meetings are confidential. As required by the Code, an annual report is provided to University Council that details all AEEC activities.

13. ONCE MY APPLICATION IS SUBMITTED, WHAT HAPPENS NEXT?

Your protocol will be circulated to the AEEC and they will be given an opportunity to provide electronic comments prior to the meeting. Where issues can be clarified ahead of the meeting then attempts are made to do so. The AEEC then considers all the comments in a quorate and formal meeting. As required under the Code, attempts are made to reach agreement by consensus. Where possible protocols are approved subject to the changes to be agreed with the PI. The PI then receives the suggested changes and these are agreed with the PI out of session wherever possible. The AEEC does have the right to reject proposals outright. Where this happens the reasons for the decision will be clearly communicated to the PI. The AEEC may also place conditions on the approval; if investigators do not understand the conditions or don’t believe they can comply they must promptly notify the AEEC.

14. HOW CAN I ARRANGE TO ATTEND AN AEEC MEETING TO EXPLAIN MY PROPOSAL?

The AEEC reviews hundreds of proposals and amendments a year and it is not possible, nor necessary, for investigators to attend for each protocol. The vast majority of proposals are reviewed and approved within one meeting cycle with minor adjustments made out of meeting by agreement with the lead researcher. Where there are particular levels of complexity the Chair can determine that a face-to-face interaction with an investigator would be beneficial.
15. WHAT EXACTLY DOES THE COMMITTEE ASSESS?

In line with the Code the Committee assesses written protocols prepared by responsible Chief Investigators. The Code states that the Committee “must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant, and may use information in addition to that obtained from the applicant.” Also see point 16.

16. WHO IS RESPONSIBLE FOR THE PROTOCOL?

The Chief Investigator is responsible for the protocol as required by the Code which states:

“Investigators must only consider using animals when they are satisfied that a case can be made that the proposed use is ethically acceptable, based on whether such use demonstrates the principles in Clause 1.1, and balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (see Clause 1.3). Investigators should seek advice and information from relevant experts, including other experienced scientists, veterinarians, animal care staff, or specialists in laboratory animals, livestock or wildlife, when necessary.”

17. DOES THE COMMITTEE TAKE INTO ACCOUNT SCIENTIFIC INFORMATION AND EXPERT ADVICE?

Yes. As noted above the researcher is expected to aid the Committee by providing sufficient information within the protocol to aid effective assessment. When necessary the Committee may take into account expert advice which it seeks. RSD can often refer researchers to particular experts upon request. RSD is further seeking to aid investigators by developing a network of advisers and specialists in areas of significant activity.

18. HOW DO I MAKE AN AMENDMENT TO MY PROJECT AFTER IT HAS BEEN APPROVED?

The nature of research means that it is often necessary to amend a protocol once approved. For example, where a particular technique is not working. Or where animal numbers need to change, the location of the work will change, new species are required etc. Amendments are handled in the same way as full proposals, minor amendments that are urgent can often be reviewed and approved out of session, however these approvals still require a quorum for approval. The decision whether or not to review and approve an amendment out of session rests solely with the
Committee, not RSD staff. The Committee is not permitted to review full protocols out of session. The amendment template can be found under the forms section of the animal ethics webpage Amendment Template (DOC, 37.5 KB)

19. WHO NEEDS TO BE INCLUDED ON AN APPLICATION TO THE AEEC FOR A PROJECT? CAN I ADD NEW PEOPLE TO AN APPROVAL IF THEY JOIN THE PROJECT LATER ON (E.G. A RESEARCH ASSISTANT)?

All researchers that are responsible for any aspect of the protocol or will undertake any work under the protocol must be included. New people can be listed to a protocol at any time by completing the appropriate form and submitting it to Research Services. New co-investigator forms can be found under the forms section at https://services.anu.edu.au/research-support/ethics-integrity/animal-ethics-policies-guidelines-training-and-forms

Principal investigators must ensure that new staff have read and understand the approved protocol, approval conditions and the Code. As well as ensuring new staff and students have undertaken the relevant training and assessment required to fulfil their obligations under the protocol and the Code.

20. HOW CAN I MAKE SUGGESTIONS FOR SPECIES-SPECIFIC EXPERTS THAT COULD BE CONSULTED ON MY APPLICATION?

Reference to published articles and species experts that have been consulted in the preparation of the Protocol should be referenced within the Protocol. The AEEC is keen that you engage with experts during the development of the Protocol. Please bear in mind that any expert view needs to be considered in the light not just of the species itself but animal welfare issues which need to be addressed to satisfy the Code.

21. WHAT IS AN UNEXPECTED ADVERSE EVENT?

In simple terms, an unexpected adverse event is something that happens that has not been laid down in a protocol. If a protocol states that there are no expected deaths at a certain stage in the experimental process and one occurs then this is classed as an unexpected adverse event. Protocols need to be drafted in the same way as risk management plans seeking to identify possible outcomes and taking those into account.
22. WHO CAN I ASK FOR HELP WITH DEVELOPING SPECIFIC ASPECTS OF MY PROPOSAL?

As noted above the PI is responsible for the development of the protocol. Help can often best be obtained from other researchers who have used a similar regime, not necessarily at the ANU. Researchers are often following an established experimental regime from the academic literature. Publications rarely contain sufficient information and therefore direct contact with the author is recommended, particularly where, the expectation is to use the experiment as part of a comparative study with previous work.

Under the Code PIs are responsible for pulling together the relevant information and expertise. Where veterinary guidance is needed this can be sought from the University Vet. Where new and difficult techniques of animal handling or experimentation are intending to be used an early discussion with the Vet is recommended.

RSD is willing to provide initial guidance and will assist in sourcing specialist advice where possible.

It must be noted that notwithstanding such inputs the protocol still needs to go through full AEEC processes and acceptance as required under the National Code.

23. WHAT ANIMAL TAXA REQUIRE AEEC APPROVAL FOR RESEARCH AND TEACHING PURPOSES?

The definition of animal is: any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose bred animals, livestock, wildlife), adult decapod crustaceans and cephalopods. The use of animal cadavers may also require prior ethics approval. Observation only studies also require AEEC approval as you may be causing disturbance to an animal’s natural behavior and their environment.

24. HOW DO I PROVIDE AND HIGHLIGHT RELEVANT ATTACHMENTS (E.G. KEY PUBLISHED ARTICLE) IN MY PROPOSAL?

Relevant documents can be uploaded to the protocol through the online ARIES application system. Upload to the document section of the online form, the AEEC expects that relevant sections of publications be referred to in the body of the application in a way that the AEEC can easily reference back to the attached document. It is the role of the PI to clearly link their application to sections within relevant publications, it is not the responsibility of the AEEC to extensively review publications to find the key information.
25. WHO DO I CONTACT IF I WISH TO APPEAL A DECISION MADE BY THE AEEC?

The grounds for appealing a decision are that:

- due process has not been followed
- the views of the Committee cannot be effectively accommodated as a consequence of the Committee acting outside of its remit.

The normal route would be to refer the concern initially to the Chair of the Committee or the Director of Research Services Division in the first instance. If this fails to alleviate the concern then the matter should be raised with the DVC(R).

The Code states: "Where complaints concerning the AEEC process of review of an application or report cannot be resolved by communication between the complainant and the AEEC that is the subject of the complaint, the institution should ensure that the complainant has access to a person or agency external to the AEC for review of the process followed by the AEC. This person or agency may be within the institution. Following this review, the AEC may need to review its process in reaching its decision regarding the application or report, and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden."