

GUIDELINES FOR THE CONDUCT OF ANIMAL ETHICS COMMITTEES





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Introduction

An Animal Ethics Committee's (AEC) primary responsibility is to ensure that all care and use of animals conducted by their nominating organisation complies with the Australian code for the care and use of animals for scientific purposes 8th edition 2013 (Australian code).

Animal Ethics Committees are bound by the Prevention of Cruelty to Animals Act 1986 (the Act), associated Regulations, the Australian code, institutional policies, and their terms of reference.

The AEC must:

- a) review applications for:
 - i. new projects
 - ii. proposed modifications to approved projects
 - iii. activities applicable to breeding programs
 - iv. activities associated with the care and management of animals in facilities.
- b) conduct follow-up review of approved projects and activities
- c) monitor the care and use of animals, including housing conditions, practices, and procedures involved in the care of animals in facilities
- d) take appropriate actions regarding non-compliance and/or unexpected adverse events
- e) approve guidelines for the care and use of animals on behalf of the institution
- f) provide advice and recommendations to the institution regarding the care and use of animals, and
- g) report on its operations to the institution.

Membership and meeting procedures

The Australian code defines an AEC's membership categories. A quorum is established by the presence of a category A, B, C and D member.

All members must be registered with Animal Welfare Victoria before they can participate in AEC meetings. Members who fulfil the requirements for more than one category may only be registered for membership in one. They may not act in another category concurrently but may change categories by amending their registration with Animal Welfare Victoria.

From 14 December 2019, all new members appointed to an AEC must complete training in their roles and responsibilities prior to, or within 6 months of their appointment. The training program must have been approved by the Minister for Agriculture. More information on approved training programs is available on the Animal Welfare Victoria website.

AEC members are registered with either voting or non-voting status. Categories C and D must together represent at least one-third of the entire AEC voting membership. Categories C and D must also represent at least one-third of the voting members present at meetings.

Additional members may be appointed to assist the AEC to function effectively, such as animal carers or persons with expertise on experimental design. This practice is recommended when it assists the AEC in its decision making. These additional members may be appointed as voting or non-voting members. Assigning 'non-voting' status to AEC members on an ad-hoc basis to manage member balance is not permitted.



The AEC may invite people with specific expertise to attend meetings, as required, to provide advice to the AEC.

The Australian code mandates that Category C and D members of an AEC must be independent of the licence holder. That is, these members must not be employed by or associated with the licensed institution that accesses the committee.

Participation in AEC activities involves considerable commitment from independent members in terms of the costs involved in foregoing wages and personal time. Section 2.2.19 of the Australian code allows for appropriate reimbursement for personal expenses incurred in carrying out AEC activities and/or payment of an allowance. The amount paid should not be seen as constituting employment by the institution, nor be of sufficient size to influence decisions of the member.

Sitting fees set by the Department of Premier and Cabinet for advisory committees (see schedule C) may be used as a guide for institutions contemplating paying external members for their services www.dpc.vic.gov.au/index.php/policies/governance/appointment-and-remuneration-guidelines

The AEC must endeavour to make its decisions by consensus in accordance with the Australian code. The final decision, and the reasons for the decision, must be promptly conveyed to the applicant. There is no legal requirement for project approvals to be signed by AEC members or the chairperson.

If a conflict of interest is identified, affected members must remove themselves from the AECs decision making. The AEC must maintain a quorum and record all conflicts of interest and their management in the meeting minutes.

The AEC Executive

The Australian code allows for the establishment of an AEC executive to facilitate approval of minor amendments between meetings. This is the only function of the executive allowed by the Australian code. The executive may not approve new projects, or amendments that are not considered minor.

The minimum number of members of an executive is two: it must include the Chairperson and an independent (Category C or D) member. Licence holders may opt to include other members. The constitution and operation of the executive should be documented in the AEC procedures or Terms of Reference.

An AEC executive must constitute at least one Category C or D member and the Chairperson. Decisions made by the Chair alone, or any combination of the Chair, category A & B members, are invalid under the Act.

All approvals by the AEC executive must be recorded and subject to ratification by the AEC at the next quorate meeting. The activities or personnel approved by the executive may commence from the date of the executive's approval.

If the executive are presented with information they do not consider to be minor, they should refer the decision back to the full AEC, rather than risk an invalid decision or refusal of ratification.

Virtual conferencing

The Australian code permits the use of virtual conferencing in circumstances where a face-to-face meeting is not possible. A virtual conference includes video, web and tele-conferencing.

Virtual conferencing must not be a substitute for regular face-to-face meetings. It should only be used when members are not able to attend in person due to an irregular event. If regular physical attendance at meetings is an issue, licensed institutions should consider rescheduling meetings to suit the attendance of all members or reassess the suitability of members that are not able to attend meetings on a regular basis.

Inquorate meetings

When AEC meetings are inquorate, the meeting should be adjourned and reconvened. The pre-review of applications and modifications by AEC members at inquorate meetings is strongly discouraged as it introduces bias into the subsequent review process.

When quorum is lost because of member withdrawal during the meeting, the AEC must not act as an executive for agenda items during which the meeting is inquorate. AECs do not have the discretion to switch between a quorate AEC and an executive committee at the same meeting.

Review and approvals

The Act and associated Regulations require that scientific procedures must not commence until the AEC nominated by the licence holder has approved:

- a) the procedure or program of procedures
- b) the premises at which the procedure or program of procedures are to be carried out; and
- c) the person or persons who are to carry out the procedure or program of procedures.

The information to be provided to an AEC in support of an application is outlined in section 2.7.4 of the Australian code. Other sections may apply, as appropriate for the circumstance.

When approved by the AEC, an application becomes a binding agreement under the Act. Investigators must adhere exactly to commitments made within the approved project. A project that is ambiguous or internally inconsistent can be interpreted in multiple ways, making compliance challenging.

Standard Operating Procedures

Standard Operating Procedures (SOPs) may be referenced within an application to the AEC to describe routine procedures carried out in a repeated fashion. They are not a substitute for an application to the AEC. Applicants and AECs must ensure that any SOP referenced in an application complies with the Australian code. Expired SOPs must not be referenced in an application. The information provided within the application must be consistent with referenced SOPs, or the variance must be explicitly described.

Prohibited activities

The AEC cannot approve:

- a group of persons, for example 'all animal technicians' employed by the institution (individuals undertaking scientific procedures within a project must have prior approval from the AEC)
- projects or activities carried out under other licences, unless the AEC is nominated on the licence or in a formal agreement supporting a collaboration between multiple licences;
- activities in another state or territory unless registered with the jurisdiction's relevant authority;
- activities specifically prohibited by the licence conditions, the Act or Regulations or other relevant legislation;
- a scientific procedure involving the eye of any animal to determine irritancy of a chemical or biological agent unless the procedure is carried out under terminal anaesthesia;
- placement or transportation of an animal in an enclosed boot of a sedan motor vehicle;
- mulesing of sheep without provision of a pain relief product that has been registered for use on sheep by the Australian Pesticides and Veterinary Medicines Authority;
- use of a twisted bit on a horse;
- use of a pronged collar on any animal;
- allowing or encouraging an animal to fight with another animal, whether or not of the same species;
- release of an animal in circumstances where it will or is likely to be pursued, injured or killed by a dog;
- causing, procuring or permitting an animal in captivity to be injured or killed by a dog; or
- use of small leghold traps on any animal other than a rabbit, or large leghold traps on any animal other than a fox, wild dogs or declared feral cats (use on these species is subject to regulation);
- use of glue traps.

Restricted activities

AECs may provide provisional approval for following activities but ultimate approval is required from the Minister for Agriculture for:

- a) the use of lethal trap devices. Lethal trap devices are devices attached to a trap that contains a lethal substance for the purpose of causing rapid death of trapped target animals through ingestion of the substance.
- b) scientific procedures involving death as an endpoint; or
- c) the use of non-human hominids (orangutans, chimpanzees, gorillas, and bonobos) in scientific procedures.

Investigators and AECs must observe the mandatory conditions imposed by the Prevention of Cruelty to Animals Regulations 2019 in relation to:

- a) possession of fighting implements
- b) use of electronic devices, electric fences, electric bird deterrents, electric prodders, electronic stunning devices, electronic ejaculators, electronic collars, remote training collars, and containment collars, and
- c) use of confinement traps, net traps, non-kill snare traps, rodent kill traps, kill traps, glue traps, and lethal trap devices.

Decisions

The AEC may make one of four responses to new applications, or applications to modify approved projects, based on the information provided to them:

1. Approved

The AEC is satisfied that they have collected all the information the Australian code requires them to consider. They agree that the project is ethically acceptable and complies with the Australian code. The application is approved by the AEC, as submitted, with no changes required.

2. Approved with condition(s)

The AEC is satisfied that the application will be ethically acceptable and comply with the Australian code, subject to a specific correction or defined alteration. Alternatively, where outcomes or effects of procedures are not well known, the AEC may wish to receive reports at specified time points to ensure the project remains ethically acceptable.

The agreed and exact condition(s) are recorded in the AEC meeting minutes as a decision of the AEC. There are two options to formalise the decision:

- a) The investigator is required to revise the original application in accordance with the instruction from the AEC and may resubmit to a person authorised by the AEC. For example, the executive officer or AEC Chairperson to administratively confirm that the instruction of the AEC has been followed exactly. The resubmission must simply be a reconciliation with instructions and not contain any new information or require a decision. The approval date of the application must not be before the date of confirmation. The revised application then becomes the application approved by the AEC.
- b) The investigator is made aware that exact conformity with specified alterations is a condition of approval. The condition(s) of approval must be defined in the letter of approval. For example, the AEC may require six monthly progress reports, direct veterinary oversight of novel procedures, or report of completion of a pilot study to the satisfaction of the AEC prior to commencing the next phase of a project.

3. Decision deferred, subject to modification to the satisfaction of the AEC

The AEC is satisfied that the application has in-principle justification, but requires additional information, clarification or refinement before it can make a final decision. The AEC must clearly convey the required modifications or additional information to the applicant. The modified application may be assessed by the AEC quorum or by an executive, depending on the nature and potential consequences of the additional information.

Minor amendments may be reviewed out-of-session, before the next AEC meeting, by the executive. A minor amendment may include a change that is not likely to cause harm to the animals, including pain and distress. AEC procedures should provide guidance on the type of activity that would be considered a minor amendment.

Examples of minor amendments include the addition of suitably experienced personnel; changes to timelines that reduce cumulative burden; and minor changes to procedures causing little impact on the well-being of the animals, e.g. change of route of drug administration where the impact is the same or less than originally approved.

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- a) Where the required modifications meet the AEC's criteria for a minor amendment, the revised application may be circulated to the designated executive for decision.
 - If the information satisfies the executive, they may approve the revised application, subject to ratification by the AEC at the next quorate meeting. The approval date is the date approved by the executive of the AEC.
 - If the executive determines that, after communicating with the applicant, the resubmitted application does not yet meet the standard required by the Australian code, it should refer the applicant to a quorate meeting of the AEC.
 - If the information contains modification(s) outside of the criteria for a minor amendment, the executive must refer the applicant to a quorate meeting of the AEC.
 - b) Any other modifications must return to the full AEC for review at a quorate meeting. Modifications that have potentially high animal welfare impact (for example, justification for inducing pain in the absence of analgesia, single housing for social species, queries as to why valid alternatives are not used) must be considered by a quorate meeting of the AEC.

4. Not approved

This situation will arise when, in the judgment of the AEC, the potential effects on the well-being of the animals involved is not justified by the potential benefits of the project. Reasons for this decision may include (Australian code sections 1.5 and 1.6):

- a) The application does not demonstrate that:
 - the project has scientific or educational merit, and has potential benefit for humans, animals or the environment
 - the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available
 - the project involves the minimum number of animals required to obtain valid data, or
 - the project involves the minimum adverse impact on the well-being of the animals involved.
- b) The application does not demonstrate the potential of the project to:
 - obtain or establish significant information relevant to the understanding of humans and/or animals
 - maintain and improve human and/or animal health and welfare, or to improve animal management or production
 - obtain or establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or
 - achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements.

The principles of procedural fairness oblige AECs to clearly communicate the reasons for their decision to the applicant and provide them with an opportunity to respond or provide additional or explanatory information.

Follow-up review of approved projects

Follow-up review of an approved project or activity occurs at scheduled times and when circumstances trigger additional follow-up review, including:

- a) interim or pilot study reports
- b) review of annual progress of an ongoing project or activity, or
- c) unexpected adverse events, or
- d) non-compliance events.



Follow-up review might entail comparing approval conditions with the information provided in the report; reconciling numbers of animals used with those approved; reconsideration of the impact of the procedures on animal welfare; outcomes of training of inexperienced investigators; inspection of a sample of records; and any other information relevant to the circumstances.

Monitoring of animal care and use

AEC procedures must outline how the AEC monitors the care and use of animals in accordance with the Australian code. The AEC monitors the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records and reports.

The AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing, and husbandry of animals) on a regular and ongoing basis to assess compliance with the Australian code and decisions of the AEC. The AEC must ensure that identified problems and issues receive appropriate follow-up and, if necessary, refer suspected breaches of the Australian code to the institution.

AECs may delegate their authority to monitor animal care and use to suitably qualified people by documented procedures. Procedures should include how reports of such monitoring are to be provided to the AEC (e.g. using still or video images) (section 2.3.23, Australian code), including projects and activities conducted at remote sites (e.g. fieldwork).

Delegation of authority to monitor does not remove the responsibility of an AEC to take appropriate actions regarding non-compliance and/or unexpected adverse events, or to provide advice and recommendations to the institution regarding the care and use of animals.

Reporting to the licence holder (institution)

Under sections 2.3.28 and 2.3.29 of the Australian code, each AEC must prepare an annual report reviewing the operation of the AEC and detailing numbers of applications, types of applications, numbers of animals, adverse incidents, site inspections, etc conducted by the AEC.

The Australian code also requires the Chairperson to meet with the institution's licence nominee (or representative) to discuss the progress of the AEC and any incidents and/or recommendations the AEC has, to ensure the institution continues to comply with the Australian code and the Act.

See also

www.agriculture.vic.gov.au/art

AEC Guideline for Decision-making

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