VICTORIA UNIVERSITY ANIMAL ETHICS COMMITTEE (AEC)

AEC – PROCEDURE FOR HANDLING ADVERSE EVENTS

DEFINITIONS

Adverse Event

Adverse events are ANY events which have a negative impact on the animal's wellbeing resulting in an abnormal physiological or behavioural response.

They are UNEXPECTED events not predicted in the AEC approved protocol. See 1 (a)

Examples of adverse events:

- Unexpected death of an animal or a group of animals
- Unexpected welfare deterioration (such as rapid weight loss, respiratory issues, collapse, diarrhoea, neurological symptoms)
- Expected adverse effects described in the approved protocol which affect greater numbers or are of a greater severity than predicted in the approved AEC project.
- Unforeseen levels of pain and distress
- and severe weather conditions in field projects. These events may impact the health of the animals in the project.

AWO *Animal Welfare Officer*

ACT *Prevention of Cruelty to Animals Act 1986 & Prevention of Cruelty to Animals Regulations 2008*

The Code: *https://www.nhmrc.gov.au/about-us/pThe Australian-code-care-and-use-animals-scientific-purposes, 8th edition 2013*

The housing code of practice: *Victorian-codes-of-practice-for-animal-welfare/code-of-practice-for-the-housing-and-care-of-laboratory-mice-rats-guinea-pigs-and-rabbits*.

Non-compliant event A procedure or process that does not comply with relevant codes of practice or the ACT

Actions

1. General
    a) The AEC must be informed via the application to the AEC of all expected or potential impacts to animal welfare as a result of the experimental interventions or circumstances related to the experiment such as age or phenotype impacts to animal welfare. Any occurrence impacting on animal welfare outside of what was anticipated within the application to the AEC is an adverse event.

b) Under the 'ACT' ANY person who finds an animal in pain or distress has a statutory obligation to initiate action to address the situation.
c) When an adverse event is detected, the investigator/teacher, their delegate, or the Animal Facility Manager must immediately initiate corrective actions.
d) Advice and assistance should be sought from the Animal Welfare Officer.

2. Remedial Action
   - If an adverse event occurs during an experimental procedure or teaching activity and the procedure is impacting directly on animal welfare, the procedure must cease immediately and the cause of the adverse event investigated.
   - Treatment to alleviate pain, distress or suffering, by the use of appropriate analgesia or euthanasia, carried out by a competent person must be taken immediately. Removal of an animal from the experimental protocol may be required.

3. Prompt initial reporting
   - As soon as the immediate animal welfare issues have been addressed, the Chief Investigator should immediately (by the next working day at the latest) advise the Secretary of the AEC by email (aeec@vu.edu.au) and provide an Interim Adverse Incident Report. The Animal Facility Manager, AEC Chair and the AWO should also be advised if not already aware of the situation, by the AEC secretary.
   - Action must be taken to ensure other animals have not and will not be impacted on in this project or any related project prior to continuing with the approved protocol. If other animals are likely to be impacted, the investigator should consult with the AEC Chair and AWO to clearly determine which areas of work may require suspension pending finalisation and review of the Adverse Event by the AEC. In situations where the severity of the unexpected adverse event would indicate there is on-going potential for the well-being of animals in the project to be adversely affected, then the AEC Chair may:
     i. Suspend the project by issuing an instruction (verbally and in writing) to the CI to immediately cease activities related to the procedure or all activities involving animals in this project (apart from ongoing maintenance of the animals' health).
     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 chief investigator subsequently submitting a written application for modification of the approved AEC project,
     iii. Suspend the project and, it will only be permitted to recommence once that request is approved a full meeting of the AEC.

   It is understood that a period of time may be required to obtain all relevant information in order to submit a complete adverse event report. This completed report must be submitted to the AEC as soon as possible after all information has been collected; this must occur within one month of the adverse event.

4. Responsibility for Reporting to the AEC.
   - Prompt reporting of an adverse event to the AEC is a requirement of the Code of practice (section 2.2.28). Failure to submit an adverse event report is considered a non-compliant event and the AEC will follow the non-compliant event procedure.
   - The chief investigator or teacher has primary responsibility for reporting an adverse event. However, the Animal Facility Manager may report non experimental adverse events such as colony management or facility equipment failure.

   Investigation and Preparation of an Adverse Incident Report : This is located at this link: https://www.vu.edu.au/researchers/research-lifecycle/conducting-research/animal-research-ethics/aec-amendments-reporting-feedback.

- If an animal has died unexpectedly, an autopsy must be performed if the body is not decomposed. Autopsies can be performed with the assistance of the Animal Welfare Coordinator or by other competent personnel. Samples should be taken for from animals requiring immediate euthanasia and submitted to a pathology lab for disease investigation if the cause of the adverse event is not clearly determined during initial stages of the investigation. Refer to guidelines for collection of pathology samples. The costs of the pathology is the responsibility of the chief investigator except in cases where the animal welfare officer deems the condition unlikely to be related to experimental procedures in which case the animal facility manager will accept responsibility for the cost of testing.
    - Full details of the incident should be gathered from all involved parties which may include animal care staff and facilities staff as well as the research team.
    - If a full report cannot be provided within one month of the adverse event, an interim report should be submitted to the AEC, with an indication of when the full report would be available.
    - The adverse event report should contain the following information:
    - A brief summary of the methodology of the approved project including the total number of animals approved.
    - Brief details of any previous adverse incidents.
    - Concise history or description of events including location, date, time of event and a summary of initial actions taken.
    - Numbers of animals affected by the incident and the welfare impact (mortality and morbidity).
    - Details of personnel present and/or involved.
    - Identification of known or likely causal factors - autopsy or pathology test results.
    - Proposed changes or actions to prevent a recurrence.

5. <u>AEC review of an adverse Incident</u>

The AEC must review the adverse incident to identify the causal and contributing factors – such as infectious diseases, phenotype related diseases, equipment failure, poorly maintained facilities, experimental procedures, poor experimental technique. The AEC should assess the impact on the animal(s) and determine whether factors have been adequately dealt with by the investigator or teacher. The AEC may resolve to make recommendations to the institution to resolve matters. The AEC must also consider and manage any non-compliance arising from the adverse event investigation.

Adverse Events should be recorded on an Adverse Event register maintained by the AWO who prepares an annual report for the AEC to identify any causation trends in Adverse Events (such as disease, equipment failure, poorly maintained facilities, experimental procedures or poor experimental technique).

Adverse Incidents should also be recorded in the project file and reported by the Investigator in the projects Annual and Final project reports.

Revised	Reason for revision	Revision author	Approved AEC
8.6.2021	Major revision	AWO	9/8/2021