

La Trobe Animal Ethics Committee
Terms of Reference, Governance and Operating Procedures

Table of Amendments

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1. Acronyms

Acronym	Definition
AEC	La Trobe Animal Ethics Committee
EIB	Ethics, Integrity and Biosafety Team
LARTF	Latrobe Animal Research and Training Facility
POCTA	Prevention of Cruelty to Animals Act
SOPs	Standard Operating Procedures
The Code	Australian Code for the Care and Use of Animals for Scientific Purposes

For a comprehensive list of definitions see '[The Code](#)'.

2. Responsibility of the AEC

- 2.1** 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 Code ([2.3.1](#)). In Victoria, AECs have prescribed functions under the [POCTA](#) Regulations including that the AEC must act in accordance with the Australian Code of Practice, in relation to any scientific procedure or program of scientific procedures carried out under the licence, when:
- a. making any recommendation and approvals as to the use of animals in the procedure or program; or
 - b. supervising the carrying out of the procedure or program; or
 - c. performing any other function in relation to the procedure or program.
- 2.2** The AEC must ([2.3.2](#)):
- a. Review applications for projects and approve only those projects that are ethically acceptable as defined by section 1.3 of the Code and conform to the requirements of the Code
 - b. 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
 - c. Conduct follow-up review of approved projects and activities (section 9.10), and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code
 - d. Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities
 - e. Take appropriate actions regarding unexpected adverse events
 - f. Take appropriate actions regarding non-compliance.
 - g. Approve guidelines for the care and use of animals on behalf of the institution.
 - h. Provide advice and recommendations to the institution.
 - i. Report on its operations to the institution.
- 2.3** In accordance with the Code ([6.1-6.6](#)) the AEC will facilitate an independent external review every four years.

3. Responsibilities of the Institution

- 3.1** The primary responsibilities of La Trobe, acting as an institution are defined in The Code ([2.1](#))
- 3.2** The Ethics, Integrity and Biosafety team acting on behalf of the institution is responsible for:
- Ensuring these Terms of Reference are available for access by the general public
 - Providing adequate resources to allow proper function of the AEC
 - Facilitating education of AEC members and assisting in conflict resolution as necessary
 - Conducting an annual review of the function of the AEC
 - Appointing a chairperson and deputy chairperson to the AEC
 - Providing administrative support to the AEC
 - Referring eligible institutions to the AEC

4. Responsibilities of AEC Members

- 4.1** The primary responsibility of members is to ensure that the use of animals for scientific purposes or other approved investigative purpose is ethically justified, provides for their welfare and incorporates the principles of Replacement, Reduction and Refinement based on collective experience and knowledge.
- 4.2** Members are responsible for
- deciding whether, in their own judgment, an application to undertake a project or any other matter under consideration by the AEC is ethically acceptable and meets the requirements of the Code ([2.2.14](#))
 - Be familiar with the POCTA Act and associated Regulations, the Australian code, the Wildlife Act 1975 and other policies and guidelines relevant to the business of the AEC.
 - Provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC.
 - Sign a confidentiality agreement that agrees to maintain confidentiality regarding the content of applications, deliberations, correspondence between the AEC and any other party/institution ([The Code 2.2.17](#))
 - Declare Conflicts of interest before any relevant deliberations of the AEC. Members are obliged to declare any interests that could influence the objectivity of their decision making ([The Code 2.2.17](#)).
- 4.3** The procedure for managing conflicts of interest is:
- Members must remove themselves from the AEC's decision making on matters that relate to the conflict of interest.
 - In the case the member is an Investigator, the member concerned is required to leave the room during discussion and only respond to questions directed to them upon returning to the room. This member will not participate in voting.
 - All declarations of interest and their management and absences of members will be minuted.
 - Where there are no declarations of interest, this will also be minuted.

5. Membership of the AEC

- 5.1** The Institution will appoint a chairperson who holds a senior position within or external to the institution, and where possible will be independent of the care and use of animals

for scientific purposes (The Code [2.2.2.-3](#)). The chairperson will be appointed in addition to Category A, B, C and D members.

- 5.2** The Ethics, Integrity and Biosafety team will appoint a Deputy or Acting Chair from the AEC membership. This person will act as the Chair in their absence.
- 5.3** The AEC must comprise at least four people, one from each of the four following membership categories (The Code [2.2.4](#)):
- 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 institution's activities or the ability to acquire relevant knowledge.
 - b. **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. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.
 - 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 institution, 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 based on active membership of and endorsement by, such an organisation.
 - d. **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.
- 5.4** The Institutions will appoint to the AEC a person responsible for the routine care of animals within the institution. The Director of LARTF will be appointed as voting member of the AEC.
- 5.5** The AEC may co-opt other persons with relevant experience or expertise as required, including persons with experience in the routine care of animals for scientific procedures. Co-opted members of the AEC cannot exercise voting rights but must adhere to the principles of confidentiality as per voting members.
- 5.6** At all times, the membership must comprise at least one third category C and D members within and outside of AEC meetings.

6. Varying and Replacing Members

- 6.1** The Institution on the advice of the Ethics, Integrity and Biosafety team may elect to vary membership or replace a member at any time per the terms of the member's appointed letter.
- 6.2** The AEC may recommend to the Institution via the Ethics, Integrity and Biosafety team that membership be amended.
- 6.3** In the event a member is obliged or elects to retire or resign during the term of the AEC, the Institution will seek nominations for a replacement member via an Expression of Interest Process as outlined in Section 9 of this document.

7. Absentee, Termination and Resignation of Members

- 7.1** Where a member fails to attend three consecutive meetings of the AEC without providing an apology or reasonable reason or has demonstrated an inability to maintain an adequate level of participation or meet the responsibilities of AEC membership, the AEC shall recommend to the Institution via the Ethics Advisor that the member be replaced by a new appointee of the same category.
- 7.2** The Ethics, Integrity and Biosafety team will notify the member in writing prior to any lapse in membership.
- 7.3** The Institution via the Executive Director of the Research Office may terminate the appointment of any member if they believe:
- It is necessary for the proper and effective functioning of the AEC
 - The person is not fit and proper to serve on an AEC
 - The person has failed to carry out their duties
- 7.4** A member can resign in writing to the Ethics Advisor at any stage during their term.

8. Appointment of Members

- 8.1** La Trobe may recruit new AEC members by calling for Expressions of Interests, which include a Duty Statement. Applicants must respond to the Expressions of Interest by providing a covering letter and current CV. Internal applicants must also provide written approval from their Head of School supporting their application.
- 8.2** All applicants that are deemed appointable (except for the Chair) will be interviewed at a minimum by the Ethics, Integrity and Biosafety Manager, the Chair of the AEC and any other stakeholders as deemed appropriate.
- 8.3** Members will be appointed by the Executive Director of the Research Office after endorsement by the interview panel, following confirmation by the Department of Jobs, Precincts and Regions.
- 8.4** Applicants for Chair will be interviewed at a minimum by the Ethics, Integrity and Biosafety Manager, Executive Director of the Research Office, the Deputy Vice Chancellor (Research and Industry Engagement) and Licence Nominee. The Chair will be appointed by the Deputy Vice Chancellor (Research and Industry Engagement) on the advisement of the Ethics, Integrity and Biosafety Manager and Executive Director of the Research Office.
- 8.5** All members including the Chair and Deputy Chairs will receive a letter of appointment. The letter of appointment will include the date of appointment, length of tenure, indemnity and termination.
- 8.6** Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and will be asked to sign a Deed of Confidentiality.
- 8.7** Members will be appointed for a period of three years with an opportunity to renew at the end of this period for a maximum second term, unless an Expression of Interest fails to find a suitable candidate or at the discretion of Executive Director of the Research Office.
- 8.8** The AEC will be a standing committee with, wherever possible, staggered re-appointment of members with the objective of continuance of effective committee functioning.
- 8.9** All new AEC members will undergo appropriate induction and have access to appropriate education programs and resources.

9. Senior Ethics Advisor to the AEC

- 9.1 The Research Office will provide a Senior Animal Ethics Advisor (or nominee) to provide administrative support to the AEC. The Senior Animal Ethics Advisor will be the first point of contact for AEC members, institutions or investigators wishing to access the AEC.
- 9.2 The Ethics, Integrity and Biosafety Team will ensure distribution of meeting papers to the members prior to each meeting, as well as maintaining records of AEC business. Records of applications and associated documents will be maintained for at least four years.
- 9.3 The Ethics, Integrity and Biosafety Team will endeavour to circulate no less than seven working days prior to a general meeting or a special meeting, an agenda setting out standing business before the AEC, all relevant proposals and related correspondence.
- 9.4 The Senior Animal Ethics Advisor will be responsible for coordinating and drafting policies and procedures in accordance with the Code and other relevant legislation and codes of practice for review by the AEC.
- 9.5 The Senior Animal Ethics Advisor will develop documentation per [the Code 2.2.32-33](#) and coordinate and conduct annual reviews of the operation of the AEC ([the Code 2.2.37](#)).
- 9.6 The Ethics, Integrity and Biosafety Team in conjunction with the AEC Chair and Executive Director of the Research Office will prepare an annual report of AEC operations for the the Deputy Vice Chancellor (Research and Industry Engagement) and Research and Graduate Studies Committee and other relevant external institutions.

10. Review and Approval of New Applications and Post Approval Documents

- 10.1 Activities for scientific purposes involving the use of animals must not start before written AEC approval is given as per the governing principles ([the Code 2.3](#)).
- 10.2 The AEC may consider for approval, in accordance with the Code, applications submitted by:
- 10.3 Individuals undertaking collection, taking, banding and marking of wildlife for research purposes. These applicants are exempt from licensing under the POCTA Act, but must hold a research permit issued by the Department of Environment, Land, Water and Planning (DELWP) in accordance with section 28A of the [Wildlife Act 1975](#).
 - a. Investigators associated with scientific procedures premises licence holders using animals for research or teaching, and specified animals breeding licence holders where the licence holder nominates the AEC under the licence.
 - b. The AEC may only approve applications that comply with the Code and other relevant legislation.
- 10.4 Applications are to be submitted for review in accordance with the AEC Standard Operating Procedure (SOP) for the submission of ethics applications as advertised on the [AEC website](#).
- 10.5 The AEC will operate in accordance with [LTU Animal Ethics Procedure](#) and guidelines to assist applicants as well as document templates and policies and procedures will be made available on the [AEC website](#).
- 10.6 New proposals must be considered and approved only at quorate meetings of the AEC and meet the requirements outlined in [the Code 1.3](#).
- 10.7 The AEC may request the applicant to supply further information in relation to an application to clarify issues that may arise during review.

- 10.8** The AEC may request an applicant attend a meeting with the AEC or the AEC Executive to facilitate review of a research protocol.
- 10.9** The Ethics, Integrity and Biosafety Team will aim to circulate the meeting agenda, previous meeting minutes and associated documents and any new applications to all members of the IBC no less than seven working days prior to the meeting.
- 10.10** The AEC may establish an AEC Executive from the available members at any time. The Executive must include the Chair and at least one member from category C or D. Other members of the AEC may also be appointed by the Chair or the Ethics, Integrity and Biosafety Team to the AEC Executive.
- 10.11** The AEC Executive:
- May approve minor amendments (as defined [the Code 2.2.23](#)) to approved projects or activities for ratification at the next quorate AEC meeting
 - May specify urgent action required in response to reports of adverse events or emergencies
 - Will not consider or approve new proposals, or requests for amendments to approved projects or activities that are not minor amendments
 - Consistent with AEC meetings, Executive members must declare if they have a conflict of interest with an item and another member must be appointed for consideration of the item.

11. AEC Meetings

- 11.1** Meetings shall be conducted in accordance with operating procedures established by the Ethics, Integrity and Biosafety Team.
- 11.2** The AEC meetings will be conducted once a month between February and December or as required.
- 11.3** The AEC meeting dates, and closing dates for the receipt of applications, will be advertised on the [AEC website](#).
- 11.4** The Committee may elect to conduct special meetings, if circumstances or the nature of business is urgent or extraordinary.
- 11.5** The AEC must have a quorum of members in attendance to conduct meetings. Such quorum must comprise at least one member from each category and at least one third category C and D members.
- 11.6** The AEC will not make decisions unless a quorum is in attendance. A non-quorate meeting of the AEC may discuss matters for future approval by a quorate meeting.
- 11.7** Attendance of quorate meetings may be facilitated by video linking or teleconferencing of some members in circumstances, where face-to-face attendance is not possible ([the Code 2.2.26\(ii\)](#)). The reason for video linking or teleconferencing will be minuted.
- 11.8** Any duly convened meeting at which a quorum is in attendance shall be able to consider and resolve any business of the AEC and shall have and may exercise all the functions of the AEC.
- 11.9** Any member of the AEC who has a conflict of interest associated with a proposal or other related matter being considered by the AEC should declare such an interest at the earliest opportunity. The member shall remove themselves from the meeting when the project is the subject of consideration. Once the AEC has considered the matter and a decision has

been reached, the member will be asked to return to the meeting. All declarations of interest and their management and absences of members will be minuted.

- 11.10** The AEC will endeavour to reach a unanimous consensus decision concerning the ethical acceptability of a research protocol. Where a unanimous decision is not reached, the AEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If necessary, the investigators should be invited to attend the next meeting.
- 11.11** 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. In this instance the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one Cat C and [or do you want 'or' here?] one Cat D member. Minority views will be recorded in the minutes.
- 11.12** Meetings will be conducted in such a way to encourage discussion, debate and the exchange of ideas

12. Fees and AEC Review

- 12.1** A fee will not be charged for applications to La Trobe University AEC for research that is administered by La Trobe University (including grants, contract administration, and institutional compliance).
- 12.2** A fee will be charged for applications submitted for assessment by the AEC from researchers who have no formal affiliation with La Trobe University (e.g. commercial partner or external institution) and/or the research is not La Trobe University administered research. The institution must be accepted as an eligible institution by the Executive Director of the Research Office on behalf of La Trobe University in consultation and with approval of relevant stakeholders.
- 12.3** Upon acceptance as an eligible institution, La Trobe University and the eligible institution must sign an agreement. A signed agreement must be in place prior to acceptance of applications to the AEC detailing the terms and conditions under which the AEC will review the application and monitor the protocol (once approved) ([the Code 2.6](#)).
- 12.4** The external researchers will be invoiced according to the La Trobe University fee structure which is made available on the [AEC website](#).
- 12.5** Institutions, that are eligible and that may have previously accessed a different AEC, must submit a new application to the AEC for any existing projects.

13. Record Keeping

- 13.1** The Ethics, Integrity and Biosafety Team will prepare and maintain an official file for each application received. This may be electronic, and will include a copy of the application, any relevant correspondence including that between the applicant and the AEC or AEC Executive in accordance with the Public Records Act 1973 (Vic). Meeting minutes will be retained in a Minutes file in accordance with the Public Records Act 1973 (Vic).
- 13.2** The Ethics, Integrity and Biosafety Team will also maintain the following records ([the Code 2.2.30 and 2.3.22](#)):
- a register of all applications to the AEC, including the outcomes of deliberations
 - minutes that record decisions and other aspects of the AEC's operation.

- c. records of inspections conducted by the AEC that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes
- 13.3** Where appropriate, the institution, in consultation with the AEC, should ensure that animal carers have access to records of approved projects and activities ([The Code 2.2.31](#)).
- 13.4** Files will be kept securely and confidentially in accordance with the Commonwealth and State privacy legislation and the Public Records Act 1973 (Vic). The Ethics, Integrity and Biosafety Team will close and archive the file in accordance with the Public Records Act 1973 (Vic).
- 13.5** Records will be held by the University for sufficient time to allow for future reference. The minimum period of retention will be in accordance with the Code and the Public Records Act 1973 (Vic).

14. AEC Monitoring and Reporting Requirements

- 14.1** The AEC will monitor approved projects in accordance with [the Code 2.3.2](#) to verify that the conduct of the research conforms to the approved proposal and to ensure that any harm, including pain and distress, is promptly detected and managed ([the Code 2.1.5 \(v\) \(c\)](#)).
- 14.2** Monitoring activities undertaken by the AEC may include:
 - a. inspecting animal housing and laboratories on a regular basis and examining records maintained by investigators, teachers and animal facility managers;
 - b. inspecting at an early stage any project likely to cause animals harm, including pain or distress (including as a condition of approval);
 - c. delegating authority to suitably qualified people to monitor animal care and use, particularly in remote sites;
 - d. reviewing the annual reports and completion reports submitted to the AEC by investigators and teachers;
 - e. conducting follow-up review of approved projects and activities (section 9.10), and ensuring activities that are not compliant with the Code cease immediately and remedial action is taken monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities;
 - f. review and take appropriate actions regarding unexpected adverse events; and
 - g. review and take appropriate actions regarding non-compliance.

15. Complaints

- 15.1** The Ethics, Integrity and Biosafety Team may receive complaints about the care and use of animals for scientific purposes or AEC operation that may be raised by any person or group, including investigators, animal carers, AECs, AEC members, students, LTU employees and members of the public.
- 15.2** Complaints that do not relate to the care and use of animals for scientific purposes or AEC operation will be directed to the relevant areas as per [La Trobe Collective Agreement 2018](#) and appropriate University policies and procedures.
- 15.3** All complaints, concerns or enquiries about the care and use of animals for scientific purposes will be treated confidentially and will be acted on in a timely fashion. Any

personnel, staff member or student may voice concerns without jeopardising their employment, careers or coursework.

- 15.4** If a member of an AEC or a researcher has any grievance about the operation of that committee or about the care and use of animals for scientific purposes, they should discuss this, in confidence, with the Senior Animal Ethics Advisor or the Chairperson of the AEC.
- 15.5** If the grievance cannot be resolved they should then take their concerns to the Ethics, Integrity and Biosafety Manager who may on-refer the complaint to the Executive Director of the Research Office, the Deputy Vice Chancellor (Research and Industry Engagement) or Licence Nominee. The referral pathway will depend on the nature of the complaint.
- 15.6** If an animal facility, academic or other staff or students has any enquiries or concerns about a non-compliance event or the well-being of animals held at La Trobe for use in breeding, research or teaching, these concerns should be reported to the Ethics, Integrity and Biosafety Team who will on-refer it to the appropriate person or committee.
- 15.7** Conscientious objection - If a staff member or student wishes to conscientiously object to participation in an activity occurring under the La Trobe Scientific Procedures Premises Licence, then this should be first addressed with the Principal Investigator. If resolution is not apparent, the objection can be provided in writing to the Ethics, Integrity and Biosafety Team who will on-refer to it to the appropriate person/s.
- 15.8** Resolution of Complaints will be handled in the following manner:
- a. If the complaint is of a serious nature, or if the matter cannot be resolved, then the Ethics, Integrity and Biosafety Manager should be notified in a timely manner by the Ethics, Integrity and Biosafety staff who received the complaint or directly by the complainant.
 - b. Under these circumstances the Ethics, Integrity and Biosafety Manager will commence an initial assessment into the complaint to determine the severity and validity of the complaint, obtain in writing the grounds of the concern or complaint and where possible categorise it. The Ethics, Integrity and Biosafety Manager may on-refer the complainant to Senior Management, the Executive Director of the Research Office, the Deputy Vice Chancellor (Research and Industry Engagement) or Licence Nominee depending on the nature and seriousness of the complaint.
 - c. A letter of acknowledgement to the complainant and a letter of notification to the principal investigator (where relevant) will be sent, outlining the complaint and the mechanism for investigating the complaint.
 - d. The complainant will be informed of the outcome of the investigation. If the complainant is not satisfied with the outcome of the investigation, then they can refer the complaint to the Deputy Vice Chancellor (Research and Industry Engagement), or Licence Nominee, or request the Ethics, Integrity and Biosafety Manager or AEC Chairperson to do so.
 - e. where complaints relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities were conducted in accordance with AEC approval.
 - f. Complaints considered to raise the possibility of research misconduct, as outlined in Australian Code for the Responsible Conduct of Research 2018, will be referred immediately to the appropriate person as per relevant institutional policies and procedures.

- g. Where a complaint alleges a type of misconduct that falls outside of the range of research misconduct as described in the current version of the Australian Code for the Responsible Conduct of Research, the matter will be dealt with in accordance with the La Trobe University Compliance Management Policy, Breach Management Policy, Compliance Management Policy, Information security Policy and other relevant policies or procedures.
- 15.9** During monitoring of facility or investigation of adverse events, the AEC may uncover potential matters of concern to animal welfare, or misconduct or research misconduct. These will be handled in a similar manner to that described above.
- 15.10** The Ethics, Integrity and Biosafety Team will maintain a record of all complaints received regarding the activities of the Committee. This record will include the complaint, the outcome of the complaint, and any related investigations. A record of complaints received regarding AEC approved research will also be maintained. This will include the complaint, the outcome of the complaint and any related investigations. This complaint record will be used to report on complaint and research integrity breach to the Research and Graduate Studies Committee on an annual basis.
- 15.11** If there is a grievance between the AEC and the Independent External Review, the AEC shall submit the complaint in writing to the review body.
- 15.12** All attempts should be made to resolve the matter between the parties, but if this is unsuccessful then the matter shall be referred to an external independent mediator. If appropriate, the regulatory Department will also be informed. If the Independent External Review has been undertaken by the regulatory Department and the matter cannot be resolved between the parties then it shall be submitted in writing to the Victorian Department of Jobs, Precincts and Regions and the Minister of the Department.

16. Business Operations

- 16.1** The AEC will examine applications for approval with the following decisions as per Animal Welfare Victoria Guidelines for the conduct of AECs:
 - a. **Approved:** The AEC is satisfied that the application is ethically acceptable and complies with the Australian code. The application is approved by the AEC, as submitted, with no changes required. and conditions will apply
 - b. **Approved with condition(s):** The AEC is satisfied that the application will be ethically acceptable and comply with the Australian code, subject to a specific correction or defined alteration. Alternatively, where outcomes or effects of procedures are not well known, the AEC may wish to receive reports at specified time points to ensure the project remains ethically acceptable. The agreed and exact condition(s) are recorded in the AEC meeting minutes as a decision of the AEC. There are two options to formalise the decision:
 - i. The investigator is required to revise the original application in accordance with the instruction from the AEC and may resubmit to a person authorised by the AEC, for example the Senior Animal Ethics advisor or AEC chair, to administratively confirm that the instruction of the AEC has been followed exactly. The resubmission must not contain any new information or require a decision, simply reconciliation with instructions. The approval date of the application must not be before the date of confirmation. The revised application then becomes the application approved by the AEC.

- ii. The investigator is made aware that exact conformity with specified alterations is a condition of approval. The condition(s) of approval must be defined in the letter of approval. For example, the AEC may require six monthly progress reports, direct veterinary oversight of novel procedures, or report of completion of a pilot study to the satisfaction of the AEC prior to commencing the next phase of a project.
 - c. **Subject to changes to the satisfaction of the AEC:** The AEC is satisfied that the application has in-principle justification but requires additional information and the required modifications meet the AEC's criteria for a minor amendment. In that instance the revised application may be considered out of session and the approval is delegated to an executive of the AEC.
 - i. If the AEC executive is satisfied with the resubmitted application, the executive may approve the revised application; subject to ratification by the AEC at the subsequent quorate meeting of the AEC. The approval date is the date approved by the executive of the AEC.
 - ii. If the AEC executive determines that the resubmitted application contains modification(s) outside of the criteria for a minor amendment it must refer the applicant to a quorate meeting of the AEC.
 - d. **Deferred:** The AEC is satisfied that the application has in-principle justification, but requires additional information, clarification or changes to make a decision that is outside of the scope of a minor amendment. In that instance the resubmitted application must return to the full AEC for appraisal at a quorate meeting. Modifications that have potentially high animal welfare impact (for example justification for inducing pain in the absence of analgesia, single housing for social species, queries as to why valid alternatives are not used) must be considered by a quorate meeting of the AEC.
 - e. **Not approved, may be re-submitted to a quorate meeting of the AEC:** The AEC generally understands the proposed animal use, and is satisfied the proposal has merit. However, the application lacks sufficient information for the AEC to fully consider the application and it does not comply with the Australian code. The AEC may elect to provide general advice to the applicant in an educational capacity with the aim of improving the quality of a resubmitted application. In this circumstance it is recommended that the AEC carefully communicate the reasons for requiring resubmission of the application to assist the applicant to be successful in the following submission. The AEC may find it beneficial to inform the applicant that upon receipt of all required information further modification may be necessary for the AEC to fully consider the application.
 - f. **Not approved** This situation will arise where, in the judgment of the AEC, the potential effects on the wellbeing of the animals involved is not justified by the potential benefits of the project. In this circumstance the AEC should clearly communicate its decision and require the applicant to withdraw the application.
- 16.2** Amendments to approved projects:
- a. An investigator may apply to have an amendment to an approved project approved during the period of its approval provided the proposed changes do not alter the substantive procedures or processes to such a degree that a new project application is warranted.
 - b. The AEC will determine if a new application is required.
 - c. The AEC must approve in writing any proposed amendments to an approved project before the change is implemented.

- d. Although there is no limitation as to how many amendments / modifications are allowed within the approved duration of the research project, minor amendments are only allowed, generally speaking, when there is no substantial change in the overall nature or direction of the project, particularly in regard to animal welfare.
- 16.3** The AEC may review and approve any guidelines related to the care and use of animals for scientific purposes at La Trobe. Guidelines and/or documents may include:
- a. How competency of those involved in animal use will be assessed and ensured.
 - b. Strategies to ensure the maintenance of a health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use.
 - c. Monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed.
 - d. Actions required for unexpected adverse events and emergencies, including those that require welfare interventions such as the emergency treatment or humane killing of any animal, to ensure that adverse impacts on animal wellbeing are addressed rapidly.
 - e. Standard Operating Procedures (SOPs). In general, SOPs for projects are submitted and reviewed separately to applications unless there are exceptional circumstances.
 - f. Annual and final reports of projects, according to [the Code Section 2](#).

17. Monitoring the Care and Use of Animals

- 17.1** The AEC monitors the care and use of animals by reviewing records and reports and as necessary inspecting animals, animal housing and the conduct of procedures.
- 17.2** The AEC will ensure that unexpected adverse events or issues identified because of monitoring receive appropriate follow-up and resolution. These may include breaches of the Code and suspected research misconduct.
- 17.3** Inspections of Animal Facilities will include the AEC Chair, the Ethics, Integrity and Biosafety Manager and/or Senior Animal Ethics Advisor (or nominee), Manager of Facilities, and a Category C or D member of the AEC.
- 17.4** The Ethics, Integrity and Biosafety team will determine the frequency and timing of inspections in consultation with the AEC.
- 17.5** The AEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes.
- 17.6** The AEC may delegate to suitably qualified people to monitor animal care and use, including projects and activities conducted at remote sites (e.g. fieldwork). Such delegation will include how reports of such monitoring are to be provided to the AEC (e.g. using still or video images).

18. Financial Arrangements

- 18.1** External members will be paid a monthly sitting fee based on their attendance and to cover nominal expenses associated with performance of their duties as outlined in their appointment letter.
- 18.2** La Trobe will provide parking vouchers for all external members.
- 18.3** La Trobe will provide indemnity for members of the AEC in respect of liabilities that may arise during the conduct of their AEC duties.

19. Annual Report and Review of Operations

- 19.1** The AEC will produce an annual report of its operations for submission to the Research and Graduate Studies Committee, any regulatory agency and eligible institutions.
- 19.2** The AEC chair and/or Ethics, Integrity and Biosafety Manager will make themselves available to meet with the relevant regulatory agency to review the AEC annual report.
- 19.3** The report should advise on:
- numbers and types of projects and activities assessed and approved or not approved.
 - the physical facilities for the care and use of animals by eligible institutions
 - 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 in AEC operations
 - any matters that may affect the eligible institution's ability to maintain compliance with the Australian code
 - any matters that may affect the AEC's ability to maintain compliance with the Australian code
 - appropriate recommendations to address matters of non-compliance and measures for effective, remedial change.

20. Reporting to Animal Welfare Victoria

- 20.1** All holders of Scientific Procedures Premises Licences and Specified Animals Breeding Licences are required by the legislation to complete an Annual Return of Animal Usage each calendar year and submit it to Animal Welfare Victoria by the specified deadline. Animal Welfare Victoria supplies a form designed for the purpose. Changes should be notified within 2 weeks of the alteration.
- 20.2** Animal Welfare Victoria needs to be notified promptly of alterations to Scientific Procedures Premises Licence or Specified Animals Breeding Licences:
- Alterations to AEC membership
 - Additions / deletions of animal facilities or laboratories to Licenses.
 - Change to the nominated person or their contact details.
- 20.3** Animal Welfare Victoria needs to be notified (prior to commencement) of La Trobe projects conducted at sites other than those listed on the Scientific Procedures Premises Licence. These sites are termed 'Field Work'.
- 20.4** 'Death as an end-point' refers to those rare procedures where death is the deliberate measure for evaluating biological or chemical processes, responses or effects (see the Code page 4). These procedures may only be carried out for the achievement of prescribed outcomes, and only where the objective cannot be achieved by any other scientific means (Prevention of Cruelty to Animals Regulations 1997).
- 20.5** Persons who seek approval to conduct scientific procedures, or a series of scientific procedures involving death as an endpoint must apply for Ministerial approval to conduct such procedures. The proposal must be given preliminary assessment by the AEC and a copy of the application to the AEC and relevant comments from the AEC must accompany the application for Ministerial approval.
- 20.6** Animal Welfare Victoria will assess this application and make recommendations to the Minister as to whether the application should be approved. It is the responsibility of the

investigator making this application to provide enough information as per the application below which will be held in confidence by Animal Welfare Victoria.

- 20.7** Animal Welfare Victoria conducts audits of licenses and AECs to assess compliance with the relevant legislation and Codes of Practice. The audit protocol is found on Animal Welfare Victoria webpage.

21. Revision of Terms of Reference

- 21.1** These Terms of Reference will be reviewed as necessary in response to changes in legislation, policies or upon the request of the AEC, or every three years, whichever occurs first.

22. Related Documents

- 22.1** [Australian Code for the Responsible Conduct of Research 2018](#)
- 22.2** [Australian Code for the Care and Use of Animals for Scientific Purposes](#)
- 22.3** [Prevention of Cruelty to Animals Act](#)
- 22.4** [Wildlife Act 1975](#)
- 22.5** [LTU Conflict of Interest Policy](#)
- 22.6** [LTU Research Misconduct Procedure](#)
- 22.7** [LTU Animal Ethics Procedure](#)