Guidelines on Adverse Events

What is an Adverse Event?

The Australian code for the care and use of animals for scientific purposes 8th Edition 2013 (updated 2021) (the Code) defines an adverse event as "*any event that has a negative impact on the wellbeing of an animal.*"

What is an Unexpected Adverse Event (UAE)?

The Code defines an unexpected adverse event as "*an event that may have a negative impact on the wellbeing of animals and 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 (e.g., during surgery or anaesthesia, or after a procedure or treatment).*
- *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."*

What is a Foreshadowed Adverse Event?

You can provide details of adverse events that you foreshadow in your application (there is a section on this in the form). In this section, you must (1) be specific about the adverse event and (2) specify a number (or percentage) of animals that may be impacted. In the application, you should provide a justification for why the adverse event can be foreshadowed. You must also include potential causes of events, along with the mitigating actions you will take to try and prevent or minimise them. If you do not foreshadow adverse events in your AEC application, then all adverse events will be treated as unexpected and must be reported promptly.

Please note that the treatment and actions that need to be undertaken in response to an adverse event are no different whether the event was Unexpected or Foreshadowed.

For example, the AEC may accept the following as foreshadowed adverse events. Please note that the below is only for guidance, and the AEC will make decisions on a case-by case basis:

Species	Foreshadowed Adverse Events
Cattle	• up to 2% mortality in feedlot cattle • up to 10% incidence of bloat in feedlot cattle • up to 2% transport related mortality in feedlot cattle • Up to 1% mild cases of acidosis not requiring treatment • Up to 10% incidence of lameness

	• Minor transrectal or reproductive tract bleeding that does not require active treatment
Sheep	• up to 10% lamb mortality • up to 5% ewe mortality due to dystocia per season • up to 10% incidence of mild Flystrike • up to 2% transport related mortality • up to 5% Pinkeye (feedlot) • Up to 1% sheep mortality (feedlot) • Up to 1% mild cases of acidosis not requiring treatment • Up to 10% incidence of shy feeders
Horses	• Side effects like sweating, smooth muscle cramping and mild colic symptoms with use of prostaglandin injection (cloprostenol) at the registered dose rate (250 µg) • Grade 1 rectal tear (mucosal abrasion) that does not require active treatment.
Poultry	• Mortality from tracheal sampling (<1%) • Minor transient stress or mild irritation from tracheal sampling
Wildlife	• Up to 25% mortality of radio-tracked northern quolls due to predation (since this is a natural predation rate) • Up to 5% minor injuries due to trapping (e.g. abrasions, tail clips). (But attention and adjustment should be made to the species and environment). • Obligate hormone-driven post-breeding mortality in appropriate species such as male semelparous dasyurid marsupials may be foreshadowed. • Normal injuries that wild animals receive during natural behaviour, such as from fighting or mating, may also be foreshadowed.
Fish	• 1-2% mortality with fish capture/handling using electrofishing and fyke netting) • 1-2 % mortality during transportation • up to 5% mortality when fish held for several weeks • >90 % mortality during early stages of life for most species • 20-30% mortality of larval fish

Action to be taken upon encountering an adverse event (whether unexpected or foreshadowed)

Prompt action must be taken, including alleviating pain and distress in response to adverse events and emergencies, in accordance with institutional and AEC policies and procedures. Action may be initiated by animal carers, and include liaising with investigators and seeking veterinary advice. In order to support rapid recognition of adverse events, ensure monitoring is undertaken with appropriate frequency, care and diligence to ensure early signs of animal problems are detected. Alleviating pain and distress must take precedence over an individual animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, animals must be humanely euthanised without delay. Please consult the "Guidelines on Veterinary Care" for further information on dealing with adverse events.

Action and Documentation steps:

1. Assess the animal promptly and take actions to alleviate pain and distress

2. Contact a veterinarian immediately if
    - the animal's condition is worsening
    - if the pain or distress cannot be managed by routine care
    - if the animal may require humane euthanasia
3. If the Chief Investigator (CI) is off-site, inform the CI and other team members as soon as possible
4. Record the animal ID, age, sex & date, time, and location of the event; describe the nature and severity of the adverse event; note all actions taken, including interventions or euthanasia; and document personnel involved.
5. Take photographs or videos of the affected animal and the surroundings where the animal is located/housed for accurate reporting.
6. Notify the AEC within 24-48 hrs of the adverse event by email to animalethics@csu.edu.au (initial reporting)
7. Review the event with the team and veterinarian to identify animals at risk to take preventive measures.
8. Submit an adverse event report to the AEC (see section below)

When is a necropsy required?

An important consideration following an Adverse Event is whether a necropsy and further diagnostic investigation should be performed. Further information on veterinary care is provided through the internal guidelines.

In general, a necropsy should be performed when 1) the cause of death is unknown, 2) other animals may be at risk or 3) the adverse event could have been caused by the experimental or teaching procedure. In the case of multiple deaths, the Chief Investigator should consider undertaking necropsies on a reasonable sample of animals and provide justification for their sample size to the AEC. Necropsies should be performed by a competent person. It is preferred (given their training) that necropsies are conducted by a veterinarian and ideally those independent of the project. If a veterinarian is not reasonably available, then another competent person should perform the examination. Wherever possible, a veterinarian should still review the observations made (including photos). Where the gross examination does not reveal the cause of illness or death, further pathological testing should be carried out to maximise the chance of determining the cause and ensure the wellbeing of other animals.

The AEC acknowledges that necropsies are not always necessary or possible. A necropsy may not be required where the cause of death is obvious, such as wildlife or livestock predation or collision with a motor vehicle. A necropsy may also sometimes not be possible for logistical reasons, such as when working in remote areas where there is no access to a suitable competent person to perform the examination. When a necropsy has not been performed, the Chief Investigator is required to state the reason for this in the Unexpected Adverse Event report.

Reporting of Unexpected Adverse Events

Chief investigators that hold AEC animal use authorities are reminded of the responsibilities for reporting Unexpected Adverse Events. The AEC **must** be notified informally, usually by email to animalethics@csu.edu.au , **within 24/48 hours of the event**. If the CI is not available, a

responsible member of the team should report the UAE. The Animal Ethics Partner (AEP), Animal Welfare Officer (AWO) or a Committee member may respond following this notification with suggestions and advice. A completed Unexpected Adverse Event form should then be submitted promptly, and where possible before the agenda due date for the next AEC meeting. This form will be received by the Animal Ethics Partner, forwarded to the Animal Welfare Officer for review and added to the next available AEC agenda. If you are unable to submit this form promptly, such as if you are in the field, you should contact the AEP as soon as possible and make them aware of the situation and that you will be submitting a UAE in due course.

Reporting of Foreshadowed Adverse Events

It is important to note that **all** adverse events, whether foreshadowed or unexpected, must be reported in the annual and end-of-project reports. In addition, all animal outcomes must be reported in the statistics for each state that the projects were carried out. Ongoing and accurate animal monitoring and record keeping is essential to ensure the wellbeing of animals is supported.

Remember to seek advice from the University Animal Welfare Officer if you are in doubt or need assistance with compiling an application to take into consideration adverse events that may be foreshadowed.