



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.

## ***011 ANU Position Paper Use of Non-Pharmaceutical Grade Compounds for Anaesthetising & Euthanasing animals V2.0***

### **General Information and Considerations**

The ANU requires that, where possible, only compounds of pharmaceutical grade (PGC) are used in animals. The ANU adheres to the Guidelines published by the US Department of Agriculture (USDA) which are supported by the National Institutes of Health (NIH) on the use of non-pharmaceutical grade compounds (NPGC).

The ANU also requires the use of best practice methodology at all times as per the NHMRC published "Best practice methodology in the use of animals for scientific purposes (2017)" and the Australian code for the care and use of animals for scientific purposes

### ***Exemptions***

Where a researcher requests permission to use a non-PGC compound, they must justify specifically why a PGC is not suitable. Simply stating that it has been used historically or that there is a cost impact is not sufficient.

Evidence must be presented as scientific justification such as;

☐ A PGC is not available (this includes new investigational compounds – see ANU Position Paper - Use of Non-Pharmaceutical Grade Discovery Compounds in Animals)

☐ A PGC is not available in the appropriate concentration or formulation, or the appropriate vehicle control is unavailable

☐ The Non-PGC is required to generate data that are part of an ongoing study, or to generate data that are comparable to previous work in order to enable effective publication (description of how a change would impact the data is required)

Where non-PGCs are requested for use under a protocol, they must be clearly identified as a non-PGC, and it is the researcher's responsibility to appropriately mitigate the risks of using such a compound

Where survival surgery is a requirement, a Standard Operating Procedure must be submitted that ensures

the risks of using non-PGCs are addressed.

The following factors must be considered;

- Whether the chemical properties are appropriate for the study and route of administration (this
- includes the purity, grade, stability in and out of solution, solution vehicle properties, pH,
- osmolality etc.)

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- *The method of preparation, volumes of preparation, reproducibility of preparation, labelling, use-by dates, storage, and administration procedures*
- *Whether the use of the non-PGC will harm the ability to achieve scientifically relevant results that*

*are able to be published or utilised effectively in research funding applications.*

*Common examples of non-PGCs include avertin and urethane for anaesthesia in rodents, and clove oil*

*for euthanasia in aquatic species.*

## Monitoring, Intervention and Reporting

### Adverse Events

Any approval given for the use of non-PGCs will be conditional on any individual adverse event (i.e. a single mouse death or complication arising in inability to utilise the data from an animal) related to the use of a non-PGC being immediately reported via the University's Unexpected Adverse Event reporting mechanism. There is no acceptable complication rate for the use of non-PGCs.

If a complication is found to be due to, or is potentially attributed to, the use of the non-PGC, a review of the protocol and its approved procedures will be undertaken. While the review is being undertaken, the use of the non-PGC may be suspended at the discretion of the AEC and ANU Veterinarians or their delegates.

Any investigator that does not follow their AEC approved procedure for the use of non-PGCs will have their approval immediately revoked.

## References and Resources

### Related Documents

Information Paper January 2020: Use of Non-Pharmaceutical Grade Compounds (Non-PGCs) and Discovery Compounds in research animals

ANU Position Paper: Use of Non-Pharmaceutical Grade Discovery Compounds in Animals  
Procedure for Managing & Reporting Unexpected Adverse Events.

### References

Australian code for the care and use of animals for scientific purposes 8th edition. 2013

Best practice methodology in the use of animals for scientific purposes (2017)