

# Unexpected Adverse Events Procedure

## Intent

The University ensures that any event that impacts adversely on animal wellbeing is promptly detected and immediate action taken in accordance with the requirements of the Code, policies and procedures of the AEC and the conditions of protocol approval.

Adverse event management and associated reporting is integral for the health and wellbeing of research animals. The process begins with project design and continues throughout the course of the project. These procedures define the actions required to respond to adverse events in the use of animals, and give effect to the *Australian Code for the Care and Use of Animals for Scientific Purposes* and so ensure the wellbeing of animals used for scientific purposes at James Cook University.

## Scope

These procedures apply to:

- (a) All persons involved in the use, care and monitoring of animals used for scientific purposes
- (b) The Animal Ethics Committee (AEC) in their role of approving and reviewing protocols and assessing the actions taken as a result of an adverse event
- (c) The Animal Welfare Officer or other delegate in their role in monitoring scientific animal use

## Definitions

Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have *Australian code for the care and use of animals for scientific purposes*.

**Adverse event** means an event or incident that has a negative impact on the wellbeing of an animal.

**AWO** means the Animal Welfare Officer.

**Investigator** means any person who uses animals for scientific purposes and is named on the AEC protocol as an investigator. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

**Protocol** means the description of the project as outlined in the application to the AEC.

**Project** means an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.

**Unexpected adverse event** means an adverse event that was not foreshadowed in the approved project or activity.

An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected;
- adverse effects following a procedure or treatment that were not expected;
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study;
- a greater level of pain or distress than was predicted during the

planning of the project or activity;

- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals;
- effects that indicate the model or experimental design is not proceeding in a way to give meaningful results and to continue would mean that animals may be wasted.

**Wellbeing**

means an animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health, of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions.

1. Adverse event management
2. AEC Review and Response

## Introduction

### 1. Adverse event procedure

The following steps must be followed when an adverse event occurs.

<p><b>Act</b></p> <p>Take immediate steps to alleviate pain or distress. The wellbeing of animals comes first, taking priority over research or teaching outcomes. Remove the animals from the situation, seek advice, treat, euthanise, address environmental conditions, examine and secure other animals that might be at risk.</p>
<p><b>Notify</b></p> <p>Notify the appropriate staff immediately. This should include the project Principal Investigator, other investigators on the project, facility managers, veterinarians, animal carers and the AWO. The AEC must be notified within 48 hours by email or phone.</p>
<p><b>Investigate</b></p> <p>Carry out any investigations necessary to find or confirm the cause. This can include carrying out thorough physical examinations, post-mortems, taking samples for pathology, examining their enclosure and other environmental factors or seeking veterinary or expert advice.</p>
<p><b>Review</b></p> <p>Review the project or procedures in light of the event looking at: how it could it have been prevented, whether it could happen again, whether it is inherent in the project's design and must be expected and the impact it will have for the future success of the project.</p> <p>In reviewing the results, a determination should be made as to whether the event was related to the project, possibly related or unrelated.</p>
<p><b>Report</b></p> <p>Reports should be completed on the AEC's 'UAE Report Form' and all questions should be answered. If you are waiting on laboratory or veterinary report or other information an interim report can be submitted with the final completed report submitted once the information is received and reviewed.</p>

One report can be used for multiple animals where the details of the UAE are the same for each animal and they are related in nature. See also the guide of what should be reported to the AEC in a UAE report.

Based on the report the Chair or AWO may decide that there is sufficient justification to suspend the project's approval to protect other animals until the AEC can review the information.

## 2. AEC review and response

Upon notification of an adverse event, the following process will be followed.

The Chair and Animal Welfare Officer will review the report when first received and decide whether it warrants any urgent action, intervention or further information.

The Animal Ethics Officer will enter the details in the UAE Register and assign it an identifying number.

The AEC will then review the report at the next meeting after its receipt.

In reviewing the report the AEC will decide whether:

- The actions taken were appropriate
- The investigations were adequate to provide the necessary information
- The conclusions reached following the investigation and review were correct
- Further investigations are required
- A breach of the legislation, Code or protocol approval has occurred
- The project can ethically proceed or should be suspended or modified in light of any new information
- Any changes are required to animal housing, care and husbandry procedures, facility environmental conditions or staffing. In such cases directions will be given to the appropriate investigators
- Whether any further information is required in order for it to make a decision

The AEC will respond to the investigator with within two weeks following the AEC meeting at which it was reviewed, unless urgent action requires an immediate response.

The project's approval may be suspended or have approval withdrawn if it is considered serious and a risk to other animals if it continues, or if there was serious non-compliance with the approval noted in the investigation.

A serious adverse event is one that:

- Has the capacity to affect the wellbeing of a significant number of animals remaining on the project, the facility or to affect the environment and so requires urgent AEC action
- Occurs as a result of non-compliance with approval, intentional cruelty, reckless behaviour, persistent negligence or misconduct
- Has the capacity to affect the reputation of the University or the AEC

## Related policy instruments

Guide for Responding to Adverse Events in Animal Projects

Animal Care and Protection Act

Animal Care and Protection Regulations

Australian code for the care and use of animals for scientific purposes

## Schedules/Appendices

Unexpected Adverse Event Report Form

---

## Administration

### Approval Details

Policy Sponsor and approver of procedure	Animal Welfare Officer
Version no	V1.0
Date for next review	05/02/2019

### Revision History

Version	Approval date	Implementation date	Details	Author
1.0	05/02/2016	05/02/2016	First version	Dr Craig Godfrey, Animal Welfare Officer

Keywords	Adverse event, Animal Ethics Committee
----------	--