VICTORIA UNIVERSITY ANIMAL ETHICS COMMITTEE

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 occur in greater numbers or greater severity than predicted in the approved protocol.
- Unforeseen levels of pain and distress
- Unrelated events, such as power failures in animal facilities and severe weather conditions in field projects.

AWO *Animal Welfare Officer*

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

The Code *The Australian Code of practice for the care and use of animals for scientific purposes 8th Edition 2013*

The housing code of practice *Code of practice for the housing and care of laboratory mice rats guinea pigs and rabbits 2004*

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 the experimental procedure or teaching activity impacting directly on animal welfare 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, on the next working day, advise the AEC by email (aeec@vu.edu.au) and providing an Interim Adverse Incident Report. The Animal Facility Manager, AEC Chair and the Animal Welfare Officer 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 Executive to clearly determine which areas of work are suspended pending finalization and review of the Adverse Event.
    - 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. Failure to submit an adverse event report is considered a non-compliant event and the AEC will follow the non-compliant event procedure.
    - The 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

5. Investigation and Preparation of an Adverse Incident Report. (The Adverse Incident Report form is available on the Office for Research Animal Ethics web page.)
http://research.vu.edu.au/aee_reporting.php#adverse

- A rigorous investigation into the cause or factors contributing to the adverse event must occur in order to prepare a full report to the AEC and recommendation to prevent future recurrence. Assistance should be sought from the AWO to prepare this report and the AWO may report separately to the AEC via the AWO report.
- If an animal has died unexpectedly, an autopsy must be performed if the carcass is not decomposed. Autopsies can be performed with the assistance of the Animal Welfare Officer 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 immediately an interim report should be submitted to the AEC.

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.

6. AEC review of an adverse Incident

The AEC must review the adverse incident to identify the causal and contributing factors – such as disease, equipment failure, poorly maintained facilities, experimental procedures, poor experimental technique impact on the animal 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.

Adverse Events should be listed on an Adverse Event register maintained by the Animal Welfare Officer who prepares an annual report for the AE to identify any causation trends in Adverse Incidents (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 Annual and Final project reports.