

GUIDANCE NOTE: AEC DECISIONS





Contents

Purpose	3
Making decisions under law	3
Administrative decisions.....	3
Ethical decisions	3
Animal Ethics Committees make ethical and administrative decisions	3
Eleven steps to making a good administrative decision.....	4
1. Know the source of the power to decide	4
2. Know whether discretion can be applied.....	4
3. Ensure the decision maker is authorised	5
4. Apply procedural fairness	5
5. Consider all requirements.....	6
6. Consider all relevant matters	6
7. Rely only on relevant matters	6
8. Know what evidence the decision is based on.....	7
9. Consider relevant policies.....	7
10. Decide, record and inform	8
11. Seek advice as necessary	8
See also.....	8
Disclaimer	8

Purpose

This guidance is provided to introduce members of animal ethics committees (AECs) to the concept of administrative decision making. It is not intended to be a comprehensive review of administrative law. It aims to assist AECs by providing a framework to support valid, compliant decision making.

It summarises the legislated powers that authorise the AEC to make decisions and provides relevant conceptual examples. AEC members have an obligation to understand their responsibilities and obligations under the *Australian Code for the care and use of animals for scientific purposes 8th edition 2013* (Australian code). The examples presented herein are used to provide context rather than replicate the Australian code.

Making decisions under law

AECs regularly make decisions about complex, often challenging proposals to use animals. The members are familiar with making ethical decisions.

An AEC familiar with the principles of administrative decision making will find it easier to decide, be confident in the validity of its decisions, and clearly communicate the reasons for its decision. A structured approach to applying the principles of administrative decision making will support consistent, transparent and fair decisions.

Administrative decisions

Administrative decisions are those decisions made under law. In Victoria the law that establishes the regulatory framework authorising the use of animals in research and teaching is the *Prevention of Cruelty to Animals Act 1986* (POCTA Act).

A good administrative decision is one that is 'lawful'; it can stand up to scrutiny if challenged.

Ethical decisions

Ethical decisions are based on the cost-benefit analysis and a person's own ethical judgement. The Australian code defines ethics: a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when animals are proposed for use, or are used, for scientific purposes.

Animal Ethics Committees make ethical and administrative decisions

The Australian code provides instruction on this issue.

2.3.4. The AEC must make a judgement on whether the proposed use, or continued use, of animals is ethically acceptable. This judgement must:

- (i) be based on information provided by the applicant (see Chapter 2.7) that demonstrates the application of the principles outlined in Section 1
- (ii) balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

2.3.5. The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of the Code.

The Australian code specifies that AEC members must make a judgement; an ethical decision, BUT only if all specified criteria have been satisfied; an administrative decision.

Eleven steps to making a good administrative decision

By considering the following steps, an AEC can be confident it is making a good administrative decision. Sometimes this represents a shift in the usual way of business. However, with practice it becomes second nature.

By applying these principles an AEC can better communicate its expectations. The regulated parties (investigators) will understand what is required and the associated reasons and will be more likely to comply.

1. Know the source of the power to decide

The power for an AEC to make a decision comes from Part 3 of the *Prevention of Cruelty to Animals Act 1986* (POCTA Act). The *Prevention of Cruelty to Animals Regulations 2019* (POCTA Regs) are made under this Act.

The POCTA Act and Regs prescribe mandatory codes of practice.

- *Australian code for the care and use of animals for scientific purposes 8th edition 2013*
- *Code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits.*

The legislation provides the AEC's decision-making authority while the Australian code prescribes the framework as to how the AEC must go about its decision making.

2. Know whether discretion can be applied

The Australian code specifies certain things that must be considered. In very limited cases, the AEC has some discretion as to whether to consider a certain element.

When an AEC determines it is appropriate to apply discretion, it should first be satisfied that it has the authority to do so, and second remain within the boundaries of that discretion.

The language of the Australian code provides guidance.

- 'Must' is an obligatory component, discretion is not allowed.
- 'Should' or 'may' indicates a recommendation or something the AEC can consider when deciding. That is, discretion is allowed.

Example:

*Australian code 2.3.8. The AEC **must** base its decisions (to review and approve new and ongoing activities) 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.*

What does this mean?

*The AEC is required to decide by considering the prescribed information within the Australian code, including within section 2.7. There is no discretion, all information prescribed by the Australian code **must** be considered.*

*The AEC has discretion to decide whether it requires additional information. For example, an AEC **may** choose to seek information from an independent subject matter expert.*

3. Ensure the decision maker is authorised

A failure to ensure the decision maker is appropriately authorised is a common reason for invalid decisions. In establishing powers for the AEC, the POCTA Act mandates its composition. A group of people that does not meet prescribed requirements for an AEC is not authorised to make decisions as an AEC.

Once properly established and quorate the AEC may make specified decisions. Most decisions must be made by the full AEC. It has limited powers to delegate its decisions.

Example:

Australian code 2.2.23. If established, an AEC Executive:

- (i) must include the chairperson and at least one member from Category C or D*
- (ii) may be delegated to approve minor amendments to approved projects or activities,*
- (iii) must not approve new applications.*

What does this mean?

*The AEC may **only** delegate a decision to a suitably convened executive **when** the decision relates to a minor amendment to an approved project or activity. There is no authority to delegate a decision to any other entity, including the AEC Chairperson.*

4. Apply procedural fairness

Procedural fairness (sometimes called 'natural justice') requires a decision maker to provide a fair hearing and be free of bias.

The Australian code specifies how conflict of interest must be managed. However, being fair goes further than managing conflict of interest. It means that everyone must be treated equally and given the opportunity to respond to issues that may have arisen during the decision-making process, on 'a level playing field'.

The principles of procedural fairness oblige AECs to communicate clearly the reasons for their decision to the applicant and provide an opportunity for a response to the decision, which might include additional or explanatory information.

Example:

Australian code 2.3.3 The AEC must provide competent, fair, consistent and timely review of applications and reports related to the care and use of animals.

What does this mean?

For example, a category B member of an AEC presents an application to the AEC. This member physically removes themselves from the room during the AEC's discussion and decision on the application, effectively managing conflict of interest. However, the AEC asks the person questions about the application and makes its decision based on this information. Unless all other applicants have the same opportunity, this is not fair. Other applicants may feel they have been adversely impacted and complain about the AEC's procedural fairness. The ultimate decision about the ethical acceptability lies with the AEC but the AEC may be required to review its process and re-evaluate its decision (Australian code 5.6)

5. Consider all requirements

The Australian code prescribes certain matters about which the AEC must be satisfied before it can decide. The AEC must be provided with all the necessary information before it can be confident it can make a valid decision.

Failure to ensure all requirements are met is a common reason for a decision of an AEC to be invalid.

One of the ways AECs can be sure they are considering all the requirements can be to design application and reporting forms in such a way that missing information is readily recognised

Example:

1.15 Regardless of the potential benefits of a project, the methods used must be scientifically valid, feasible, well designed and carefully conducted so that there is a reasonable expectation that the aims of the project will be achieved. Projects that are not scientifically valid must not be performed, no matter how mild the impact on the wellbeing of the animals.

What does this mean?

The Australian code specifies certain matters the AEC must be satisfied with prior to approving a project. Every word is important. In this example the AEC must consider potential benefits, scientific validity, methods used, feasibility, project design, the care taken, aims of the project, reasonable expectation of achieving aims and impact to wellbeing of animals. If the AEC is not provided with information to satisfy all of these points it cannot approve the project.

6. Consider all relevant matters

Is there additional information that could be provided to add to the information considered by the AEC before deciding.

Example:

Australian code 2.3.8. The AEC must base its decisions (to review and approve new and ongoing activities) 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.

What does this mean?

By referring to direct discussions with the applicant the Australian code implies an obligation to obtain information by discussion with the applicant where this may impact on the decision. Animal Welfare Victoria recommends AECs meet with investigators, especially in cases where a person may be adversely impacted by the decision.

7. Rely only on relevant matters

An AEC must only consider matters within the scope of its authority.

Certain procedures are prohibited under legislation and the AEC has no power to approve.

Other procedures have certain restrictions imposed by legislation that the AEC must adhere to; such as conditions related to use of traps and activities requiring approval by the Minister for Agriculture.

An AEC is obliged to only consider matters specified within the legislation. Factors such as the opinion of an AEC member on use of livestock in food production are not relevant and must not influence that member's judgement.

8. Know what evidence the decision is based on

In addition to information supplied by an applicant and AEC may consider other persuasive evidence when deciding. Such additional information must be obtained fairly. The AEC may seek advice from experts as required. The Australian code provides guidance on this issue by specifying the AEC may recruit additional members with skills and background of value to the AEC and invite people with specific expertise to provide advice.

Example:

2.4.8 During planning, investigators must consider the following factors and be satisfied that: (viii) the methods and procedures to be used accord with current best practice and are appropriate for the purpose of the project.

What does this mean?

When the AEC is asked to consider an application involving unfamiliar scientific procedures, it can only be satisfied that the proposed methods accord with current best practice by accessing additional information, such as the opinion of an independent expert.

9. Consider relevant policies

The POCTA Act establishes a coregulatory framework. That is, licence holders in consultation with the AEC are obliged to implement policies and procedures to support animal use. The AEC must take these into consideration when deciding.

The principles of procedural fairness oblige AECs to ensure the person that is the subject of the decision has ready access to those policies and procedures.

Example:

2.1.8 Institutions must ensure that all people involved in the care and use of animals understand their responsibilities and the requirements of the Code, are competent for the procedures they perform or are under the direct supervision of a person who is competent to perform the procedures, and have access to appropriate education programs and resources, by: With respect to investigators

(i) ensuring that investigators are well informed of their responsibilities under the Code and their legal responsibilities

What does this mean?

In meeting this obligation under the Australian code, the institution may develop a procedure to mandate that investigators undertake training in their responsibilities prior to seeking approval from the AEC to undertake scientific procedures. The AEC therefore must be satisfied a person has met this standard prior to approving.

10. Decide, record and inform

The AEC must clearly communicate to investigators its decisions, the reasons for its decisions and any conditions attached to an approval in writing as promptly as possible.

The AEC should consider face-to-face meetings with applicants to resolve issues. When given the decision, the investigator(s) should be advised of their rights to apply for review.

The AEC should record its decision, including the reasons for that decision based on the evidence and factors that were considered.

11. Seek advice as necessary

If an AEC is not clear about the correct interpretation of an aspect of the legislation, or the Australian code, advice should be sought.

The Licensing and Audit team, Animal Welfare Victoria, may be contacted for compliance advice where clarification is required.

See also

www.agriculture.vic.gov.au/art

Guidelines for the conduct of animal ethics committees

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