

# Research Animal Ethics Procedure

## Section 1 - Key Information

<b>Policy Type and Approval Body</b>	Academic - Academic Board
<b>Accountable Executive - Policy</b>	Deputy Vice-Chancellor (Research and Innovation)
<b>Responsible Manager - Policy</b>	Executive Director, Research Strategy & Operations
<b>Review Date</b>	12 June 2028

## Section 2 - Purpose

(1) La Trobe University (LTU) has established policies and procedures to ensure that animal use at LTU, and studies carried out by LTU and students, conform to the [Australian Code for the Care and Use of Animals for Scientific Purposes \(8th Edition, 2013\)](#) (the Animal Code), legislative requirements and current best practice. The LTU Animal Ethics Committee (LTU AEC) is responsible for approving for ensuring that all activities relating to the care and use of animals are conducted in compliance with the Animal Code.

(2) All teaching and research involving animals at all LTU campuses, and fieldwork and wildlife studies undertaken off campus are subject to review by the LTU AEC. This Procedure provides information for LTU researchers on management of those activities.

## Section 3 - Scope

(3) Refer to the [Research Governance Policy](#)

## Section 4 - Key Decisions

<b>Key Decisions</b>	<b>Role</b>
Reviewing, approving and monitoring applications for work with animals	AEC

## Section 5 - Policy Statement

(4) This procedure forms part of the [Research Governance Policy](#) suite which governs its application.

## Section 6 - Procedures

## Part A - Relevant Legislation and Guidelines

(5) The use of all vertebrate species other than humans (mammals, birds, fish, amphibians, reptiles), certain crustaceans (lobster, crabs, crayfish) and cephalopods (octopi, squid, cuttlefish, nautilus) for research and teaching is governed by the Animal Code and by the [Victorian Prevention of Cruelty to Animals Act 1986](#) (POCTA) and the [Prevention of Cruelty to Animal Regulations 2019](#) (the Regulations). The Department of Energy, Environment and Climate Action through Animal Welfare Victoria (AWV) has oversight of animal ethics committees in the State and inspects animal facilities and the operation of animal ethics committees on a regular basis.

(6) For projects undertaken in the field, interstate, or at other institutions, LTU investigators must comply with the appropriate permit requirements and seek approval, when necessary, from other animal ethics committees in addition to approval from LTU AEC.

(7) LTU is the licence holder for the Scientific Procedures Premises Licence and Scientific Procedures Fieldwork Licence issued by AWV in Victoria.

## Part B - Role of the Animal Ethics Committee

(8) All use of vertebrate species other than humans (mammals, birds, fish, amphibians, reptiles), certain crustaceans (lobster, crabs, crayfish) and cephalopods (octopi, squid, cuttlefish, nautilus) for research and teaching must be reviewed by the LTU AEC. No animals should be used in teaching or research without written LTU AEC approval. The LTU AEC:

- a. applies the principles outlined in the Animal 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 Animal Code;
- d. monitors all activities relating to the care and use of animals for scientific purposes including compliance with LTU AEC approved protocols and procedures; and
- e. monitors and inspects all animal facilities and comments on plans for changes and developments to animal holding areas.

## Part C - AEC Terms of Reference

(9) The LTU AEC Terms of Reference comply with those specified in the Animal [Code](#). As a subcommittee of the Research and Graduate Studies Committee (RGSC), the LTU AEC reports to them on a regular basis. The Terms of Reference are publicly available on the Ethics, Integrity and Biosafety (EIB) website.

## Part D - Researcher Responsibilities

(10) 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 LTU AEC where it is conducted under an LTU licence;
- 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.

(11) Researchers must fulfill all responsibilities listed under Section 2.4 of the Animal [Code](#), and by POCTA and the

regulations.

(12) In submitting a project for review by the LTU AEC, the named Principal Investigator on a project must be a fixed-term or ongoing LTU staff member or have Emeritus status conferred by Academic Board. Projects by Student and Honorary appointees other than Emeriti must be conducted with their academic supervisor as Principal Investigator on the ethics application. Academic supervisors must be ongoing or fixed-term university staff members. This approach is aligned with the [Australian Code for the Responsible Conduct of Research 2018](#) (the Code) and the LTU [Honorary Appointments Policy](#).

## **Part E - Fieldwork and Observational Studies**

(13) Fieldwork will often require, in addition to LTU AEC approval, permission from other state or territory government authorities. Copies of permits will be lodged with the LTU AEC prior to the commencement of field work. The LTU AEC or its authorised delegate may inspect field work from time to time.

(14) Observational studies involving any interventional activity must not take place without approval from the LTU AEC.

## **Part F - Multi-Centre Research**

(15) Where applications involve more than one institution, a Memorandum of Understanding will be drawn up between the LTU AEC and the other institution that is involved, detailing arrangements to protect the welfare of animals involved and the responsibilities of each part in a Delegation of Responsibility.

(16) When LTU staff are listed on a project approved by an AEC at another institution, the staff member must notify the LTU AEC prior to commencement through the submission of LTU AEC Notification of External Approval Form.

## **Part G - Disallowed Activities**

(17) Use of animals for testing cosmetics: Section 7 of the Australian Code for the Care and Use of Animals for Scientific Purposes prohibits the use of animals for testing cosmetics. LTU strictly adheres to this ban and does not use animals for testing finished cosmetic products or chemical ingredients, except where the proposed use of animals is justified for purposes beyond cosmetics.

(18) The LTU AEC endorses the National Health and Medical Research Council statement on the forced swim test in rodent models and prohibits the use in any new projects for any purposes unless there is robust evidence to support the scientific validity of its use and compelling justification that use of alternatives to the forced swim test will not achieve the scientific aims of the proposed research.

(19) The LTU AEC endorses the National Health and Medical Research Council Statement on smoke inhalation procedures in rodent models and prohibits the use in any nose-only exposure procedures in any projects. The use of the whole-body exposure procedure in a new project may be approved only if justified as to its use and adequate consideration to the requirements under the NHMRC statement.

(20) If death is a likely outcome in a procedure involving animals, a humane preterminal endpoint must be selected instead. The LTU AEC will not approve any procedure where death is the endpoint.

## **Part H - Post-Approval Requirements**

(21) Annual Progress Reports: The Principal Investigator (PI) of an LTU AEC approved project must submit an Annual Progress Report to the LTU 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 LTU AEC. New

submissions will not be accepted from a researcher with outstanding reports.

(22) The PI of an LTU AEC approved project is required to submit a Request for Amendment Form if they intend to modify their approved project. The request for amendment form must be accompanied by a track changed version of the original approved protocol with the proposed amendment and a clean copy of the modified protocol. Amendments to LTU AEC approved projects can only be granted if there is no significant change to the direction of the study. Amendments may include a change in animal numbers, a change to or addition of procedures or techniques, the addition or removal of investigators, a reasonable extension of the study duration or administrative changes.

(23) Final Reports: It is a requirement of all LTU AEC approved projects that a final report is submitted by the PI within three (3) months of the conclusion of the project or within 3 months of the expiry date whichever is the lesser. Final Reports are reviewed by the LTU AEC and kept by the LTU as an official record from the PI regarding the outcome of all animals used or produced during the approval period. New submissions will not be accepted from a researcher (as neither a PI nor coinvestigator) with outstanding reports.

(24) Annual Reporting to Government Authorities on Animal Use: The PI of an LTU AEC approved project must submit an annual Animal Usage Report to EIB prior to the required date. It is the responsibility of the licence holder or delegate to complete and submit the return to the relevant state or territory government authority. If a PI fails to submit their animal usage by the required date, they may have their project suspended until the report has been received and reviewed by EIB.

(25) If the PI of an active LTU AEC approved project plans to leave the LTU or transfer to another institute, the PI must notify the EIB team prior to their departure. The PI has the option to:

- a. nominate a different LTU staff member as the new PI through a modification request to the LTU AEC;
- b. request a transfer through the new institution's AEC, the LTU AEC Secretariat will facilitate by providing records to the new AEC;
- c. provide a final report closing the project.

(26) Failure to complete this step may result in a report of non-compliance or research misconduct.

## **Part I - Unexpected Adverse Events**

(27) In keeping with the conditions for ethics approvals, the PI must notify the LTU AEC of Unexpected Adverse Events (UAEs) by email to [animaethics@latrobe.edu.au](mailto:animaethics@latrobe.edu.au) within 24 hours. The notification must be followed by the completion of an Adverse Event Report via PRIME as soon as practicable. Upon review, the LTU AEC may appoint an Assessment Officer to collect more information and prepare a Breach Notification Report in accordance with the University Compliance Framework if the UAE may be related to non-compliance with the Animal Code.

(28) Findings of non-compliance that also relate to a breach of the Code, including evidence of animal research conducted without ethics approval, will be dealt with according to the LTU [Research Misconduct Procedure](#).

## **Part J - Risk-Based Monitoring of AEC Approved Projects**

(29) All activities, including projects, that involve the care and use of animals for scientific purposes are subject to ethical review, approval and monitoring by the LTU AEC. According to the Animal Code, monitoring means measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Animal Code.

(30) The LTU Council mandated a framework of risk-based monitoring for research undertaken at LTU. For animal research the purpose is to ensure that the care and use of animals for scientific purposes is conducted in compliance with the Animal Code, and in accordance with LTU AEC approval. The system is based on an established set of criteria outlined in the LTU [Risk-based monitoring framework](#). Monitoring will depend on the degree of risk that arises from the

research and should be proportionate to that risk.

(31) Risk-based monitoring at LTU involves various levels of staff involved in animal research including the research team, animal carers and the LTU AEC to ensure research is conducted in compliance with the relevant approval/s and regulatory requirements. Risk-based monitoring is a joint responsibility between LTU AEC and EIB.

(32) Risk-based 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 LTU AEC, share their work and ask questions.

(33) Risk-based monitoring will be defined on a case-by-case basis and may include:

- a. Pre-monitoring review of all relevant documentation in PRIME by the EIB team prior to the monitoring visit;
- b. Monitoring visit:
  - i. Face-to-face visits (in-person or remote) can include a meeting with the project PI and relevant co-investigators and laboratory staff or facility manager;
  - ii. Remote observation can be used for field research and research conducted at remote sites - researchers may demonstrate by video or photographs selected field procedures and equipment used;
  - iii. For-cause visits can be arranged to address unanticipated issues that arise which require remediation. These will only be conducted on an as needed basis;
  - iv. Close-out visit, if required, to confirm recommended actions have been completed.
- c. Focused monitoring will be conducted where areas of a project have been identified to carry higher risk, examples include – monitoring surgical procedures or management of conflicts of interest.

(34) Risk-based monitoring activities and recommended actions will be documented and communicated to the PI.

(35) Results of risk-based monitoring including recommendations for preventative and corrective actions will be prepared by the EIB team, with appropriate consultation with the committee/s, where required. The EIB team will ensure these actions are appropriately followed up and actioned.

(36) Findings from a pre-monitoring review or risk-based monitoring that indicate a breach of the Code, including evidence of research conducted without ethics approval, will be appropriately managed according to the La Trobe University [Research Misconduct Procedure](#).

## **Part K - Complaints**

(37) In all cases, attempts should be made to resolve the issues through discussion or mediation.

(38) Grievances or complaints against the LTU AEC should be made initially to the Senior Manager, Ethics Integrity and Biosafety (SM,EIB) via phone or email. The SM,EIB will confer with the LTU AEC Chair to try and resolve the grievance in an informal manner. If the nature of the grievance is regarding approval of a project or report, the investigator/complainant may be invited or can request to attend the next LTU AEC meeting to address any questions and discuss concerns.

(39) If the grievance cannot be resolved, a written complaint should be submitted via email to EIB at [eib@latrobe.edu.au](mailto:eib@latrobe.edu.au). This complaint will be presented to the LTU AEC at the next scheduled meeting, or if urgent, may be referred to the AEC Executive Committee.

(40) Should a grievance not be resolved in the above manner, the complainant can lodge a written complaint to DVC(R&I) (or delegate).

(41) The DVC(R&I) will look at the processes involved in the decision making, whether they were compliant with the

Animal Code, and that they are consistent with policies and procedures. The DVC(R&I) may also examine the practice in other AECs, and in some cases precedents. The complainant should outline the grounds of their complaint in relation to these points.

(42) The DVC(R&I) will provide written advice to both the LTU AEC and the aggrieved person regarding the review of the matter. The DVC(R&I) may require the LTU AEC to reconsider its decision or procedures in the light of the advice or may endorse the decision or procedures of the LTU AEC.

(43) If the LTU AEC is required to reconsider its decision or procedures, the LTU AEC must consider any advice given to it by the DVC(R&I).

(44) Any advice by the DVC(R&I) on the matter referred will be deemed to be the final advice of the DVC(R&I) on the matter.

(45) The ultimate decision regarding the ethical acceptability of an activity lies with the LTU AEC and must not be overridden (Clause 5.6, the Animal Code).

(46) Should the applicant remain dissatisfied with the decision of the LTU AEC, they may appeal to an external agency as per this procedure.

## **Part L - Non- Compliance**

(47) If a researcher identifies a non-compliance within LTU, it must be reported as detailed in the AEC Non-compliance procedure available on the Animal Ethics website.

## **Section 7 - Definitions**

(48) For the purpose of this Procedure:

(49) Animal Ethics Committee (AEC): a committee constituted in accordance with the terms of reference and membership laid down in the [Australian Code for the Care and Use of Animals for Scientific Procedures \(8th Edition, 2013\)](#).

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

(51) Animal welfare: The Animal 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.

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

(53) 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**

(54) This Procedure is made under the [La Trobe University Act 2009](#).

(55) Associated information includes:

- a. [Ethics, Biosafety and Integrity website](#)



## Status and Details

<b>Status</b>	Current
<b>Effective Date</b>	12th June 2025
<b>Review Date</b>	12th June 2028
<b>Approval Authority</b>	Academic Board
<b>Approval Date</b>	12th June 2025
<b>Expiry Date</b>	Not Applicable
<b>Responsible Manager - Policy</b>	Alistair Duncan Executive Director, Research Strategy & Operations
<b>Enquiries Contact</b>	Ethics, Integrity and Biosafety