ANU Animal Ethics Experimentation Committee Approved Document

This document has been developed by the Australian National University's (ANU) Research Ethics Office. It has been endorsed by the ANU Animal Experimentation Ethics Committee (AEEC). 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 such as research and teaching. They have been prepared in consultation with the NHMRC’s *Australian code for the care and use of animals for scientific purposes 8th edition, 2013* (the Code).

**Document 011: Use of Non-Pharmaceutical Grade Compounds for Anaesthetising & Euthanasing Animals V1.0**

1. Background

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)”

Under section 2.4.18 of the Code, we are also required to ensure that the use of anaesthesia is consistent with current veterinary practice.

2. Considerations

**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.)
- 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.

3. 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, 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 AEEC and ANU Veterinarians or their delegates.

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

4. 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

The 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)