

LA TROBE UNIVERSITY
ANIMAL ETHICS COMMITTEE

Procedures for handling Unexpected Adverse Events, Non-compliance and Complaints

This document describes the procedures adopted by La Trobe University for handling the following events:

1. Unexpected Adverse Events
2. Non-compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition 2013
 - A. Activity within an approved project that does not accord with what was approved by the AEC (including by a researcher, an animal carer or an external party)
 - B. Project or activity involving animals for which no AEC approval has been sought
 - C. Failure to lodge a report in a timely manner
 - D. Non-compliance by the AEC or a University official
 - E. Projects involving more than one institution
3. Complaints (regarding)
 - A. An AEC decision or process
 - a) Disagreement between the AEC and an investigator
 - b) Disagreement between AEC members
 - c) Disagreement between the AEC and the University
 - B. Use of animals in teaching or research
 - C. Activities involving animals other than for teaching or research
 - D. External audit decision or process
 - E. Research misconduct
4. Conscientious objection to involvement in a teaching activity using animals
5. Appeals

ABBREVIATIONS

AEC	La Trobe University Animal Ethics Committee
AEC Management Committee	Comprises the AEC Chair, the LARTF Senior Manager and the Senior Animal Ethics Officer
VGAWU	The unit within the Victorian Government Department with responsibility for oversight of animal welfare in Victoria (currently Licensing and Audit; Agriculture, Energy & Resources; Agriculture and Rural Division; Department of Economic Development, Jobs, Transport and Resources)
CI	Chief Investigator on an approved AEC application

DVC(R)	Deputy Vice-Chancellor (Research)
LARTF	La Trobe Animal Research and Teaching Facility
LARTF Veterinarian	Compliance, Training and Veterinary Services Manager, LARTF
POCTA	Prevention of Cruelty to Animals Act 1986
SEAO	Senior Animal Ethics Officer (AEC Executive Officer)
SPPL	Scientific Procedures Premises Licence
<i>Code</i>	Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition 2013

IMPORTANT NOTE:

For all of 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 *Protected Disclosure Policy*.

1. UNEXPECTED ADVERSE EVENT

1. An *Unexpected Adverse Event* is an event that may have a negative impact on the wellbeing of animals and *was not foreshadowed* in the project or activity that was approved by the AEC for those animals. It is the responsibility of any investigator, LARTF staff member, AEC member or any other person who becomes aware that an unexpected adverse event may have occurred to immediately inform the CI (or delegated representative, referred to hereafter as the CI), if he/she is not already involved.
2. If the event is confirmed as an unexpected adverse event, the CI must then liaise with relevant co-investigators and/or animal carers (normally including the LARTF Veterinarian) to ensure that action is taken to immediately address the well-being of any affected animals. If the CI is not available, animal carers are authorised to take the necessary action to avoid animals suffering further pain or distress. In remote wildlife situations, wherever possible, arrangements should be made in advance for the management of possible incidents and for veterinary advice to be available if required.
3. The CI must report the event to the AEC Chair, LARTF Senior Manager and Senior Animal Ethics Officer via the email address animalincidents@latrobe.edu.au at the earliest opportunity.
4. If there is on-going potential for the well-being of animals in the project to be adversely affected, then
 - i. The AEC Chair may suspend the project by issuing an instruction (verbally and in writing) to the CI to immediately cease all activities involving animals in this project (apart from ongoing maintenance of the animals).
 - ii. The AEC Chair may arrange a meeting of all relevant parties to discuss actions needed to ensure the on-going well-being of animals used in the project. This may result in the CI subsequently submitting a *Request for Minor Variation* for appropriate changes to be made to the project and,

if the project has been suspended, it will be permitted to recommence only once that request is approved by the AEC Executive or by a full meeting of the AEC.

5. At the discretion of the AEC Chair, or by decision of the AEC, a meeting of all relevant parties may also be arranged even when the well-being of animals in the project is not threatened. The purpose of such a meeting would be to discuss possible improvements to, for example, AEC-approved protocols, LARTF procedures, AEC procedures, procedures on animals or the care of animals that arise as a result of the unexpected adverse event.
6. The CI must undertake or arrange for an investigation of the cause of the adverse event, including, for example, a necropsy in the case of an unexpected death.
7. Once the results of the investigation are known, the CI must submit a completed *Unexpected Adverse Event Report* form to the SAEO via animalethics@latrobe.edu.au.
8. The AEC will review the report at the next available meeting and either endorse the actions recommended in the report or (1) request further information; (2) require further steps to be taken to reduce the risk of further occurrences of the adverse event; (3) establish a panel (that must include the AEC Chair) to further investigate the event and report back to the AEC, or (4) take any other action it deems appropriate.

2. NON-COMPLIANCE WITH THE CODE

A. Activity within an approved project that does not accord with what was approved by the AEC for that project (includes activities by an investigator, an animal carer or an external party)

1. Any person working with animals who becomes aware of a potential non-compliance has a duty to report the circumstances. This will normally be done through the LARTF Veterinarian or the LARTF Senior Manager, who will provide a brief written report on the suspected non-compliance to the AEC Chair. That report must also contain an assessment of any adverse welfare impact on animals and a summary of what actions have been taken to address that impact. Questions about possible non-compliance may also arise during a meeting of the AEC, in which case the brief report will be prepared by the SAEO.
2. If there is ongoing potential for the well-being of the animals in the project to be adversely affected, the Chair may suspend the project by issuing an instruction (verbally and in writing) to the project's CI to immediately cease all activities involving animals in the project (other than ongoing maintenance of the animals).
3. Upon receiving the report, the AEC Chair will determine if a prima facie case exists that non-compliance has occurred. In so doing, the Chair may consult with the LARTF Senior Manager, the SAEO, the LARTF Vet and/or other members of the AEC.
4. If the AEC Chair determines that no prima facie case exists, the relevant parties will be informed of that determination in writing. The original report of suspected non-compliance and the Chair's response will be tabled at the next available AEC meeting for discussion by the full Committee.
5. If the AEC Chair determines that a prima facie case of non-compliance does exist, then the AEC Management Committee, augmented by whomever the AEC Chair deems appropriate, will form a panel to investigate the alleged non-compliance. The SAEO will notify the CI, other personnel directly

implicated in the alleged non-compliance and the SPPL holder of the investigation and provide each of them with a copy of the report outlining the suspected non-compliance. The investigation panel will act as an advisory panel to the AEC Chair, who will make the final recommendation to the AEC on the existence or otherwise of non-compliance, on any sanctions to be imposed and on any proposed actions in relation to the project.

6. If the non-compliance is deemed to be purely administrative or technical, with no potential impact to animal welfare, the AEC Chair has discretion to deal with it directly. Otherwise, the SAEO will arrange a meeting of the investigation panel with the CI and other personnel implicated in the alleged non-compliance. The purpose of the meeting will be to ascertain a complete picture of the circumstances surrounding the alleged non-compliance, provide the CI and others the opportunity to explain those circumstances and then, in the absence of the CI and others, for the investigation panel to discuss whether or not non-compliance has been established. The panel will categorize any non-compliance as non-existent, minor, moderate or serious, with the categorisation being used to inform any sanctions and/or other actions (such as reporting the event to the VGAWU) that the panel recommends. The panel may gather any information it deems relevant prior to and/or after the meeting.
7. Having regard for all the available evidence, the AEC Chair will make a recommendation on the category of non-compliance and on any sanctions to be imposed, as well as any changes required to be made to the project. The recommendations should have as their primary purpose improvements in processes or procedures that will safeguard animal welfare and reduce the risk of future occurrences of the non-compliant event. If sanctions or changed processes are recommended, a period of review should be specified.
8. The AEC Chair's recommendations will be discussed at the next available AEC meeting, to which the CI (or nominee) may be invited to attend. Following discussion, the AEC will make the final decision on any sanctions and other actions required. The CI may contribute to the discussion of the alleged non-compliance and the AEC Chair's recommendations, but the final decision on sanctions and other actions is taken in the absence of the CI. Any breaches of *the Code* deemed to have had a significant impact on animal welfare will be reported to the VGAWU.
9. The SAEO will inform the CI, other personnel implicated in the event, the Licence Holder and other persons deemed relevant of the AEC's decision and ensure any required review is placed on the AEC's agenda at the appropriate time. A report of the event and of the AEC's response to it will be forwarded to the VGAWU, if required.
10. Prior to the date of review, the CI (if not the person against whom sanctions were imposed) and/or the LARTF Veterinarian and/or the person deemed most relevant will be requested to provide a report to the AEC on adherence to any sanctions and on the outcomes of any other measures imposed by the AEC.

B. Research or teaching project or activity involving animals for which no AEC approval has been sought

1. Any person who becomes aware of a research or teaching project or activity involving animals for which no AEC approval has been granted has a duty to report it to the SAEO. An activity for which no AEC approval has been granted includes an activity that is part of a project for which an application has been submitted, but AEC approval is still pending.

2. On receiving the report, the AEC Chair will instruct the person responsible for the activity to immediately cease all activities involving animals and inform the person that an application must be submitted to and approved by the AEC before the activity can recommence. The AEC Chair will also request a veterinary assessment of the animals.
3. Depending on the extent to which the activity has the potential to adversely affect animal well-being, the AEC Chair will issue a warning to the person responsible, or proceed with the non-compliance procedure for activities within an approved project or refer the matter to the DVC(R).
4. A report on the non-compliance and the outcome will be tabled at the next available AEC meeting.

C. Failure to lodge a report in a timely manner

1. The SAEO will notify all CIs in writing of the due dates for submission of Progress Reports, Final Reports and Animal Usage Reports approximately two months before the due date(s), with reminders sent approximately one month and approximately one week before the due date(s).
2. Extensions beyond the due date(s) may be granted on an individual basis where a valid reason for the extension is provided.
3. The SAEO will email CIs who fail to submit a report by the due date, informing them of possible suspension if the report is not submitted without further delay. This will be followed up by a telephone call to the CI if the report is still not received within a week of the email being sent.
4. If a report is still outstanding a week after the telephone call to the CI, the SAEO will notify the CI's Head of School, the AEC Chair and the SPPL holder of the non-compliance and possible suspension.
5. Should the report still not be submitted, the AEC Chair will instruct the CI to cease all activities involving animals in the relevant project(s) except ongoing care and maintenance of animals. Normally, such activities would be required to cease immediately, but if doing so has the potential to adversely affect animal well-being, cessation may be required once a particular activity is completed.
6. Steps 5-10 of the non-compliance procedure for activities within an approved project will then be followed.

D. Non-compliance by the AEC or a University official

Anyone who becomes aware of or suspects that the AEC or a University official has made a decision, taken an action or used a process that is not in accordance with *the Code* must report the suspected non-compliance to the DVC(R), who will decide what action is appropriate, taking all circumstances into account. Consultation by the DVC(R) will normally include the Licence Holder.

E. Projects involving more than one institution

Where an AEC-approved project involves more than one institution, the La Trobe University AEC (through the SAEO) must keep the AEC of the other institution(s) informed of any cases of non-compliance with *the Code*. In particular, the outcomes of any La Trobe University AEC decision on non-compliance in a multi-institution project must be communicated to all other participating institutions.

Where an agreement exists between institutions in relation to a multi-institution project, that agreement should include a clause requiring full disclosure by each institution's AEC to each of the other institution's AECs of all cases of non-compliance.

3. COMPLAINTS

NOTES:

1. Complaints may be lodged by a student, member of staff or member of the public and should normally be directed to the Manager, Ethics and Integrity using the *Ethics and Integrity Complaints* form. Complaints may also be lodged with any senior official of the University relevant to the complaint and should contain full contact details of the complainant and a full account of the complaint. If the complaint involves an AEC-approved project, then the number and title of the project and the name of the Chief Investigator should be provided, if known.
2. Should the complaint relate to a teaching project, the complaint may be lodged in accordance with the *Student Complaints Management Policy*.
3. Should a complainant or a party to the complaint not be satisfied with the proposed resolution under any of the following processes, an appeal against the decision made can be made to the University Ombudsman.
4. As part of the following processes, the VGAWU may be consulted for advice that may assist in resolving a complaint.
5. If a complaint has the potential to impact on the University's SPPL, the Licence Holder must be kept informed throughout the complaint handling process.

A. Complaint about an AEC decision or process

a. General

Any person who has a concern about an AEC decision or the process by which that decision was reached should, in the first instance, raise the concern with the AEC Chair. Any resolution reached through the discussion process must be approved by the AEC before coming into effect. If the concern cannot be resolved through discussion, then a formal complaint may be lodged with the Manager, Ethics and Integrity, using the *Ethics and Integrity Complaints* form. The complaint will then be forwarded to the DVC(R) for resolution, noting that the DVC(R) cannot override an AEC decision on the ethical acceptability of an activity.

b. Disagreement between the AEC and an investigator

If a disagreement between the AEC and an investigator cannot be resolved through discussion between the AEC Chair and the investigator, then the matter is referred to the DVC(R) for resolution, noting that the DVC(R) cannot override an AEC decision on the ethical acceptability of an activity.

c. Disagreement between AEC members

AEC decisions are made on the basis of consensus. If consensus cannot be reached after extensive discussion and possible modifications to an application by the CI, followed by further discussion, a vote is taken. If a disagreement between AEC members persists following this

process, or arises in another way, - resolution should be sought through discussion between the AEC Chair and the relevant AEC members. Should the disagreement remain unresolved following discussion with the AEC Chair, the matter is referred to the DVC(R) for resolution, noting that the DVC(R) cannot override an AEC decision on the ethical acceptability of an activity.

d. Disagreement between AEC and the University

If the disagreement cannot be resolved through discussion between the AEC Chair, the DVC(R) and a relevant University representative, then the matter is referred to the University Ombudsman for resolution, noting that the Ombudsman cannot override an AEC decision on the ethical acceptability of an activity.

B. Complaint about the use of animals in teaching or research

A complaint about the use of animals in teaching or research should be lodged with the AEC Chair. If it is lodged with another University official, it must be forwarded to the AEC Chair for consideration in the first instance. If the AEC Chair determines that there is a potential non-compliance with the *Code*, then the procedures for non-compliance will be followed. Otherwise, the AEC Chair, following discussion with those persons deemed relevant and having undertaken whatever other investigation is deemed appropriate, will draft a written response to the complaint. The draft response will then be forwarded to the DVC(R), who will, following any further consultation deemed appropriate, formulate the response of the University and forward the response to the complainant, with a copy to the AEC Chair.

C. Complaints about activities involving animals other than for teaching or research

The University's *Pets on Campus Policy* governs the presence and treatment of pets on campus. Complaints about other non-teaching, non-research activities involving animals should be forwarded to the SAEO, who will seek further information and recommend an appropriate response to senior management. Should the complaint involve a possible breach of relevant state or territory legislation, the appropriate regulatory authority will be informed. The University's *Compliance Policy* procedures will be followed, as appropriate.

D. External audit decision or process

A person having a concern about a decision or process or any aspect of a finding of an external audit of the AEC or an AEC-related matter should discuss that concern with the AEC Chair in the first instance. The AEC Chair may then discuss the concern with relevant parties and if a complaint is deemed warranted, prepare a written recommendation to the AEC that clearly spells out the concern. If the AEC determines that a complaint is warranted, the complaint should be forwarded to the DVC(R) who will make the final determination on whether the complaint should proceed, possibly with amendments. If the complaint is to proceed, the DVC(R) will forward it, on behalf of the University, to the organisational head of the person or panel that conducted the audit.

Any person not satisfied with the decision reached by the AEC may write to the DVC(R) directly with their concerns. In that case, following consultation with the AEC Chair and other parties deemed relevant, the DVC(R) who will make the final determination on whether a complaint should be lodged with the auditor's organisation.

E. Research misconduct

The University's *Research Integrity – Higher Degree Student Research Misconduct Policy and Research Misconduct Procedure* set out the policy and procedure for the handling of allegations of possible research misconduct.

4. CONSCIENTIOUS OBJECTION TO INVOLVEMENT IN A TEACHING ACTIVITY USING ANIMALS

The policy and procedure for handling conscientious objections to a teaching activity involving animals are detailed in the University's *Conscientious Objections Policy*.

5. APPEALS

The final recourse within the University for persons who have exhausted the complaints procedures and remain discontented is an appeal to the University Ombudsman. A complainant may contact the VGAWU, the relevant regulatory authority or the Victorian State Ombudsman if they believe their complaint has not been satisfactorily resolved by the University processes.