



This document has been developed by The Australian National University's (ANU) Research Ethics Office. It has been endorsed by the ANU Animal Ethics Committee (AEC). It is designed to provide guidance regarding current best practice to institutional animal users and carers on the care and use of animals for scientific purposes. It has been prepared in consultation with the Australian code for the care and use of animals for scientific purposes 8th edition 2013 (the Code).

## Document 001: Procedure for Managing & Reporting Unexpected Adverse Events Involving Animals Used in Research & Teaching V3.1

### Background

This procedure applies to all ANU research and teaching activities that involve the care and use of animals as approved by the ANU Animal Ethics Committee (AEC). It applies only to Unexpected Adverse Events (UAEs). It is a condition of approval on all animal ethics protocols that in accordance with sections 2.4.18 (ix) and 2.4.34 (ii) of the Code, investigators must promptly notify the ANU Animal Ethics Committee (AEC) of any UAEs that impact, or have the potential to impact, on animal wellbeing. Notification must be done in accordance with this procedure. It is an obligation of all animal carers (such as facility technicians) to communicate with investigators and the ANU Vet Team regarding UAEs, in accordance with section 2.5.5 (iv) of the Code.

Documentation of UAEs is managed using the ANU Research Ethics Management System (REMS).

### Definitions

The below definitions are in accordance with the Code.

**The Code:** The NHMRC Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

**Adverse Event:** Any event that has a negative impact on the wellbeing of an animal

**Unexpected Adverse Event (UAE):** Any event that may have a negative impact on the wellbeing of any animals and was not foreshadowed in the approved project or activity.

**Animal:** Any live non-human vertebrate, that is, fish, adult decapod crustaceans, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid.

**Animal Carer:** Any person involved in the care of animals that are used for scientific purposes, including during their acquisition, transport, breeding, housing and husbandry.

**Animal Ethics Committee (AEC):** A committee constituted in accordance with the terms of reference and membership laid down in the Code.

**Distress:** an animal is in a negative mental state and has been unable to adapt to stressors so as to sustain a state of wellbeing. Distress may manifest as abnormal physiological or behavioural responses, a deterioration in physical and psychological health, or a failure to achieve successful biological function. Distress can be acute or chronic and may result in pathological conditions or death.

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**Investigator:** Any person who uses animals for scientific purposes. 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.

**Primary Investigator:** ANU defines the Primary Investigator (PI) as the person who has ultimate responsibility for the care and use of animals in a project, as per Section 2.4.5 of the Code.

**Facility Manager:** Person responsible for the overall management of a facility used for the breeding and holding of animals.

**Wellbeing:** 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 and of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions

### What is an Unexpected Adverse Event (UAE)?

A UAE occurs when there is an event that has had, or may have had, a negative impact on the *wellbeing* of animals, or affected the intended usage of animals, which was not foreseen in the approved animal ethics protocol. Please note, that only adverse events which are **reasonably related** to experimental activities should be included as adverse events that may be "foreseen" in a protocol.

Some examples of situations that are defined as unexpected adverse events include:

- More deaths or complications than foreshadowed in the approved animal ethics protocol, e.g. 10% of animals died following surgery when a 5% fatality rate was expected and justified
- a particular group of mice displays more aggressive behaviour than expected and incurs a higher rate of fight wounds than the accepted rate.
- Death of animals not described in the approved animal ethics protocol, e.g. an animal found dead the day after surgery, death after routine handling, or death of an animal post trapping.
- Complications not foreshadowed in the approved animal ethics protocol, e.g. allergic drug reactions, suboptimal drug effect (e.g. anaesthetic not inducing appropriate restraint), animals develop abscesses at the surgical or treatment site, or unexpected predation of animals in the field.
- Facility or equipment failure potentially compromising animal welfare or the success of the activity, e.g. malfunction of water sippers causing a cage flood; power loss to a facility that could impact air quality and control of light cycles; equipment breakdown leading to inability to perform planned procedures at a critical timepoint, resulting in wastage of animals
- Unexpected changes to a known phenotype during breeding programs, which may result in wastage of animals intended for experimental use, or have potential adverse impacts on husbandry and wellbeing.

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- Animal wellbeing is compromised due to a deficiency in routine husbandry practices, such as the provision of suitable food, water, bedding, or appropriate animal handling
- An unexpected event that leads to termination of an ongoing animal experiment without the ability to collect useful data. For example, a tumour model where the tumour does not behave as expected, resulting in animal wastage

Failure to follow protocol, resulting in potentially adverse welfare outcomes. For example, performing experimental activities on animals that have not reached the minimum age specified in an approved protocol, or activities with animals that were transported, before they completed their acclimation period in new housing

This list is not exhaustive. If there is any uncertainty around whether an event should be reported, then advice should be obtained from the ANU Vets on 02 6125 1130 as soon as possible.

## Managing and reporting UAEs

The formula for Managing and reporting UAEs is Act, Inform and Report (AIR)

### 1. ACT

Act quickly to:

- Determine and remove obvious hazards while responding to the immediate needs of sick or at-risk animals.
- Alleviate immediate unexpected pain and distress in the animal. The immediate welfare of the animals is paramount. This may include euthanasia.
- All reasonable attempts to contact Investigators should be made in the event of imminent euthanasia
- For severely injured or ill wildlife, if euthanasia is not possible (due to species and availability of a suitable method), all efforts must be made to immediately transport the animal to a suitable location/person for euthanasia
- **Ensure that for any animals that die unexpectedly, a necropsy is performed** by a vet OR suitably qualified person as directed by a vet and that the results are recorded. If possible, keep a visual record with photos and/or videos  
Ensure that carcasses are placed in the fridge NOT in the freezer unless instructed by the ANU Vet.

### 2. INFORM

Reporting of UAEs is mandatory, not voluntary. You must ensure that:

- **An ANU Vet is contacted as soon as practically possible.** Timely treatment, post mortem examination, testing or further risk minimisation strategies may be required. The ANU Vet Team is available **24/7 by dialling 612 51130**. Calls are forwarded to individual mobile phones without caller ID, please leave a voicemail with a return number if required.
- The Primary Investigator is contacted.
- **Samples are not taken from the animal until you have spoken to one of the ANU Vets** and they have provided advice on the next actions.
- The Animal Facility Manager (where relevant) is contacted. The animal facility manager **must** be contacted if the UAE is related to animal husbandry in an animal facility scenario.

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- If an external vet and/or vet clinic is listed on the approved animal ethics protocol for field work, the ANU Vet should also be contacted via the emergency phone number as soon as possible about the UAE.

### 3. REPORT

It is ANU policy for all UAE notifications to be submitted to the AEC via REMS **within 72 hours** of the occurrence (this time frame includes weekends and public holidays).

Investigators working in remote field locations must make every effort to notify the ANU Vet Team as soon as possible, and submit a written report to the AEC via REMS within 10 days.

- All UAE reports are lodged by PI's/Nominees/facility managers on a project using the REMS "add form function."
- **HUSBANDRY** events: UAEs which occur solely due to a husbandry event, where animals have not undergone experimental activity, may be submitted against the facility form and are not required to be linked to a specific Project. However please ensure the relevant Ethics Protocol is noted in the UAE description. Examples include equipment failures, power outages, cage floods, malocclusions, random deaths of animals NOT involved in any experimental activities. Note that only certain levels of facility staff will have access to Create and Submit UAE forms in REMS.
- **EXPERIMENTAL** events UAEs related or potentially related to experimental activities must be lodged against the specific Ethics Protocol within REMS. Note that although all Team Members have viewing rights, only PIs or Nominees have the ability to SUBMIT a UAE form in REMS. This is in accordance with Code requirements for PIs to take ultimate responsibility for their animals' welfare.
- Include as much detail regarding the event as possible. Try to be unbiased and descriptive when describing the events. Avoid making assumptions, rather, describe clinical signs and presentation. Avoid speaking in first person if possible.
- The ANU Vet Team reviews all UAE submissions and may request further information or clarification to be submitted in a revised submission of the UAE form. UAE Forms within REMS can undergo multiple edits using track changes.

### Outcomes:

Once UAE reports have been submitted and reviewed by the Research Ethics Office and ANU Vets, additional documentation where applicable (e.g. necropsy and/or vet reports), will be attached to the notification and the UAE will be tabled at the next AEC meeting.

Depending on the seriousness or urgency of the event, the AEC may undertake one or more of the following:

- Close the UAE with no further action
- Request further information
- Request immediate veterinary intervention (if this has not already occurred).
- Require that the experiment (or part of the experiment) cease until the matter has been investigated further especially where there are ongoing perceived risks to animal welfare.
- Suspend the project pending further investigation
- Withdraw approval
- Make recommendations for improvements, request pilot studies, or request progress reports be submitted relating to the ongoing research

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- Request amendments arising from UAE outcomes

The AEC will provide a written response to the Primary Investigator detailing outcomes. All AEC instructions must be followed.

## Complaints

Any complaints regarding the management and response of a UAE will be managed as per the AEC Operating Procedures and/or ANU Policy.

## References and Resources

ANU. Research Integrity <https://services.anu.edu.au/research-support/ethics-integrity/raising-concerns>

NHMRC. Australian code for the care and use of animals for scientific purposes 8<sup>th</sup> Edition 2013 (Section 4.4.3) <https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes>

NHMRC. Best practice methodology in the use of animals for scientific purposes 2017 <https://www.nhmrc.gov.au/about-us/publications/best-practice-methodology-use-animals-scientific-purposes>

NHMRC. Australian Code for the Responsible Conduct of Research 2018 <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

ANU. Code of Research Conduct [https://policies.anu.edu.au/ppl/document/ANUP\\_007403](https://policies.anu.edu.au/ppl/document/ANUP_007403)

ACT Government. Animal Welfare Act 1992 <https://www.legislation.act.gov.au/a/1992-45/>