

Animal Ethics Procedure

Section 1 - Background and Purpose

- (1) The use of live non-human vertebrates and higher-order invertebrates in research and teaching is governed by State legislation and the NHMRC Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition, 2013 (the Code). The Department of Economic Development, Jobs, Transport and Resources (DEDJTR) has oversight of animal ethics committees in the State and inspects animal facilities and the operation of animal ethics committees on a regular basis.
- (2) La Trobe University has set in place policies and procedures to ensure that animal usage in La Trobe university and studies carried out by La Trobe staff conform to the Code, legislative requirements and current best practice. The La Trobe University Animal Ethics Committee (AEC) has responsibility for approving all teaching and research involving animals at any campus, and for approving fieldwork and wildlife studies undertaken off- campus.

Section 2 - Scope

(3) Refer to the Research Integrity Policy.

Section 3 - Policy Statement

(4) Refer to the Research Integrity Policy.

Section 4 - Procedures

Part A - Regulatory Environment

- (5) The University is the licence holder for the Scientific Procedures Premises Licence (SPPL) issued for La Trobe University by the relevant government authority in Victoria.
- (6) The licence nominee, who has oversight of animal ethics and welfare at La Trobe and chairs the La Trobe Animal Research and Teaching Facility (LARTF) Steering Committee, is the Pro Vice-Chancellor (Research Development). The LARTF Steering Committee has members drawn from the areas covered by the SPPL, as well as Infrastructure and Operations, Finance, LARTF and the AEC gives advice and recommendations to the LARTF Steering Committee regarding provision for animal usage at the University.

Part B - Relevant Legislation and Guidelines

(7) The use of live non-human vertebrates and higher-order invertebrates for research and teaching is governed by the <u>Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013)</u>, and by the <u>Victoria Prevention of Cruelty to Animals Act 1986</u> and regulations. The latter is enforced by the relevant government authority. For projects undertaken in the field, interstate, or at other institutions, La Trobe University investigators need to comply with the appropriate permit requirements and seek approval, when necessary, from other animal

Part C - Role of the Animal Ethics Committee

(8) All use of live non-human vertebrates and higher-order invertebrates for research and teaching is reviewed by the AEC. No animals are used in teaching or research without explicit AEC approval. The AEC:

- a. applies the principles outlined in the Code in determining whether the use of animals is to be approved;
- b. ensures that provision is made for the welfare of all animals used in teaching and research;
- c. oversees compliance with the principles of Replacement, Reduction and Refinement described in the Code; and
- d. monitors and inspects all animal facilities and comments on plans for changes and developments to animal holding areas.
- (9) Policy support and secretariat to the AEC is provided by the Research Office.

Part D - AEC Terms of Reference

(10) The AEC terms of reference comply with those specified in the Code. As a subcommittee of the Research and Graduate Studies Committee (RGSC), the AEC reports monthly to the RGSC. The Terms of Reference are publicly available at the Research Office website.

Part E - AEC Membership

- (11) The AEC comprises the Chair and at least one member appointed to each of the following four categories:
 - a. 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 activities of the University. Veterinarians who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animals used.
 - b. Category B a suitably qualified person with substantial recent experience as an investigator using animals in research or teaching activities.
 - c. 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 University, and who is not involved in the care and use of animals for scientific purposes. Category C members are, where possible, selected on the basis of active membership of, and nomination by, an animal welfare organisation.
 - d. Category D a person who is both independent of the University 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. A Category D member 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.
- (12) The Senior Manager of the La Trobe Animal Research and Teaching Facility (LARTF) is also a member of the Committee.
- (13) Additional members with the skills and background of value to the AEC may also be appointed.
- (14) In practice, more than one Category B member will appointed, in order to take account of the range of animal research and teaching carried out in the University. In keeping with the Code, Categories C and D must together represent at least one third of the AEC membership.
- (15) In addition to the members defined as above, there may be other attendees including ex officio the Pro Vice-Chancellor (Research Development) and the University Training, Compliance and Veterinary Services Manager, may

be required to attend. When required, investigators will be invited to discuss and clarify applications, but final decisions in such cases will not be taken while investigators are present. The AEC is empowered to solicit independent external advice from time to time on scientific, statistical, welfare or other matters.

- (16) The Chair of the AEC will hold, or be appointed to, a senior position in the University, and is nominated by the Deputy Vice-Chancellor (Research and Industry Engagement) and approved by the RGSC. Normally, a Category B member of the AEC will be nominated as Deputy Chair. Appointments to the various categories are made by the RGSC on the advice of the Chair, AEC, Heads of School or Pro-Vice Chancellors of the Colleges will make recommendations to the Chair in the case of Category B members. The term of office for all members is three years and is subject to annual review.
- (17) All members will be required to acknowledge in writing their acceptance of the terms of reference of the AEC and sign a confidentiality agreement.
- (18) Members who resign during their period of appointment will provide at least five working days' notice in writing to the Research Office. Members who are staff of the University are required to seek approval from their Head of School or Pro-Vice Chancellor of their College prior to submitting a notice of resignation.
- (19) The AEC will appoint an Executive that includes the Chair and at least one Category C or D member. The Executive approves minor variations to projects where the welfare of the animal is not negatively impacted, and deals with emergencies, but does not approve new proposals. Executive decisions are subject to review and approval at the next AEC meeting.
- (20) An AEC meeting cannot proceed or continue unless quorate. In accordance with the Code, a meeting is quorate only when (a) Category C and D members constitute at least one-third of the members present, and (b) at least one member from each of Categories A, B, C and D is present.

Part F - Conflict of Interest

(21) The AEC will deal with situations in which a conflict of interest arises by:

- a. Requiring that any apparent conflicts of interest are declared at the start of each AEC meeting and documenting the declarations and resolutions in the minutes;
- b. Requiring members to disclose the nature of their interest and conflict as soon as an apparent conflict of interest is known; and
- c. Ensuring that any member whose own application, or an application where they are a co-investigator, is being discussed is not present at the time a decision on the application is made.

Part G - Review and Monitoring

(22) The AEC will approve only those studies for which the use of animals is essential and justified and which meet all the requirements of the Code. In order to give weight both to the impact on the animals and to the anticipated scientific or educational value of proposed animal use, the committee will:

- a. Consider only those applications, or requests for variation, submitted on an approved application form completed to the committee's satisfaction;
- b. Assess, as part of its deliberations, whether the information provided by the Chief Investigator adequately and concisely details appropriate justification of the proposed animal use, the impact on the animals and adequately shows how such impact will be minimised in keeping with the principles of Replacement, Reduction and Refinement;
- c. Reject applications that are not written in plain language comprehensible to all members of the AEC;

- d. Ascertain whether the Chief Investigator has obtained, or will obtain, all relevant wildlife permits or approvals to use genetically modified organisms;
- e. Invite advice as required from persons with specific scientific, statistical or technical expertise;
- f. Seek clarification of, or agreement to suggested amendments to, an application from the Chief Investigator or nominee. The Chief Investigator or nominee will be invited, when necessary, to address the AEC in person or by telephone.
- g. Make decisions on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC will explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.
- (23) The AEC may suspend or withdraw approval for any project when:
 - a. An inspection detects activities that unduly compromise the welfare of animals. The Chair, or Deputy Chair, acting on behalf of the AEC, is able to require that such activities cease immediately and that remedial action is initiated where appropriate. In such cases, the matter will be reviewed at the next scheduled AEC meeting.
 - b. An animal is used in a way other than as approved in the initial application or subsequent approved modification or amendment to an application.
 - c. It becomes aware that an activity has a higher negative welfare impact than was approved.
 - d. An unexpected adverse event occurs.
 - e. Annual reporting requirements are not fulfilled by the Chief Investigator.

(24) In reviewing cases of non-compliance or situations in which animal welfare has been compromised, in accordance with the <u>AEC Procedures for Handling Unexpected Adverse Events, Non-compliance and Complaints</u>, the Committee may impose sanctions and/or recommend disciplinary action be taken.

Part H - Multi-Centre Research

(25) Where applications involve more than one institution, a letter of understanding will be drawn up between the La Trobe AEC and any other AEC's involved, clearly identifying each party's responsibility in the planned work, and detailing arrangements to protect the welfare of all animals involved. When La Trobe University staff conduct work with animals held solely by another institution, and when that work is subject to approval by that Institution's Animal Ethics Committee, the researchers must notify the La Trobe University AEC.

Part I - Annual Reporting

(26) The AEC reports regularly to RGSC. Minutes of AEC meetings are forwarded within two weeks of being approved, and the annual report to RGSC is completed by 31 March covering the previous calendar year. The annual report includes:

- a. numbers and types of applications approved or rejected;
- b. comments on the physical facilities for the care and use of animals by the institution;
- c. descriptions of activities that have supported the educational needs of AEC members, and of personnel involved in the care and use of animals;
- d. an account of administrative and other difficulties being experienced; and
- e. any matters that may affect the University's ability to maintain compliance with the Code and recommendations on how to deal with these.

(27) In addition, the AEC reports as required to regulatory authorities. Such reports will be forwarded for noting and

comment to the RGSC and, where necessary, signed by the Deputy Vice-Chancellor (Research and Industry Engagement).

- (28) Annual Progress Reports: Chief Investigators of AEC approved projects must submit an Annual Progress Report to the AEC as a condition of project approval. Chief Investigators who fail to submit a Progress Report by the due date may have their project suspended until a report has been received and reviewed by the AEC.
- (29) Final Reports: All Chief Investigators of AEC approved projects must submit a Final Report within three months of the expiry date or conclusion of their project as a condition of project approval. Final Reports are reviewed by the AEC and kept by the University as an official record from the Chief Investigator regarding the outcome of all animals used or produced during the approval period.
- (30) Annual Reporting to Government Authorities on Animal Use: Chief Investigators of AEC approved projects must submit an annual Animal Usage Report to the relevant state or territory government authority prior to the required date as a condition of project approval. It is the responsibility of the licence holder to complete and submit the return, however this task may be delegated to the Senior Animal Ethics Officer.

Part J - Operating Guidelines

(31) AEC operating guidelines, as endorsed by RGSC, regarding applications, training, record keeping, animal displays and field-based teaching and research are displayed on the AEC web site.

Part K - Unexpected Adverse Events and Complaints

- (32) Refer to the AEC Procedures for Handling Unexpected Adverse Events, Non-compliance and Complaints.
- (33) Allegations of research misconduct, including evidence of animal research conducted without ethics approval, must be dealt with according to the La Trobe University Research Misconduct Procedure.

Part L - Animal Facilities Inspections and Record Keeping

- (34) La Trobe University animal facilities are inspected and approved by the AEC and registered with the relevant government authority. The AEC inspects the facilities on an annual basis. Inspection teams must include the Chair and at least one Category C or Category D member. Reports of inspections are included in the AEC minutes and in the annual report to the RGSC.
- (35) Record keeping of animal usage complies with the conditions approved by the AEC, and these are set so as to meet the requirements of the relevant government authority.

Part M - Field Work and Observational Studies

- (36) Fieldwork will often require, in addition to AEC approval, permission from other state or territory government authorities. Copies of permits will be lodged with the AEC prior to the commencement of field work. The AEC or its authorised delegate may inspect field work from time to time.
- (37) No observational studies involving animals will take place without approval from the AEC.

Section 5 - Definitions

(38) For the purpose of this Procedure:

(39) Animal:

- a. a live member of a vertebrate species including any
 - i. fish or amphibian that is capable of self-feeding; or
 - ii. reptile, bird or mammal, other than any human being or any reptile, bird or other mammal that is below the normal mid-point of gestation or incubation for the particular class of reptile, bird or mammal; or
- b. a live adult decapod crustacean, that is
 - i. a lobster: or
 - ii. a crab; or
 - iii. a crayfish; or
- c. a live adult cephalopod including
 - i. an octopus; or
 - ii. a squid; or
 - iii. a cuttlefish; or
 - iv. a nautilus
- d. Animal Ethics Committee (AEC): a committee constituted in accordance with the terms of reference and membership laid down in the <u>Australian Code for the Care and Use of Animals for Scientific Procedures (8th Edition, 2013)</u>.
- e. Animal facilities: places where animals are kept and/or used, including yards, paddocks, tanks, ponds, cages, laboratories and buildings.
- f. Animal welfare: The Code defines an animal's welfare as an animal's quality of life, which encompasses the diverse ways an animal may perceive and respond to their circumstances, ranging from a positive state of wellbeing to a negative state of distress.

Status and Details

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Unit Head	Alistair Duncan Executive Director, Research Office
Author	Angela Astbury Senior Animal Ethics Officer
Enquiries Contact	Ethics and Integrity