Does this need AEC approval?

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Introduction

Part 6 of the Animal Welfare Act 1999 covers the use of animals in research, testing and teaching (RTT), and requires all such work involving animals to be covered by approval from an Animal Ethics Committee (AEC). Considerations for the AEC include the likely harm to the animals of the procedures, and whether the benefits expected will outweigh this harm. A wide range of benefits may be possible, including maintenance or protection of human or animal health, production and productivity of animals, achievement of educational objectives, and understanding and management of animals, humans, and ecosystems.

The Act specifically excludes any therapy or prophylaxis necessary or desirable for the welfare of an animal from requiring AEC approval. The boundary between clinical treatment and research work is not always clear for veterinarians in practice. Undertaking research work without AEC approval is a breach of the Animal Welfare Act (1999) and can also mean that the results of the work may not be publishable.

Animal Welfare Act 1999

The Animal Welfare Act (1999) covers the care and management of all animals, with Part 6 specifically covering the use of animals in RTT. All use of animals in RTT must be approved by an AEC and carried out in accordance with any conditions imposed by the AEC. AECs are set up by organisations under a Code of Ethical Conduct (CEC) which is approved by the Director General of the Ministry for Primary Industries (MPI).

The key definitions under the Act are those that define animals, manipulations and RTT.

Animals:
- Living non-human vertebrates.
- Living octopus, squid, crab, crayfish, lobster.
- Unborn or unhatched animals in second half of gestation.

Manipulations:
- Mating where there is a risk of compromised welfare in offspring.
- Deliberately deriving animals of usual care.
- Deliberately subjecting animals to a procedure that is unusual or abnormal.
- Interfering with normal physiology, behaviour, or anatomy of an animal.
- Killing specifically to collect tissues.

Research includes all investigative, experimental, and diagnostic work. Testing includes toxicity, efficacy, and potency work, as well as evaluation of product safety. Teaching covers all manipulations of animals specifically for the purposes of instruction. The production of antisera and other biological products is also covered by RTT.

Veterinary research

The key difference between veterinary clinical work and veterinary research is whether the work is being undertaken to answer a question about the treatment or management of a specific group of animals on a particular farm or a small group of farms with similar conditions or problems, or whether the work is asking a question that requires comparing groups of animals with different backgrounds, managed under different conditions, and using a scientific approach to find the answer.

Points to consider with regard to the proposed work are:
- Is this being done to address a specific question rather than evaluate a clinical treatment on an individual farm, herd, or flock?
- Is this being done across multiple farms, herds, or flocks?
- Is this being done to create data or a paper for publication?
- Does the work require recruiting animals with a specific condition from a number of farms?
- Is the work a non-routine treatment/management regime?
- Is the work testing a theory for a new combination of treatments or drugs?
- Is the work evaluating a new unregistered treatment?
- Is the work designed as an experiment (treatments plus controls)?
- Is the work funded as a research project?

Work that matches these points is likely to be research and will need AEC approval prior to commencing. The results of the work are likely to be new information for the academic literature and be peer reviewed and published in a refereed journal.

However, if the work is being done to address a specific problem on a client's farm, herd or flock, or is comparing two doses of a routine treatment on a single property or trying to answer a clinical question specific to a farm, herd or flock being treated by the veterinarian, then AEC approval is not required. If results are published, this is likely to be a brief communication such as a clinical note or letter to the editor.

AEC applications

Veterinarians wishing to undertake RTT will need to contact an AEC and make arrangements to work under the approval of the AEC. The Ministry for Primary Industries can assist with contacts.

Details of the proposed work will need to be submitted in writing to the AEC for their consideration. It is likely that there will be a detailed form to complete, and time should be allowed for this, noting that AECs will meet at varying frequencies (often monthly, but some are less frequent) and the application needs to be presented and evaluated at a committee meeting.

The AEC will be looking for specific and well-defined information; so ensure the proposed work is described in detail – standard operating procedures and timelines for the work will assist with this. The numbers of animals involved must be accurate and include all those screened prior to entering the trial as well as a reasonable estimate of numbers born during the trial. Details of animal management should be included. The location of the work, and who is going to be involved needs to be included. Contingency plans for managing all aspects of animal health and dealing with unexpected events will also be needed.

The 3 Rs are important considerations and may need to be specifically addressed in the application. These are:

- *Reduction* - using the minimum number of animals necessary to get valid results.
- *Refinement* - minimising the impact of the procedures – for example use of pain relief/sedation, enrichment especially for housed animals, special diet or care for the animals, prior exposure or training of the animals for experimental conditions
- *Replacement* - can you do this work without animals, if not, why not? Does this work provide data, so animals won't be needed in future (e.g. for models)?

It is also worth noting that research work on farms can be challenging and additional time, resources and staff should be allowed compared to work being carried out in more controlled environments such as laboratories. Farms and farmers should be selected carefully as trial work can be very disruptive to normal farm routines – will the farmer be able to commit to the extra work required and do so for the entire length of the trial, and will the farmer commit to following the experimental protocol without deviation?

Reporting

There are mandatory reporting requirements for research work. By regulation, animal use statistics for the purposes of RTT must be reported to MPI each year. The AEC is also likely to have non-statutory reporting requirements, which will almost certainly include a report at the end of the work and may include some interim reports.

Any adverse event must to reported to the AEC as soon as possible, and include any actions being taken to prevent the event occurring again.

References

Anonymous. *A Culture of Care, a guide for people working with animals in research, testing and teaching.* https://www.mpi.govt.nz/dmsdocument/1473-A-Culture-of-Care-A-Guide-for-People-Working-with-Animals-in-RTT (accessed 24 September 2021). National Animal Ethics Advisory Committee, Wellington, New Zealand, 2002

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Anonymous. *Good Practice Guide for the use of animals in research, testing and teaching.* https://www.mpi.govt.nz/dmsdocument/33585-Good-Practice-Guide-for-the-use-of-animals-in-research-testing-and-teaching (accessed 24 September 2021). Ministry for Primary Industries, Wellington, New Zealand, 2021

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