

Procedure for handling Complaints, Grievances and Non-compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes

ABBREVIATIONS

AEC	La Trobe University Animal Ethics Committee
AEC Executive	A sub-committee of the AEC comprising the AEC Chair and at least one Cat C or D member
Animal Code	<u>Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition 2013</u>
Code	<u>Australian Code for the Responsible Conduct of Research</u>
DO	Designated Officer under the La Trobe University Research Misconduct Procedure
DVCRIE	Deputy Vice-Chancellor (Research Industry and Engagement)
LARTF	La Trobe Animal Research and Teaching Facility
LARTF Veterinarian	Veterinarian and Compliance Manager, LARTF
PI	Principal Investigator
POCTA	<u>Prevention of Cruelty to Animals Act 1986</u>
<i>Prima facie</i>	Based on first impression
Senior Coordinator AEB	Senior Coordinator Animal Ethics and Biosafety
Senior Manager EIB	Senior Manager Ethics, Integrity, and Biosafety
SPPL	Scientific Procedures Premises Licence
VC	Vice Chancellor
VGAUW / aka Animal Welfare Victoria (AWV)	The unit within the Victorian Government Department with responsibility for oversight of animal welfare in Victoria (Agriculture Victoria, Department of Energy, Environment and Climate Action)

SECTION 1 – KEY INFORMATION

1. The La Trobe University ('the University,' 'LTU') Animal Ethics Committee (AEC) is responsible for ensuring, on behalf of the University or any other organisation for which it acts, that all activities relating to the care and use of animals by the University or any other organisation for which it acts are conducted in compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition 2013 (Animal Code), The Prevention of Cruelty to Animals Act 1986 (POCTA) and regulations, and the corresponding legislation in each State that the University is registered in.
2. The Principal Investigator and all persons working on approved projects must carry out animal work with a high level of integrity, respectfully, and ethically; and must work in compliance with legislation, the Animal Code, established guidelines and procedures, as well as in accordance with the AEC approval conditions.
3. All participants must accept responsibility for their roles, actions and work on their project; however, the Principal Investigator accepts overall accountability for project participants, the conduct of the project and the project's outcomes.

4. For all the events covered in this document, if an investigation is required, it is essential that the investigation be conducted in a timely manner and that its processes accord with procedural fairness and the principles of natural justice. The investigation must respect the confidentiality of all parties to the investigation and adhere to the University's [Public Interest \(Whistleblower\) Disclosure Policy](#).
5. Where an incidence of non-compliance also reflects a breach of legislation, La Trobe University will advise the relevant state or territory government authorities of the alleged breach of legislation and any significant impact on animal wellbeing.
6. The welfare of animals must always remain a priority.

SECTION 2 - PURPOSE

These procedures provide clear guidelines on the handling of complaints, grievances and non-compliance regarding the use of animals for scientific purposes.

These procedures ensure effective, confidential processes that accord with procedural fairness and the principles of natural justice to all parties, whilst always giving priority consideration to the wellbeing of the animals.

This is a compliance requirement under the Animal Code.

Complaints will be treated confidentially, unless:

- the University has an obligation to disclose details of the complaint by law; or
- disclosure of details is required in the investigation to accord with procedural fairness and natural justice. Any request for anonymity will be discussed and explored as to whether the request is feasible.

SECTION 3 - SCOPE

These procedures apply to all University students and staff using animals for scientific and teaching purposes.

These procedures also apply to any organisations with contracts, formal agreements or MOUs with La Trobe University for use of animals for research or teaching purposes or using the services of the La Trobe AEC.

These procedures do not apply to animal welfare complaints for animals not used for scientific or teaching purposes.

Where research misconduct, as described in the [Australian Code of the Responsible Conduct of Research](#), is a possibility for University projects, the matter will be handled in accordance with the La Trobe University [Research Misconduct Procedure](#).

SECTION 4 - PROCEDURE

Overview of complaints, grievances and non-compliance

This document outlines procedures for the following scenarios:

- Non-compliance;
- Complaints:
 - concerning the care and use of animals in teaching or research;
 - concerning the process for independent external review;
- Grievances concerning AEC processes or decisions including:
 - disagreements between the AEC and investigators;
 - disagreements between AEC members; and
 - disagreements between the AEC and the institution.

Non-compliance and complaints concerning the care and use of animals in teaching or research

A non-compliance occurs when a person has not acted in accordance with:

- the Animal Code;

- POCTA and Regulations, or other relevant state/territory welfare legislation, including conducting work with the relevant permits; or
- the conditions of AEC approval.

Examples of non-compliance include:

- unauthorised animal use (use of an animal species not approved; overuse of animals; conduct of a procedure that is not approved);
- variation made to approved project details without AEC approval;
- failure to submit an annual report by the anniversary of the project approval date;
- unauthorised investigator performing animal procedure;
- failure to report unexpected adverse events;
- use of animal for scientific purposes without seeking AEC approval; and
- use of animals continuing after approval has been withdrawn or suspended.

A non-compliance may be detected via numerous means, including:

- routine oversight of animals, facilities, or documentation;
- media reports, conversations or hearsay; or
- complaints.

Complaints about non-compliance should be submitted to either the Senior Manager Ethics, Integrity and Biosafety, (Senior Manager EIB) or the Veterinarian and Compliance Manager and where possible should be in writing including supporting documentation.

It is the position of the AEC that most of the animal welfare and non-compliance issues are unintentional and often easily rectifiable. Therefore, initial investigations will take the form of an informal inquiry to gather information and determine further action.

Where the non-compliance/complaint relates to an activity that may affect an animal's welfare or presents a breach to legislation, activities must cease immediately, and ethics approval may be withdrawn or project approval suspended.

The Senior Manager EIB will review the non-compliance/complaint and reach a resolution; or refer it to the AEC Chair, the AEC (or the AEC Executive Committee), or the Deputy Vice-Chancellor Research and Industry Engagement (or delegate) as appropriate.

(a) Review of a non-compliance/complaint may include, but is not limited to:

- review of documentation;
- discussions with project personnel;
- facility inspections; or
 - animal health inspections (either by the Veterinarian and Compliance Manager, another registered veterinarian, or a nominated suitably qualified person).

(b) At any stage of the investigation process, the AEC Chair, Senior Manager EIB and Veterinarian and Compliance Manager may take immediate action to ensure animal welfare or prevent a recurrence of the non-compliance.

- A response may include ordering emergency treatment, relocation of animals, or the emergency euthanasia of animals if deemed essential for animal welfare.
- The actions taken may precede a response to the complainant, the alleged person/s involved, or the VC/DVCRIE/licence holder/organisational head if deemed urgent.
- Communication of required actions will be dispersed to all relevant parties as soon as practicable.

(c) All non-compliances detected/complaints received and reviewed by the Veterinarian and Compliance Manager and the AEC Chair will be reviewed by the AEC at the next quorate meeting.

(d) An extraordinary AEC meeting may be called if required.

Action resulting from investigation into a non-compliance/complaint may include, but are not limited to:

- the project may continue with no changes;
- issuance of a warning from the AEC for issues of a minor nature (such as administrative oversights);
- a requirement from the AEC for modifications to a project or activity;
- a request for further supportive material/documentation, or for animal health inspections and/or facility inspections to be conducted;
- suspension or cancellation of a project's approval; and
- a recommendation to the institution for disciplinary action.

Where the actions result in a varying of a condition of project approval, suspension of project approval or cancellation of project approval, before acting the AEC will:

- notify the Principal Investigator of the proposed action and the reasons for it; and

- allow the Principal Investigator a reasonable opportunity to make representations about the proposed action within a reasonable period specified in the notice.

Where an AEC-approved project involves more than one institution, the La Trobe University AEC (through the Senior Manager EIB) must keep the AEC of the other institution(s) informed of any cases of non-compliance with the Animal Code.

All non-compliances/complaints must be documented and reported.

- The Veterinarian and Compliance Manager will document records of non-compliance via a Non-Compliance Report and provide a copy to the Senior Coordinator Animal Ethics and Biosafety who will enter the details into the Non-Compliance Register maintained by the Ethics, Integrity and Biosafety team, on behalf of the AEC. A non-compliance report will be submitted for AEC review to the next quorate AEC meeting (or the AEC Executive Committee if required).
- The Veterinarian and Compliance Manager will document records of complaints or welfare concerns via a Welfare/Complaint Report and provide a copy to the Senior Manager EIB who will enter the details into the Complaints and Animal Welfare Register maintained by the Ethics, Integrity and Biosafety team, on behalf of the AEC. A welfare/complaint report will be submitted for AEC review to the next quorate AEC meeting (or the AEC Executive Committee if required).

Reporting requirements

As soon as practicable after deciding to act, the AEC will give a decision notice to the Principal Investigator and Dean of the School.

Any contraventions to POCTA must be reported to the La Trobe University License Nominee, Animal Welfare Victoria and the AEC in compliance with section 74 of the Act:

- The report must be made within 7 days of forming the belief on reasonable grounds.
- Failure to make a report is an offence under POCTA.
- Non-compliances involving contravention to project approval, project approval conditions, or the Animal Code, are offences under the Act and must be reported if deemed that the person was reckless in relation to the result.

The details of any serious non-compliance/complaint will be provided to the Vice-Chancellor, DVCRIE and appropriate University departmental management personnel (or relevant institutional head for external AEC users). This will include any incident that may have animal welfare implications, that may breach legislation, or that may have media implications/public interest.

For any events that may have an impact on animal welfare, a copy of the reports will be submitted to Animal Welfare Victoria.

For projects involving collaboration with another institution, details are to be provided to the other institution's animal ethics committee (or reporting should follow the relevant formal agreement in accordance with clause 2.6.4-2.6.7 of the Animal Code).

Non-compliance and complaint reports will be included in the AEC Annual Report.

The outcome of an investigation into a non-compliance/complaint will be relayed to:

- the person making the allegation;
- the investigator/s involved; and
- the investigator's supervisor, head of department and Dean of the School. For investigators from external institutions using the AEC, the person responsible for the registration and the Director/Executive Officer of the institution should be informed of the outcome.

Where a resolution cannot be reached from the above procedures, the matter will be referred to the Deputy Vice-Chancellor Research and Industry Engagement (DVCRIE) for formal resolution.

Where a person is not satisfied with the outcome of a non-compliance/complaint, and resolution has not been achieved through University procedures, the person may refer the matter to an external body for appeal as outlined in this procedure.

Where a non-compliance/complaint occurs involving an external institution using the AEC, the AEC may withdraw its services:

- If the non-compliance or animal welfare issue is of a serious nature.
- In cases of repeated episodes of non-compliance or animal welfare events.
- Where the AEC is not satisfied that it can provide sufficient oversight of the project/s to ensure compliance and animal welfare.

- In line with the requirements of the External User Deed. This may include immediate termination if a material provision of the Act or the Animal Code is breached; or if a breach to any provisions of the deed has occurred and has not been remedied within 30 days after receiving written notice to do so.

Complaints concerning the process of independent external review

The University must conduct an independent external review as required by the Animal Code.

During the preliminary planning of the external review:

- The external review panel must develop a process the way the review is to be conducted, in consultation with the University. This process should accord with the principles of natural justice.
- Any appeal against the process of the review is to be negotiated between the external review panel, the AEC Chair, the Senior Manager EIB and the Executive Director Research Office. If negotiations are not successful, an alternative external review panel should be employed.

A person with a complaint regarding an independent external review should direct their concern to the Senior Manager, EIB in the first instance.

- Complaints may be in relation to the process of the review, or any finding or decision of the review panel.
- The Senior Manager, EIB, should investigate the concern, and if the concern is deemed warranted, this should be submitted to a scheduled AEC meeting for review.
- If the AEC supports the findings that the concern is warranted, the concern is to be forwarded to the Deputy Vice-Chancellor Research and Industry Engagement.
- If further resolution is required, the Deputy Vice-Chancellor Research and Industry Engagement should forward a deidentified summary of the concern to the external review panel Chair.

Complaints concerning the Animal Ethics Committee process or decisions

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

Grievances or complaints against the AEC should be made initially to the Senior Manager EIB via phone or email. The Senior Manager EIB will confer with the 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 AEC meeting to address any questions and discuss concerns.

If the grievance cannot be resolved, a written complaint should be submitted via email to the Ethics, Integrity and Biosafety (EIB) team at eib@latrobe.edu.au. This complaint will be presented to the AEC at the next scheduled meeting, or if urgent, may be referred to the AEC Executive Committee.

Should a grievance not be resolved in the above manner, the complainant can lodge a written complaint to the Deputy Vice-Chancellor Research and Industry Engagement (DVCRIE) (or delegate).

The DVCRIE 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 DVCRIE 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.

The DVCRIE will provide written advice to both the Committee and the aggrieved person regarding the review of the matter. The DVCRIE may require the Committee to reconsider its decision or procedures in the light of the advice or may endorse the decision or procedures of the Committee.

If the Committee is required to reconsider its decision or procedures, the Committee must consider any advice given to it by the DVCRIE

Any advice by the DVCRIE on the matter referred will be deemed to be the final advice of the DVCRIE on the matter.

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

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

Grievances between the Animal Ethics Committee and a member of the Animal Ethics Committee

Grievances may occur between the AEC and a member of the AEC over AEC processes, or an action or decision made by the AEC noting that:

- AEC decisions should be made by consensus as per clause 2.3.11 of the Animal Code.

- Objections raised by an AEC member over a decision made or action taken during a meeting should be minuted to serve as a record of their views.

If the member is not satisfied with the response of the AEC, they may lodge a formal complaint through the Senior Manager, EIB, and request that the matter be reviewed by the AEC Chair, and if appropriate, re-reviewed by the AEC.

If the member remains unsatisfied with the response, the complaint should be forwarded to the DVCRIE, and steps followed at the Complaints concerning the AEC process or decisions section above.

Grievances between the Animal Ethics Committee and La Trobe University

Grievances between the AEC and La Trobe University should be handled confidentially and all attempts should be made to resolve the issue locally through mediation and discussion.

If the matter cannot be resolved, the matter should be referred to an appropriate external organisation as outlined below.

External avenue for appeal

The outcome of an appeal is final and there are no further avenues of recourse within the University

Where a person is dissatisfied with the outcome of an appeal, they may refer the matter to an appropriate external organisation, usually (but not limited to) Animal Welfare Victoria or the Victoria Ombudsman.

Persons may choose to take their appeal to other regulatory or statutory authorities, guided by their stated scope of power or jurisdiction.

SECTION 5 – OTHER NON-COMPLIANCE

Non-compliance with Governance Documents is considered a breach of the Code of Conduct, as applicable, and is treated seriously by the University. Reports of concerns about non-compliance will be managed in accordance with the applicable disciplinary procedures outlined in the La Trobe University Enterprise Agreement 2023.

All staff members have an individual responsibility to raise any suspicion, allegation or report of fraud or corruption in accordance with the Fraud and Corruption Control Policy and the Public Interest (Whistleblower) Disclosure Policy.

Version Control

VERSION	DATE	AMENDMENT	AUTHOR	CONTRIBUTORS
2.0	X February 2025	Procedure rewritten after 2024 External Committee Review to better align with regulations.		

The LTU AEC would like to acknowledge Charles Stuart University and Charles Darwin University whose policies were assistive in considering the development of this procedure.

APPENDIX 1: NON-COMPLIANCE CATEGORY EXAMPLES

The AEC will use the following terms when considering the seriousness of a non-compliance incident.

Non-compliance with the Animal Code includes:

- Use of animals with no AEC approval
- non-compliance with an approved protocol
- non-compliance with the conditions of AEC approval (incl. length of study).

Non-compliance with the Code can also infer non-compliance with POCTA Act and Regulations.

Minor Non-Compliance

A minor non-compliance is one with no or minimal animal welfare or health impacts or that did not result in animal harm, distress, pain, death, humane killing, or euthanasia. Examples include:

- AEC-approved project conditions not being met (keeping of animals beyond AEC approved project duration)
- protocol deviations that had no animal welfare impacts (e.g. missed monitoring points according to approved protocol, missed procedures with no welfare impact)
- missing records

Moderate Non-Compliance

A moderate non-compliance is one with animal welfare or health impacts that resulted in animal harm, distress, pain (or with potential animal welfare impacts if interventions are not put in place); did not result in need for humane killing or euthanasia. Examples include:

- mistaken injection of unapproved agents that had no apparent impact on animal health
- missed monitoring that led to slower detection of ill-health
- missed analgesia that was part of AEC-approved protocol
- personnel not assessed as competent for procedures undertaken
- housing or use of facilities not in accordance with SPPL licence conditions

Serious Non-Compliance

A serious non-compliance is one with serious animal welfare or health impacts including incidents that resulted in animal death, need for humane killing or euthanasia. Examples include:

- injection of unapproved agents that had impact on animal health,
- performing unapproved procedures that had animal welfare or health impacts
- using animals that are not part of an AEC-approved protocol.