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.

**Document 010: ANU Position Paper - Use of Non-Pharmaceutical Grade Discovery Compounds in 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 definitions and 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)”

2. **Considerations**

   **Definition of Discovery Compound**

   Where a researcher requests to utilise a non-pharmaceutical grade compound for discovery purposes (i.e. a potential new drug) they must specifically justify what steps they have taken to minimise any impact on animal welfare.

   Where non-PGCs are requested to be utilised 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. The following factors must be considered;

   - Has the compound been used in any animal species previously and if so, what dose rates and routes of administration were found to be safe and effective?
   - If not used in any animal species previously what measures will be taken to trial the compound at different doses, has any in vitro work been completed?
   - Demonstrate that the chemical properties and route of administration are appropriate for the study (this includes the purity, grade, stability in and out of solution, solution vehicle properties, pH, osmolality etc.)
   - The method and volumes 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 used effectively in future research funding applications.

3. Monitoring, Intervention and Reporting

**Adverse Events**

Any approval given for the use of non-PGCs will be conditional, 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 must be immediately reported via the University's Unexpected Adverse Event Procedure. 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 investigators that do not to follow their AEEC approved procedure for the reconstitution 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 Compounds for Anaesthetising & Euthanasing 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)