



## Guidelines on Adverse Events

### What is an Adverse Event?

The Australian code for the care and use of animals for scientific purposes 8<sup>th</sup> 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.”*

### Clarification on actions and reporting of adverse events to the University Animal Ethics Committee (AEC):

#### Understanding the difference between foreshadowed events and unexpected events.

It is the responsibility of the chief investigator to take “*prompt action, including alleviating pain and distress and promptly notifying the AEC, in response to **unexpected adverse events and emergencies**, in accordance with institutional and AEC policies and procedures. Alleviating unanticipated 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 killed without delay.*”

To promptly notify the AEC of an UAE you must complete and submit an ‘Unexpected Animal Event Report’ (ACEC-AE) to [animalethics@csu.edu.au](mailto:animalethics@csu.edu.au). This form will be received by the Animal Ethics Partner (AEP), forwarded to the Animal Welfare Officer (AWO) for review and added to the next available AEC agenda. You should receive a receipt of your submission but will not receive anything from the AWO unless they have any queries concerns or recommendations. If you are unable to submit this form promptly, such as if you are in the field, you should contact the AEP or AWO as soon as possible and make them aware of the situation and that you will be submitting a UAE in due course.

You can provide details of adverse events that you foreshadow in your application. It is important that you are as specific as possible about the possible number (or percentage) of animals impacted and the justification or potential causes of events, along with the mitigating actions you will take to try and prevent or minimise them. The AEC may accept these as foreshadowed adverse events. An example of a foreshadowed event could be a percentage of expected lamb deaths based on recognised industry averages. Foreshadowed events that occur as described, do **not** need to be reported to the AEC on an UAE form.

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.

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 animal monitoring and record keeping is essential as well as scrutiny as to whether an event is classified as unexpected to ensure the wellbeing of animals is supported.

### When is a necropsy required?

An important consideration following an Unexpected Adverse Event is whether a necropsy and further diagnostic investigation should be performed.

In general, a necropsy should be performed when the cause of death is unknown, and 1) other animals may be a risk or 2) the cause of death could potentially have been caused by the experimental or teaching procedure. In such cases a necropsy 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. Costs related to these examinations are the responsibility of the project therefore the Chief Investigator.

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, male antechinus death in the spring after breeding 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.

**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.**

\*foreshadowed = a warning or indication of a future event

