

# **Research Animal Ethics Procedure**

### **Section 1 - Key Information**

Policy Type and Approval Body	Academic – Academic Board
Accountable Executive - Policy	Deputy Vice-Chancellor (Research, Industry & Engagement)
Responsible Manager - Policy	Executive Director, Research Office
Review Date	27 September 2026

# Section 2 - Purpose

(1) La Trobe University has established policies and procedures to ensure that animal use at La Trobe, and studies carried out by La Trobe staff and students, conform to the <u>Australian Code for the Care and Use of Animals for</u> <u>Scientific Purposes (8th Edition, 2013)</u> (the Code), legislative requirements and current best practice. The La Trobe University Animal Ethics Committee (AEC) is responsible for approving all teaching and research involving animals at all La Trobe campuses, and for approving fieldwork and wildlife studies undertaken off-campus.

### Section 3 - Scope

(2) Refer to the <u>Research Governance Policy</u>

# **Section 4 - Key Decisions**

Key Decisions	Role
Reviewing and approving applications for proposed work with animals	

### **Section 5 - Policy Statement**

(3) This procedure forms part of the <u>Research Governance Policy</u> suite which governs its application.

# **Section 6 - Procedures**

#### Part A - Relevant Legislation and Guidelines

(4) The use of live non-human vertebrates and higher-order invertebrates for research and teaching is governed by the <u>Code</u>, and by the Victoria <u>Prevention of Cruelty to Animals Act 1986</u> and Prevention of Cruelty to Animal Regulations 2019. The Department of Jobs, Precincts and Regions (DJPR) has oversight of animal ethics committees in

the State and inspects animal facilities and the operation of animal ethics committees on a regular basis.

(5) 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.

(6) The University is the licence holder for the Scientific Procedures Premises Licence (SPPL) and Scientific Procedures Fieldwork Licence (SPFL) issued for La Trobe University by the relevant government authority in Victoria.

#### Part B - Role of the Animal Ethics Committee

(7) 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 written Animal Ethics Committee (AEC)approval. The AEC:

- a. applies the principles outlined in the Code in determining whether the use of animals can ethically 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.

#### Part C - AEC Terms of Reference

(8) The AEC Terms of Reference comply with those specified in the <u>Code</u>. As a subcommittee of the Research and Graduate Studies Committee (RGSC), the AEC reports to the RGSC on a regular basis. The Terms of Reference are publicly available on the Ethics, Integrity and Biosafety (EIB) website.

#### Part D - Researcher Responsibilities

(9) All activities, including projects, that involve the care and use of animals for scientific purposes must:

- a. be subject to ethical review, approval and monitoring by an AEC
- b. commence only after approval has been granted by an AEC
- c. be conducted in accordance with the AEC approval
- d. cease if approval from the AEC is suspended or withdrawn

(10) Researchers must fulfill all responsibilities listed under Section 2.4 of the <u>Code</u>, and by the Victoria <u>Prevention of</u> <u>Cruelty to Animals Act 1986</u> and regulations.

#### Part E - Fieldwork and Observational Studies

(11) 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.

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

### Part F - Multi-Centre Research

(13) Where applications involve more than one institution, a Memorandum of Understanding (MoU) will be drawn up between the La Trobe AEC and any other AEC that is involved, detailing arrangments to protect the welfare of animals involved and the responsibilities of each part in a Delegation of Responsibility (DoR).

(14) When La Trobe University staff are listed on a project approved by an animal ethics committee at another institution the staff member must notify the La Trobe University AEC prior to commencement.

### Part G - Reporting Requirements

(15) Annual Progress Reports: The Principal Investigator (PI) of an AEC approved project must submit an Annual Progress Report to the AEC as a condition of project approval. PIs 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.

(16) The PI of an AEC approved project is required to submit a Request for Amendment Form if they intend to modify the project. Amendments to AEC approved projects can only be granted if the amendment is minor and there is no significant change to the direction of the study. Amendments may include a change in animal numbers, a change in procedures or

techniques, the addition or removal of investigators, an extension of the study duration or administrative changes.

(17) Final Reports: The PI of an AEC approved project 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 PI regarding the outcome of all animals used or produced during the approval period.

(18) Annual Reporting to Government Authorities on Animal Use: The PI of an AEC approved project must submit an annual Animal Usage Report to EIB prior to the required date as a condition of project approval. It is the responsibility of the licence holder or delegate to complete and submit the return to the relevant state or territory government authority.

(19) If the PI of an active AEC approved project plans to leave the University or transfer to another institute, the PI must notify the EIB team prior to their departure by sending an e-mail to animalethics@latrobe.edu.au. The PI can either nominate a different La Trobe staff member as the new PI, transfer the project to another institute or request to close the project.

### Part H - Unexpected Adverse Events and Complaints

(20) In keeping with the conditions for ethics approvals, the PI must immediately report Unexpected Adverse Events (UAEs) to the AEC by submitting a report to the EIB team. Upon review, the AEC may appoint an Assessment Officer to collect more information and prepare an Incident Report if the UAE may be related to non-compliance of the Code.

(21) Findings of noncompliance that also relate to a breach of the <u>Australian Code for the Responsible Conduct of</u> <u>Research</u>, including evidence of animal research conducted without ethics approval, will be dealt with according to the La Trobe University <u>Research Misconduct Procedure</u>.

(22) For processes outlining UAEs and complaints, please refer to the information and templates provided on the <u>Animal Ethics website</u>. Complaints about an approved project, the conduct of a researcher or the conduct of the AEC should be made under the Complaints procedure as listed on the Animal Ethics website in writing or on the form provided and submitted to eib@latrobe.edu.au.

### Part I - Monitoring of AEC Approved Projects

(23) According to the Code, monitoring means measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Code. Monitoring occurs at different levels (including those of investigators, animal carers and AECs). All activities, including projects, that involve the care and use of animals for scientific purposes must be subject to ethical review, approval and monitoring by an AEC. Monitoring is an AEC responsibility but can be delegated to the EIB team, as required.

(24) The purpose of post-approval monitoring is to ensure that the care and use of animals for scientific purposes is conducted in compliance with the Code, and in accordance with AEC approval.

(25) The monitoring visits will be conducted in partnership with the researchers. Prior to project monitoring, the purpose and process will be clearly communicated to the researchers. It is also an opportunity for the researchers to meet members of the AEC, share their work and ask questions.

(26) Monitoring will depend on the degree of risk that arises from the research and should be proportionate to that risk and will focus on existing AEC approved projects that involve:

- a. the performance of commonly occurring procedures
- b. intrusive experimental procedures on animals
- c. projects that have been identified to cause moderate to serve impact on animal welfare, and
- d. projects that have history of significant unexpected adverse event (s) and/or non-compliance event(s).

(27) The monitoring process will be carried out by the AEC Chair, a representative from EIB, and any volunteering AEC members (including at least one Category C or D member).

(28) The monitoring process may include more than one of the following, on a case-by-case basis:

- Documentation/Record keeping check (desktop check can be conducted by a member of the EIB team to prepare the visit)- Animal usage, animal transportation record, competency record, updated standard operating procedures, material safety data sheets, cross check personnel and procedures listed in approved application/amendment;
- b. Face-to-face meeting with project PI and any other co-Investigators (on request) Discussion around project progression, difficulties encountered, update on animal welfare status etc.;
- c. Laboratory/facility visit Animal housing, observation of daily operation, demonstration of specific procedure (on request), monitoring records;
- d. Field research and research at remote sites- researcher may demonstrate by video or photographs selected field procedures and equipment used.

(29) Monitoring performance, including inspection and any corrective action, will be documented and communicated to the researchers.

(30) Results of performance monitoring including close out of any corrective actions will be reported to the AEC.

# **Section 7 - Definitions**

(31) For the purpose of this Procedure:

(32) 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>.

(33) Animal facilities: locations where animals are kept and/or used, including yards, paddocks, tanks, ponds, cages, laboratories and buildings.

(34) Animal welfare: The Code defines animal welfare as the quality of life of an animal, 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.

(35) Principal Investigator (PI): refers to the researcher primarily responsible for the conduct of the research.

(36) Unexpected Adverse Event (UAE): an event that may have a negative impact on the wellbeing of the animals and was not foreshadowed in the approved project or activity.

# **Section 8 - Authority and Associated Information**

(37) This Procedure is made under the La Trobe University Act 2009.

- (38) Associated information includes:
  - a. Ethics, Biosafety and Integrity website

#### **Status and Details**

Status	Current
Effective Date	27th September 2023
Review Date	27th September 2026
Approval Authority	Academic Board
Approval Date	27th September 2023
Expiry Date	Not Applicable
Responsible Manager - Policy	Alistair Duncan Executive Director, Research Office
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