



## Elanco Animal Ethics Committee (EAEC)

Animal Ethics Committees govern the use of animals in research, teaching and product testing.

The primary responsibility of the Elanco Animal Ethics Committee (EAEC) is to ensure that the care and use of animals by company personnel complies with the *Australian code for the care and use of animals for scientific purposes* (the *Code*), the Animal Research Act 1985 and the Animal Research Regulation 2010.

The EAEC applies a set of principles, outlined in the *Code*, that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the EAEC is to ensure that the use of animals is justified, provides for the welfare of those animals, and incorporates the principles of Replacement, Reduction and Refinement (the 3Rs).

The EAEC is established under the Animal Research Act 1985.

## Terms of Reference

The Elanco Animal Health Animal Ethics Committee (EAEC) has been established to give effect to section 25A of the Animal Research Act 1985. The EAEC is responsible for consideration of applications for Animal Research Authorities (ARA) and for the supervision of animal supply for research by the institution.

The following sections outline in detail the Terms of Reference of the EAEC.

### AEC Responsibilities

The primary responsibility of an AEC is to ensure, on behalf of the institution for which it acts, that all activities relating to the care and use of animals are conducted in compliance with the Legislation and the Australian Code for the Care and Use of Animals for Scientific Purposes (2013) ("The Code"); and that the use of animals in research is justified and incorporates the principles of Replacement, Refinement and Reduction, as set out in the Code.

The EAEC must;

- Review applications for projects and approve only those projects that are ethically acceptable (see 'The Code', clause 1.3) and conform to the requirements of the Code.
- Review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and conform to the requirements of the Code.
- Conduct follow-up review of approved projects and activities (see 'The Code', Clause 2.2.32 [ii]), and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code.
- Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities.



- Take appropriate actions regarding unexpected adverse events.
- Take appropriate actions regarding non-compliance.
- Approve guidelines for the care and use of animals on behalf of the institution.
- Provide advice and recommendations to the institution.
- Submit an annual written report on its operations advising on;
  - Numbers and types of projects and activities assessed, approved or rejected
  - The physical facilities for the care and use of animals by the institution
  - Actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals
  - Administrative or other difficulties experienced
  - Any matters that may affect the institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.
- Conduct an independent external review, in conjunction with Elanco Australasia, of its compliance with the Code, at least every 4 years, in accordance with section 6 of the INSTITUTIONAL ACCOUNTABILITY. This review is conducted by ARRP.

The institution must;

- Ensure appropriate animal ethics committee membership, as detailed in section 4.1.2, below (see 'The Code', Clause 2.2.4).
- Ensure that the AEC has Terms of Reference and that they are made available to the public. EAEC Terms Of Reference can be found on the company's website <https://www.elanco.com.au/>
- Provide the AEC with adequate resources to carry out its responsibilities and to maintain the AEC, and respond effectively to recommendations from the AEC regarding resources and workloads. Resources will include;
  - i. Staffing and administrative assistance
  - ii. Orientation and education of AEC members
  - iii. Where appropriate, reimbursement of out-of-pocket expenses.
- Establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use. These procedures will include declarations of interest and management of conflicts of interest, confidentiality, administrative procedures, meeting procedures, communication, complaints and non-compliance, records and documentation.
- Conduct an annual review of the operation of the AEC to ensure the institution's compliance with the Code and institutional policies. This includes an assessment of the AEC's annual report and a meeting with the AEC Chairperson if required.



- Conduct an independent external review, in conjunction with the AEC, of its compliance with the Code, at least every 4 years, in accordance with section 6 of the Code. This review is conducted by ARRPP.

Additionally, the institution must;

- Ensure, through the AEC, that all scientific activities involving the use of animals comply with relevant legislation and the Code.
- Ensure that investigators and staff are aware of their responsibilities under the Code, including by the provision of educational programs, continual training and workshops.
- Respond promptly and effectively to recommendations from the AEC to ensure compliance with the Code.
- Seek comment from the AEC on all matters that may affect the welfare of animals used by Elanco Australasia, including the provision of facilities.
- Ensure the AEC approves relevant SOPs and guidelines and that these are implemented.
- Provide relevant personnel and AEC members with details on Elanco Australasia confidentiality policy and Freedom of Information legislation.
- Provide personnel and AEC members with information on potential disease hazards and other Work Health and Safety issues associated with the care and use of animals.
- Ensure that there are adequate numbers of appropriately trained and skilled staff to care for the animals including provision of appropriate veterinary services.

## Membership

Elanco Australasia will appoint four or more persons to each AEC, with at least one in each of the following categories to ensure a quorum:

Category A: A person with qualifications in veterinary science that are recognized 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 a demonstrable commitment to, and established experience in, furthering the welfare of animals 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 AEC, and must not fit the requirements of any other category.

Each person nominated in any category must receive approval from the Animal Research Review Panel before appointment. Before appointment, all members of the AEC should acknowledge in writing their acceptance of the terms of reference, operating procedures, grievance procedures, confidentiality agreement and the provisions for confidentiality outlined in section 56 of the Animal Research Act 1985.

### **Appointment of members**

If a position becomes vacant, a replacement must be appointed to ensure at least one member from each category is represented on the EAEC. Details of the new member must be submitted to ARRP for approval prior to them becoming a voting member. New members cannot vote at a meeting until approval from ARRP has been granted. ARRP must be contacted to ensure that all corrected documentation is submitted.

A member of the EAEC is taken to have vacated his or her office if the member:

- Resigns in writing
- Dies, becomes mentally incapacitated or is convicted of an offence punishable by imprisonment
- Absents himself or herself from four consecutive meetings without the consent of the EAEC.