Australian National University

Animal Ethics 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 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 (updated 2021).

Document 011: Standards for the Use of Non-Pharmaceutical Grade Compounds for Anaesthesia and Humane Killing in Animals V2.0

Background

The use of non-pharmaceutical grade compounds (non-PGCs) may compromise animal welfare, as well as impact the quality of research produced, as outlined by The National Research Council's (US) Guide for the Care and Use of Laboratory Animals. Due to these reasons, and others, it is considered best practice to use pharmaceutical grade compounds in animals.

The ANU requires the use of best practice methodology at all times as per the NHMRC Best Practice Methodology in the Use of Animals for Scientific Purposes and the Australian Code for the Care and Use of Animals for Scientific Purposes. The ANU, therefore, requires that where possible, only compounds of pharmaceutical grade are used in animals. For further Information see position paper on the use of non-PCGs

General Information and Considerations

Exemptions

Where a researcher requests permission to use a non-PGC for anaesthesia or humane killing of animals, they must justify its use. The justification for the use of a non-PGC cannot be based solely on its historical use or cost.

A scientific justification must be provided, such as;

- A pharmaceutic grade compound (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-PCGs are requested for use under a protocol, they must be clearly identified as a non-PCG, and it is the researcher's responsibility to appropriately mitigate the risks of using such a compound. Where survival surgery is a requirement, the researcher must outline the risks associated with the use of the non-PGC, as well as ways to mitigate these risks, in their animal ethics protocol.

The following factors must be considered;

- Whether the chemical properties are appropriate for the study and route of administration planned (this includes the purity, grade, stability in and out of 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 anaesthesia and humane killing 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 that Impacts the ability to utilise the data from an animal). Any adverse event related to the use of a non-PGC must be 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.

Minimum requirements

- The ANU requires that where possible, only compounds of pharmaceutical grade are used in animals for anaesthesia and humane killing
- Where non-PGCs are requested to be utilised under a protocol, they must be clearly identified as a non-PGC
- The use of a non-PGC for anaesthesia and humane killing of animals must be justified in your application to the Animal Ethics Committee
- Any adverse event related to the use of a non-PGC must be immediately reported via the University's Unexpected Adverse Event reporting mechanism. There is no acceptable complication rate for the use of non-PGCs

References and Resources

ANU Training and Support

The ANU Veterinary Services Team are available to provide advice on the appropriate use of non-PGCs in animals for anaesthesia and humane killing. The Veterinary Services team are also able to discuss alternative methods of anaesthesia and humane killing that are suitable for your project.

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)
National Research Council Guide for the Care and Use of Laboratory Animals: Eighth Edition (2011)