

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 <u>The Code</u>, 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 person responsible for oversight of research and teaching involving animals is the Deputy Vice-Chancellor (Research) who is also the licence holder for La Trobe University registered with relevant government authority in Victoria. The licence holder delegates this responsibility to each of the four licence nominees covering the following Scientific Procedures Premises Licences (SPPLs):

- a. School of Life Sciences
- b. School of Molecular Sciences
- c. School of Psychology and Public Health
- d. Murray Darling Freshwater Research Centre
- (6) Oversight of animal ethics and welfare at La Trobe is delegated by the Deputy Vice-Chancellor (Research) to the Pro Vice-Chancellor (Research) who chairs the La Trobe Animal Research and Teaching Facility (LARTF) Steering Committee, and has oversight of both the LARTF and the AEC and of all official communications with state or territory government authorities. The Director LARTF reports to the PVC (Research) and is responsible for all animal holding areas in the University, and for all matters related to ordering, management and breeding of animals at all campuses. An Animal User Group with members drawn from the SPPL areas 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 ethics committees.

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;
- 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 is a subcommittee of the Research and Graduate Studies Committee (RGSC) reporting monthly to the RGSC, and its terms of reference comply with those given in The Code. 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 and with experience relevant to the activities of the University. Veterinarians who lack this experience will 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; and
 - 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 under-graduate education. A person who would qualify for appointment in one of the above three categories is not eligible for appointment as a Category D member.
- (12) The Director 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) and the University Training, Compliance and Veterinary Services Manager, by invitation. 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 approved by the RGSC. Normally, a Category B member of the AEC will be nominated as Deputy Chair. Appointment procedures are detailed in the Terms of Reference. 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 (in the case of category B members) and external bodies (e.g. animal welfare organisations or relevant Victorian Government Authority, in the case of C and D members). Terms of office for all members are for three years and are subject to annual review. Members will not normally serve for more than six consecutive years.
- (17) 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.
- (18) The AEC will appoint an Executive that includes the Chair and at least one Category C or D member. The Executive approves some minor modifications to projects and deals with emergencies, but does not approve new proposals. Executive decisions are subject to review and approval at the next AEC meeting.
- (19) An AEC meeting cannot proceed unless quorate. A quorum consists of the Chair and a representative from each for the four membership categories (categories A, B, C and D), and that categories C and D comprise one-third of the quorate and Committee membership.

Part F - Conflict of Interest

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

- a. Requiring members to disclose the nature of their interest and conflict as soon as an apparent conflict of interest is known;
- b. 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;
- 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

- (21) The AEC will approve only those studies for which the use of animals is essential and justified with reference to 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 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 in order to achieve consensus. If consensus is still unachievable, the AEC should only proceed to a vote after members have been allowed a period of time to review their positions, followed by further discussion. If,after such deliberation, two or more members remain opposed to approving an application, it will normally be rejected.

(22) The AEC will 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. Annual reporting requirements are not fulfilled by the Chief Investigator.
- e. In reviewing cases of non-compliance or situations in which animal welfare has been compromised, the committee may recommend disciplinary action be taken against investigators or other staff involved.

Part H - Multi-Centre Research

(23) 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 staff conducts work with animals held solely by another institution, and when that work is subject to approval by another institutional ethics committee, the researcher must notify the La Trobe University AEC.

Part I - Annual Reporting

(24) 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
- d. AEC members, and of personnel involved in the care and use of animals;
- e. an account of administrative or other difficulties being experienced; and
- f. any matters that may affect the University's ability to maintain compliance with The Code and recommendations on how to deal with these.

(25) 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 DVC(R) or PVC(GR).

- (26) 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 an annual progress report may have their ethical clearance suspended until a report has been received and reviewed by the AEC.
- (27) Annual Reporting to Government Authorities on Animal Use in AEC Approved Projects: 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 annually as a condition of project approval. It is the responsibility of the licence holder to complete and submit the return, however this task can be delegated to the AEC Executive Officer.
- (28) Final Reports: All Chief Investigators 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.

Part J - Operating Guidelines

(29) 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 - Role of the University, Training, Compliance and Veterinary Services Manager

(30) The role of the University Training, Compliance and Veterinary Services Manager is to help ensure that the high standards of animal welfare goals set by the University are met in all aspects of teaching and research. In conjunction with the Director, LARTF, the University Training, Compliance and Veterinary Services Manager carries out a program of post-approval monitoring, and arranges for training and education for researchers and research trainees, develops resource materials, engages in professional development, and provides general veterinary advice and services where necessary. The University Training, Compliance and Veterinary Services Manager investigates matters relating to animal welfare and reports on these to the Director, LARTF. The University Training, Compliance and Veterinary Services Manager provides a monthly report of activities to the AEC through the Director LARTF, and may be invited to attend AEC meetings as appropriate.

Part L - Adverse Events and Complaints

- (31) Any impacts on the welfare of animals beyond those approved by the AEC are required to be reported promptly by the responsible personnel to the AEC. Staff employed by LARTF report adverse events of any kind immediately to the Director LARTF and to the Chair of the AEC. Staff and students engaged on approved projects report any adverse incident to the Chief Investigator, who in turn immediately passes the information to the Director LARTF, or nominee, and the Chair of the AEC.
- (32) The Chair of the AEC has the authority to suspend work on an approved project, and request treatment (including euthanasia) of affected animals until a report on any adverse event has been reviewed by a full meeting of the AEC. In the absence of the Chair, either the Deputy Chair of the AEC or the PVC (Research), may exercise the same authority. Failure on the part of academic staff or students to report adverse incidents, unexpected illness or death of experimental animals may lead to action under appropriate misconduct provisions.
- (33) In respect of treatment of animals in La Trobe facilities, any complaints by staff, students, members of the public or other people not directly involved in animal research will be presented to the PVC (Research) for consideration. Where it appears that a prima facie case exists, that animal welfare has been adversely affected, the PVC (Research)

will pass the complaint and all relevant information to the AEC for action.

(34) The University has established a complaints and grievances mechanism for La Trobe University personnel, students and persons external to the University to allow the voicing of concerns regarding animal research and teaching. Such concerns can be submitted in writing to the AEC Secretariat. Complaints or grievances by La Trobe University personnel about decisions reached by the AEC can be submitted in writing to the Deputy Vice-Chancellor (Research) or the University Ombudsman.

(35) Allegations of breach or research misconduct, including evidence of animal research conducted without ethics approval, must be dealt with according to the La Trobe University Research Misconduct Procedures.

Part M - Animal Facilities and Inspections and Record Keeping

(36) Animal facilities used by La Trobe research and teaching staff are approved and inspected by the AEC, and those in Victoria are also registered with the relevant government authority. The AEC inspects the facilities on an annual basis. Reports of inspections are included in the AEC minutes and in the annual report to the RGSC.

(37) 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 N - Field Work and Observational Studies

(38) 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.

(39) No observational studies involving animals will take place without approval from the AEC.

Section 5 - Definitions

(40) For the purpose of this Procedure:

- a. Animal: any non-human vertebrate, such as fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods including octopus, and squid.
- b. 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>.
- c. Animal welfare: DEPI defines an animal's welfare as good when it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane killing.
- d. Facilities: places where animals are kept including yards, paddocks, tanks, ponds, cages and buildings.

Status and Details

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