Animal Research Review Panel Guideline 24

Consideration of high impact projects by AECs

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Reviewed February 2023

Introduction

While all research projects using animals must be evaluated and approved by an Animal Ethics Committee (AEC) prior to commencement, this guideline aims to enhance the capacity of AECs to undertake effective consideration of high-impact research projects.

This guideline was developed in response to surveys carried out by the Panel in 2015 and 2020, and is supplementary to guidelines already issued by the Panel, under the umbrella of "Operation of Animal Ethics Committees", and the National Health and Medical Research Council's Australian code for the care and use of animals for scientific purposes (the Code) issued by the Federal government.

Animal Ethics Committees and the Australian Code

Clauses 1.5-1.7 of the Code requires that to permit research to proceed, researchers need to demonstrate that the project has scientific or educational merit and potential benefit for humans, animals or the environment, and that that there is sufficient evidence to support a case that the proposed use of animals is justified. Ethical justification is also required, recognising that an animal has inherent value and that the interests of the animal need to be considered.

The core task of an AEC therefore is to only approve those studies for which animal use is essential and justified and which conform to the requirements of the Code. This includes the consideration of the overall wellbeing of animals (Clauses 1.8 and 1.9), taking into consideration the relevant aspects of species-specific biology, physiology and behaviour.

High-impact research projects

High-impact research projects can be considered as those in which animals experience a moderate or large degree of pain and/or distress which is often referred to under the collective term of "harm". Even though it may be difficult to evaluate in animals, unless there is evidence to the contrary, it must be assumed that procedures and conditions that would cause pain and distress in humans cause pain and distress in animals (Clause 1.10 The Code). This may be acute, chronic and/or cumulative with duration playing a factor, whereby long-lasting mild suffering can become moderate, and long-lasting moderate suffering can cross from moderate into severe.

AECs should also recognise that procedures using animals that are not necessarily classified as high-impact by researchers may be considered high-impact by other stakeholders including the general public.

In NSW, statistics on animal use in research and teaching are collected and published by the NSW Department of Primary Industries. The statistics, collected via Form L, group animal use into 'procedure categories'.

The sorting of procedures into categories aims to give some indication of the 'invasiveness' or 'impact' of the research being undertaken on the animals involved. Procedure categories range from P1 – P9, with categories P5, P7 and P8 considered to be 'high-impact'.

P5 Major surgery with recovery

Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Postoperative pain is usually considerable and at a level requiring analgesia.

Examples

- Orthopaedic surgery
- Abdominal or thoracic surgery
- Transplant surgery

P7 Major physiological challenge

Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.

Examples

- Major infection
- Major phenotypic modification
- Oncogenesis without pain alleviation
- Arthritis studies with no pain alleviation
- Uncontrolled metabolic disease
- Isolation or environmental deprivation for extended periods
- Monoclonal antibody raising in mice
- Forced swim test
- Nose-only smoke exposure

P8 Death as an endpoint

This category only applies in those rare cases where the death of the animal is a planned part of the procedures and animals die but are not euthanised. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, they may be placed in category P6 or P7.

Examples

- Lethality testing (including LD50, LC50)

It does not include death by natural causes; animals which are euthanased as part of the project; animals which are euthanased if something goes wrong; animals euthanased for dissection or for use as museum specimens; or accidental deaths.

Recommendations for AECs when assessing high-impact projects

The Panel has developed the following recommendations for AECs to consider when assessing high-impact projects noting however these principles can equally be applied to consideration of all applications.

1. Researchers should ensure they provide in their applications the following:
    a. explanations of the work that will be conducted in layman's terms, to enable all members of the committee to understand the anticipated risk of harm to the animals
    b. detailed explanations of the expected or potential impacts on the animal/s, including the type of harm and level of pain and distress the animal/s is expected to experience, including the cumulative impact of the research on the animals over their lifetime
    c. Procedures detailing how the harm will be evaluated, and what measures and limits will be set for pain/distress with clearly defined humane endpoints
    d. provision of information about the likelihood of adverse events and strategies that are being implemented to both reduce risk of such events occurring
    e. detailed assessment of refinements that have been examined in developing their project that will mitigate anticipate pain and distress (eg anaesthesia, analgaesia, environmental conditions) as well as plans for ongoing review to assess whether further refinements can be enacted during the course of the project,
    f. detailed assessment of alternatives that have been examined in developing their projects and comprehensive justification for why the use of animals is unavoidable and necessary.
2. Establishments should ensure that AEC members have adequate time and access to resources that will enable them assess research applications fully and if required obtain additional information.
3. The Chair of the AEC should ensure that the committee functions effectively and allows all committee members to have an equal and valid voice in discussions and the decision-making process.
4. AECs should where appropriate draw on the expertise of specialists to help inform their decision making. This can include ethics or species experts and statisticians, which may be external to the AEC and/or establishment. This can provide the AEC with guidance on species specific harm assessment, proper experimental design and the likelihood of a valid scientific outcome
5. AECs should routinely invite principal investigators to attend committee meetings to respond directly to questions and concerns. This is helpful to both parties and often results in improvements to the experimental design, better animal welfare and a greater understanding between the AEC and investigators.

Additional resources

Balancing harm and benefit (ANZCCART)

The ethical judgements required in the assessment of a project can be difficult to make. Ethicists have developed several techniques to help resolve ethical issues. ANZCCART describes one of these techniques, the harm-benefit analysis. For further information on this method visit the ANZCCART website.

ARRP Guideline 31: Ethical decision-making in Animal Ethics Committees

Available on the Animal Ethics Infolink website here. This guideline aims to is to enhance the capacity of AECs to undertake effective, ethical decision-making. It has been produced to

provide guidance on decision-making processes that have respect for animals at the core of their function.

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

This document provides advice on the conduct of animal-based studies to ensure that the studies are rigorous, transparent and reproducible and lead to useful outcomes. It is in line with the Australian Code for the care and use of animals for scientific purposes, 8th edition (2013).

ARRP 2022 Webinar series

In 2022 the ARRP, in conjunction with NSW DPI, hosted a series of webinars to assist AECs and the animal research community.

- Webinar 2 on Animal Research Statistics promoted the correct analysis of data related to the use of animals in research and the principles of the 3Rs as a framework for ethical decision making, and
- Webinar 3 discussed concepts around ethical decision making.
- Recordings of the webinars can be accessed here.

Conclusion

The use of animals in research entails a range of societal and ethical issues, and there is widespread consensus that animals are to be kept safe from unnecessary suffering. The use of animals for scientific purposes must have scientific or educational merit; must aim to benefit humans, animals or the environment; and must be conducted with integrity.

When animals are used, the number of animals involved must be minimised, the wellbeing of the animals must be prioritised, and harm, including pain and distress, in those animals must be avoided or minimised and replacement of animals considered wherever possible.

Additional Reading

Australian community attitudes towards the use of animals in research (2022) by Dr Alex Whittaker, Dr Emily Buddle and Professor Rachel Ankeny
https://anzccart.adelaide.edu.au/ua/media/664/attitudes-animal-research-survey-report2.pdf

Chen, P.J. (2017) Animal welfare officers in Australian higher education: 3R application, work contexts, and risk perception Laboratory Animals 51: 636–46

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NHMRC (2013) Australian code for the care and use of animals for scientific purposes, 8th edition Canberra: NHMRC

Rose, M. (2011) Challenges to the development and implementation of public policies to achieve animal welfare outcomes Animals 1: 69–82

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Tjärnström, E., Weber, E. M., Hultgren, J., & Röcklinsberg, H. (2018). Emotions and Ethical Decision-Making in Animal Ethics Committees. *Animals, 8*(10), 181. https://www.mdpi.com/2076-2615/8/10/181

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Schuppli C (2011) Decisions about the use of animals in research: ethical reflection by animal ethics committee members. *Anthrozoos* 24 (3): 409 - 428

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Acknowledgments

The revision of this guideline was informed by responses to a survey on AEC education and training resources, carried out by NSW Department of Primary Industries and the Animal Research Review Panel in November 2020. The generosity of respondents in sharing their thoughts and insights is gratefully acknowledged.

Published by the Department of Primary Industries.