



Operating Procedures Animal Experimentation Ethics Committee

Background

Under the *Australian Code for the Care and Use of Animals for Scientific Purposes* (the Code) animal ethics committees 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 Experimentation Ethics Committee (AEEC). The AEEC is a Committee established through the Deputy Vice-Chancellor (Research & Innovation).

Membership and Chair

Appointment of Committee Members

The ANU is responsible for appointing all members. The Chair is appointed by the ANU Deputy Vice-Chancellor (Research & Innovation) (DVC-RI). The nomination of Category C Members should be supported by an animal welfare organisation. Suitable candidates for the other categories are organised by Research Services Division Ethics Office through close consultation with the Chair and Director Research Services. Once a suitable candidate is identified, Research Services 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 AEEC Terms of Reference.

Term of Appointment

Membership is for an initial term of six months, followed by an offer of three years if all parties 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, ensure that the time commitments are understood, without making a long-term commitment, and also enables the ANU to ensure new candidates are suited to the role.

Induction of new members

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

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

Resolution of Conflicts of Interest

Members are required to declare interests, and these are reviewed by the Chair and Director of Research Services to identify and manage any conflicts. Conflicts of interest may arise when proposals in which AEEC members are involved are considered by the Committee; the member must declare the conflict of interest at that time and may be asked, at the discretion of the Chair, to excuse themselves from the discussion of that item.

Re-appointment

Before a three year appointment ends the Chair, in consultation with the Director Research Services, considers the benefits of recommendation of another term of appointment, and provides the recommendation to the DVC-RI as per the recruitment procedure above. Members will be notified in writing by the Chair when their term has expired.

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 assessed as being suitable and assists with their particular 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 AEEC 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 Animal Ethics Committee will be arranged for members through the RSD Ethics Office.
3. A range of appropriate development opportunities will be identified based on suggestions by AEEC members, and approved by the Director Research Services in consultation with the Chair and subject to the availability of funds.
4. An equitable process, using agreed criteria, will be implemented to target professional development to areas of greatest need and value. The criteria will include considerations such as professional development needs, training opportunities already afforded to the member, and availability of funds.
5. The level of funding available for professional development will be determined in part by the opportunities identified and the number of members attending each event. It will also be dependent on other divisional budgetary considerations. It is anticipated that members will be asked to nominate for specific events in advance.

Meetings

Schedule

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

Quorate Meetings

AEEC meetings must be quorate as required by the Code, which requires that

- At least one member of categories A, B, C, and D must be present: and
- Categories C plus D must represent not less than one third of category and voting members present.

In addition to Category A, B, C, and D members the AEEC appoints one or more people responsible for the care of animals at the ANU as voting members defined as Category E members.

Voting members include all Category A-E members present and the Chair also has the right to a vote.

Observers may attend an AEEC 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 video linking or teleconferencing.

New protocols and annual reviews must only be decided at a quorate meeting. As per the Code, the Committee must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings.

Committee Executive

The AEEC may agree to establish an AEEC Committee Executive as per 2.2.23 of the Code. This must include the chairperson and at least one member from Category C or D. The Committee Executive is approved to review minor amendments that are in the view of the University Veterinarian or the Chair **not likely to cause harm to animals or change the level of the pain and distress as outlined in the original application.**

The Committee Executive may review applications such as (but not limited to);

- 3 month extension requests (e.g. simple requests of time only)
- Additions of new strains that do not expect to have any adverse phenotype
- Limited change in numbers of animals requested
- Location changes providing to an approved facility
- Minor changes to procedures (e.g. where pain/distress may be reduced or change in practices directed by the ANU veterinarians).

If any member of the Committee Executive assesses that the protocol should go to the full Committee, they must declare this to the Chair and RSD Research Ethics Office staff and it must be transferred to the Committee for full assessment at the next appropriate meeting.

The Committee Executive must not review new protocols and they may not review amendments that include the addition of new procedures that will likely require training of individuals on the protocol for new techniques or veterinary oversight.

Special Meetings

Special meetings may occur if circumstances dictate, for example if an unexpected adverse event requires consideration by the Committee. Special meetings are called at the discretion of the Chair.

Reporting to the University

Chair Meetings with Responsible Person

The Chair of the AEEC will meet quarterly (or more often) with the ANU Deputy Vice-Chancellor (Research & Innovation). One meeting per year will be dedicated to a review of the AEEC's operation as per 2.1.9 of the Code.

Assessment of Proposals

Proposals and amendments that are to be considered at a particular meeting must be submitted via the ANU approved system, by the date published on the Animal Ethics Webpage. Research ethics administration will allocate a protocol number to all new proposals.

Review Process

1. Proposals, amendments, annual reviews, meeting agendas, minutes and items of general business are circulated electronically by Research Services Division (RSD), Research Ethics Office to the Committee members. Protocols and amendments will be circulated in a timely manner prior to the scheduled meeting date.
2. AEEC members will review proposals, amendments, annual reviews and any circulated items of general business prior to the meeting, and then direct questions relating to proposals through a Research Ethics Officer to the Primary Investigator. Investigator responses to questions will be sent back to the Committee via email or the ANU online system. Replies from the Primary Investigator are required by a stated due date relevant to the date of the upcoming meeting.
3. Collated questions and answers will be provided to the Committee prior to the meeting, and will be reviewed at the meeting to facilitate Committee discussion and decision-making. The AEEC may wish to speak to a Primary Investigator to clarify points and if this is required the Primary Investigator is notified in advance of the meeting. Where

different concerns have been highlighted by members, the Chair will ensure a full discussion of all relevant issues within the remit of the Committee occurs.

4. The Committee may:
 - Approve a proposal without conditions; or
 - Approve a proposal with conditions; or
 - Defer a decision until receipt of further information or advice: or
 - Not approve a proposal.

Decisions of the AEEC are final and may only be amended by AEEC as required by the Code. When answers to questions are agreed to be satisfactory by all members, the proposal or amendment is approved and formally approved by the Chair. If AEEC members are not satisfied with the detail provided in the proposal, the answers to questions, or if the AEEC are not satisfied with that the potential effects on the wellbeing of animals is justified by the potential benefits, or if the proposal does not address ethical concerns, a decision may be deferred, extra information may be requested and circulated out of session or the proposal may be rejected. Where an investigator has outstanding reports, such as annual reviews and expiry reports, the AEEC reserves the right to defer a final decision on any current applications which may be held over until the reporting obligations are met.

Minor Amendments

The AEEC may approve minor amendments (that being a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress) to proposals out of session (OOS). The RSD Research Ethics Office will either circulate the proposed amendment electronically to all members or to the AEEC Executive Committee (established per the Code); once approval is given by one member from each category (quorum) or from the entire AEEC Executive Committee, approval for the amendment is granted. If any AEEC member expresses concern, or questions with regards to the welfare impact or implications of the amendment are raised, the amendment will be referred to the next formal full Committee meeting. All out of session approvals or those approved by the AEEC Executive Committee will be provided to the AEEC at the next scheduled AEEC meeting for information and ratification.

Approval Process

The ACT Animal Welfare Act 1992 section 41 requires that protocols can only be approved for a maximum of three years. However, Principal Investigators may apply for a one off three-month extension of a protocol with good reason. The extension requests must be submitted and reviewed as an amendment. A reason for the extension request must be provided and it must be submitted before the protocol expiry date and in time for proper review by the AEEC.

Three Month Extension requests may be reviewed by the AEEC Executive.

Approval for Continuation of Projects

Annual project reviews are required for each protocol and must be provided on the template approved by the AEEC. They will be considered on a case-by-case basis at the AEEC meeting and may be used to determine if a protocol may continue, be suspended, be modified or be discontinued.

Approval by Consensus

In line with the Code, AEEC decisions are made on the basis of consensus, with the AEEC's definition of consensus being that all members agree concerning the point under consideration. Should consensus not be reached the AEEC may work with the applicant to identify ways of modifying the project or activity that may lead to consensus. If consensus cannot be reached the Chair reserves the right to move to a majority decision but only after members have been

given time to review their positions, request further information and engage in further discussion.

Other Responsibilities of the Committee

Inspection of Sites and Delegation of Authority to Inspect Sites

The AEEC must inspect and approve all animal-holding facilities before they are occupied.

The AEEC must be notified during the planning stages of new animal holding facilities.

In accordance with the Code the AEEC must undertake an annual inspection of all animal-holding facilities as per the ANU AEEC Terms of Reference. The AEEC may delegate a sub-committee of its members to inspect sites. It may also delegate a member of the Research Services Division (RSD) Ethics Office, or a veterinarian to monitor projects at remote sites or where it requires a report concerning a specific project.

Handling of unexpected adverse events involving research animals

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

All unexpected adverse events involving the use of animals as part of ANU research and teaching activities must be reported to the AEEC. Please see the ANU's Unexpected Adverse Event Procedure for submitting adverse event reports.

Depending on the seriousness or urgency of the event, the AEEC, in consultation with one of 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 AEEC meeting.
- Call a special AEEC meeting to discuss the event.
- Suspend or withdraw approval for the project or activity either temporarily or permanently as required.
- The AEEC will provide a written response to the Primary Investigator outlining any further action required. AEEC instructions must be followed.

Immediate use of Animals

The AEEC 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 AEEC. However, where timing does not allow the involvement of the full Committee the Chair may approve the immediate use of animals. For this purpose approval in advance is interpreted as approval in advance of an animal ethics application.

Record Management

All protocols and amendments are recorded in the University ethics system as the primary database for ethics approvals.

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

Dealing with Non-Compliance

Concerns regarding Non-Compliance to AEEC procedures and policies must be raised via the University's mechanisms.

In the first instance this may include raising the concern with the Primary Investigator. If the Committee believes there is a case for non-compliance then this may be considered as Research Misconduct and must be reported via the University's procedure. The case may be reported by the AEEC Chair or any member of the Committee.

Complaints

Complaints with regards to the AEEC procedures and operations are to be managed in line with the Animal Ethics Complaints Procedure. A complaint cannot result in the decision of the AEEC being over-turned or amended other than by the AEEC itself as stated in the Code

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