A Guide for Lay Members of Animal Ethics Committees

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National Animal Ethics Advisory Committee

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1. Introduction

The system that controls the use of animals in research, testing and teaching (RTT) in New Zealand has been set up to ensure that the welfare of animals used in this way is given the consideration that societal expectations demand. An important part in ensuring the integrity of this system is the inclusion within it of people who have no commercial association with the particular institution on whose Animal Ethics Committee (AEC) they sit and, as such, who act as representatives of society at large.

Most of those who undertake this important role will have limited knowledge of the scientific and experimental work undertaken in this country. This guide is designed to give an overview of the system as well as to provide reassurance to lay members of the importance and legitimacy of their particular roles within AECs, no matter their lack of experience in this area.

2. Legislation

The use of animals in research, testing and teaching (RTT) in New Zealand is governed by Part 6 the Animal Welfare Act 1999, a specific area of legislation that acknowledges that in the course of such activities, the welfare of animals may be deliberately compromised in ways that are unacceptable under non-RTT circumstances. Because of this, as well as public concern about the welfare of experimental animals, a system has been set in place that allows for a closer scrutiny than for any other uses of animals.

Under this system, any research, testing or teaching that involves the manipulation of an animal can only be done by an individual or institution that holds a code of ethical conduct (CEC) approved by the Director-General of Agriculture or by an individual or organisation that has a formal arrangement to use another institution's code of ethical conduct and animal ethics committee. Such arrangements have no legal effect until the code holder has notified MAF in writing of the agreement. Further, no project can be undertaken unless it has been approved by an AEC constituted under the CEC. Compliance with the CEC and the legislation by both the institution and its AEC is reviewed at a maximum of every five years.

There are two exceptions to this requirement to have projects approved by an AEC. The first relates to any research, testing or teaching involving non-human hominids (gorillas, chimpanzees, bonobos and orangutans). All projects involving non-human hominids must be approved by the Director-General of Agriculture. The second relates to research or testing in the national interest. This may be approved by the Minister of Agriculture.

3. Role of AECs

The holder of a code of ethical conduct must form an AEC, whose membership must include:

- *A minimum of 4 members*
- *A minimum 3 external members including:*
  - *A New Zealand Veterinary Association nominee*
  - *An approved animal welfare organisation nominee*
  - *A territorial authority or regional council nominee.*

The functions of the AEC as set down in the legislation are:

- considering and making decisions on project applications including renewals, suspensions and revocations;
- setting conditions on project approvals;
- monitoring compliance; and
- monitoring animal management and facilities.

When making its decisions on particular projects, the AEC is required to consider the following (refer to section 7 for assistance on considering and making decisions on proposals):

- The scientific or educational objectives;
- The likely harm and distress to the animal/s and its potential alleviation;
- A weighing of the costs and benefits in the first two considerations;
- Whether the experimental design allows the objectives to be met;
- Whether the choice of species is appropriate;
- Whether the number of animals has been appropriately justified;
- What measures will be taken to ensure the animals' general health and well-being;
- Whether the personnel involved in manipulations are suitably qualified;
- Whether the project duplicates previous work, and if so, whether the duplication is justified;
- Whether the work involves repeated use of animals, and if so, whether this is justified and managed appropriately; and
- Whether there is a commitment to use, promote or publish the results.

4. Role of lay members

The importance of the role of lay members of AECs in ensuring the integrity of the system controlling use of animals in RTT cannot be overemphasised. The following factors cover the most important aspects of their contribution:

- **Independence** – although it is expected that institutions will provide recompense for the time external members of their AECs spend on committee work, this does not compromise the independence of such members from the commercial or everyday activities of the institutions. The three legislatively required external members ensure a degree of public scrutiny that is important in maintaining the integrity of the system.

- **Public representation** – the role of lay members as representatives of the public is the other important aspect in ensuring the integrity of the committee process. While public opinion on the use of animals in RTT varies greatly, an independent survey conducted for MAF in 2005 (Williams et al 2007) showed that a majority of the respondents (68% for research and testing; 72% for

teaching) accepted the use of animals provided there was no unnecessary suffering involved. However, the survey also showed that only 21% of the respondents knew about legislation covering this area, with only about a third of those (i.e. 8% of the total respondents) knowing either "a lot" or "a fair amount" about this legislation. This means that you are representing a public that has little knowledge of the processes of and controls on the use of animals in RTT so that what you may perceive as a somewhat daunting lack of knowledge of this field is absolutely intended and should not be regarded as a handicap.

- **Animal advocate** – as members who are external to the aims and procedures of the various research institutions, lay members may more readily see issues from the animals' point of view, with a focus on improving welfare.

- **Fresh perspective** – familiarity with issues and procedures can sometimes obscure possibilities of change for the better. The value of being able to see research projects and the way animals are used within them from what may be regarded as the relatively naïve perspective of the lay members of AECs has often been proven.

5. Use of animals in RTT in New Zealand

The institutions holding CECs in New Zealand carry out a wide range of activities that fall under the requirement of needing AEC approval. It is important to realise, in determining just which procedures do require such approval, that the everyday meaning of some everyday words may differ in a legal context. An example is the word "animal" for which the legal definition (see below) does not include many of the species which are part of the animal kingdom in a biological sense. The Animal Welfare Act 1999 defines "research, testing and teaching", "manipulation" and "animal" in the following very specific terms:

"Research, testing and teaching" includes:

- *Any work (investigative, experimental, diagnostic, toxicity testing or potency testing) that involves the manipulation of any animal; or*
- *Any work involving the manipulation of any animal to produce antisera or other biological products; or*
- *Any teaching that involves the manipulation of any animal.*

"Manipulation" means:
interfering with the normal physiological, behavioural, or anatomical integrity of an animal by:

- *Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice,*
- *Depriving an animal of usual care*
- *Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or*
- *Enforced activity, restraint, nutrition, or surgical intervention.*

"Animal" is defined as any:

- *Mammal, bird, reptile, amphibian, fish, octopus, squid, crab, lobster, crayfish; and*
- *Mammalian, avian or reptilian pre-hatched young in the last half of gestation or development, and marsupial pouch young.*

Animals are "manipulated" for the purposes of RTT in New Zealand in the following areas:

- Medical research, for example the investigation of treatments for brain damage at the time of birth;
- Veterinary and agricultural research, for example investigations into methods of pain relief for on-farm procedures;
- Biological research including conservation research, for example investigation into the relative humaneness of poisons used in pest control;
- Education – training of doctors, veterinarians, animal technicians and nurses, university and school students, for example the teaching of methods of pregnancy diagnosis to veterinary students;
- Development of veterinary and medical drugs and vaccines, including the testing of their efficacy and safety, for example the development and testing of worming products for farm animals;
- Toxicity testing of food and household products, e.g. testing for marine biotoxins in shellfish;
- Commercial production of antisera and blood products e.g. blood agar for microbiological use.

Most AECs tend to have a particular focus although some of the larger ones, those of the universities for example, may cover a number of different areas.

6. The Three Rs

In 1959, in a book entitled *Principles of Humane Experimental Technique*, two scientists, William Russell and Rex Burch, introduced the concept of the "Three Rs" which have become the fundamental principles underlining the humane use of animals in science and teaching. The "Three Rs" are replacement, reduction and refinement.

a. **Replacement** – To replace sentient animals in experiments at every opportunity. Methods include:
   - The use of less sentient or non-sentient organisms e.g. using invertebrate animals such as earthworms for dissection instead of rats.
   - The use of *in vitro* techniques e.g. using tissue cultures to screen products for toxicity.
   - The use of non-biological replacement alternatives e.g. the use of sophisticated models for the teaching of veterinary procedures such as intubation and intravenous injections.
   - The use of human studies e.g. the use of volunteer human subjects for drug testing.

b. **Reduction** – To reduce both the numbers of experiments, and the number of animals used within experiments, to the minimum possible. This might include:
   - Ensuring that experiments are necessary in that there is no other way to find the information sought.

- Ensuring that experiments are necessary in that the work has not been done before.
- Ensuring that statistical analyses are used to reduce numbers of animals within experiments to the minimum consistent with achieving meaningful results.

c. Refinement - To minimise or eliminate any animal suffering involved. This might include:
- Improving animal husbandry and environmental conditions for research animals.
- The use of anaesthesia and analgesia where appropriate.
- The use of humane endpoints (see Glossary).

7. Considering proposals

a. Ensure you are familiar with the way your particular AEC operates. You should be given a copy of the CEC which will detail committee processes. For example, you need to know whether your committee makes its decisions on a consensus or a majority basis. There should also be mechanisms in place to ensure that all members, including lay members, have opportunities to express their opinions, ask questions or air concerns. You should also be given a copy of any standard operating procedures (SOPs) your AEC uses.

b. Do not be afraid to ask questions. In order to fulfil your role on the AEC, it is essential that you ask as many questions as you need to understand what is being proposed in terms of the research, testing or teaching. While other members of the committee may be familiar with scientific terms and procedures, they will understand that lay members may not be, and will welcome your questions.

c. What to look for – the list of considerations required of AECs when assessing RTT proposals is listed in Section 3. Further clarification is given below:

- *The scientific or educational objectives* – you need to be able to clearly understand what these are in order to make a sound assessment. This means that the objectives **must** be given in language that a lay person can understand. You need to be able to understand the benefits of this research, testing or teaching.

- *The likely harm and distress to the animals and its potential alleviation* – information on this may be available from other committee members with appropriate experience, or from the veterinarian (or animal technician if present) on the AEC. If this cannot be adequately determined, it is common practice for AEC members to observe procedures for themselves if they so request. If procedures are considered to have a higher degree of impact on the animals concerned, methods to minimise pain and distress need to be considered, and the frequency of monitoring of the animals must be acceptable to the AEC members. Committee members need to be satisfied that those who will be doing the monitoring are skilled in identifying pain in the relevant animal species. Harm and distress should be considered in terms of overall impact on the animal, including both the invasiveness of procedures and their duration. Researchers should also have contingency plans in place in case of unexpected outcomes, established humane endpoints and

methods of euthanasia should be appropriate to the species – the veterinarian on the AEC should be able to give information on this. See also Reilly (2001).

- *A weighing of the costs and benefits in the first two considerations* – this will depend on the assessments made in the first two bullet points and weighs up the benefits of the research against the cost to the animals. Generally speaking, the higher the cost in terms of harm and distress to the animal, the greater must be the justification in terms of the perceived benefits to animals or people for carrying out the procedure.

- *Whether the experimental design allows the objectives to be met* – the way the research is to be carried out must be both logical and practicable. If the objectives cannot be met, the animals will have been used, and may have been exposed to pain or distress, unnecessarily.

- *Whether the choice of species is appropriate* – the type of animal chosen needs to be justified, including why animals need to be used at all.

- *Whether the number of animals has been appropriately justified* – it is important that the numbers of animals used is the minimum necessary to obtain statistically valid results. Too few animals will result in wastage if results are statistically invalid. A statistical justification is important where appropriate.

- *What measures will be taken to ensure general health and well-being* – it is part of the role of the AEC to monitor the institution's animal management and facilities. This means that the AEC must be satisfied that the environmental, nutritional and behavioural needs of animals are being taken into consideration. *The Good Practice Guide for the Use of Animals in Research, Testing and Teaching* contains information on best practice for the management of animals and facilities.

- *Whether the personnel involved in manipulations are suitably qualified* – experience of personnel should be specified. If personnel are inexperienced, a system of training and monitoring should be specified.

- *Whether the project duplicates previous work, and if so, whether the duplication is justified* – researchers should be aware through literature searches, collegiality and journal reading as to developments in their particular field of research. However, it is not always possible to ascertain duplication of work as issues such as commercial sensitivity, or even failure of the research to achieve meaningful results, may preclude publication of results. However, researchers should be able to justify their proposed work as novel to the best of their ability.

- *Whether the work involves repeated use of animals, and if so is this justified and managed appropriately* – there are certainly instances where it is appropriate to re-use animals a number of times, but this is always something that needs to be looked at closely, and well justified.

- *Whether there is a commitment to use, promote or publish the results* – in order to justify the use of animals in this way, the work being done must have some meaning that will impact on the lives of humans or animals.

8. Appendices

a. Glossary

Term	Meaning
Alternatives	Procedures or approaches in a particular line of research that are preferred above others because they replace, reduce or refine the use of animals in that research
Anaesthesia	State of unconsciousness induced to enable surgical procedures
Analgesia	Pain relief
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research and Teaching
Distress	The signs of inability of an animal to adapt to changing circumstances. This is often recognised by changes in the behaviour typical of the species.
Euthanasia	Induction of a humane death.
Humane endpoint	"The point at which an experimental animal's pain and/or distress is terminated, minimised or reduced by taking actions such as humanely killing the animal, terminating a painful procedure, or treating to relieve pain and/or distress". (Canadian Council for Animal Care)
In vitro	Outside the living body and in an artificial environment.
In vivo	In the living body.
NAEAC	National Animal Ethics Advisory Committee
Pain	An unpleasant sensory and emotional experience associated with actual or potential tissue damage.

b. Resources and references

Anon. (2002) Good Practice Guide for the Use of Animals in Research, Testing and Teaching. NAEAC, MAF, Wellington.

Anon. (2000) The Use of Animals in Research, Testing and Teaching - Users Guide to Part 6 of the Animal Welfare Act 1999. MAF, Wellington.

Monamy V. (1996) Animal experimentation: a student guide to balancing the issues. ANZCCART.

Reilly J (ed) (2001). Euthanasia of Animals Used for Scientific Purposes (ed. J Reilly) 2nd edition, ANZCCART.

Smith, JA and Jennings, M. (2003) A resource book for lay members of local ethical review processes. Royal Society for the Prevention of Cruelty to Animals.

Williams VM, Dacre IT, Elliott M. (2007) Public attitudes in New Zealand towards the use of animals for research, testing and teaching purposes. New Zealand Veterinary Journal (In press)

http://altweb.jhsph.edu/index.htm - Altweb, the Alternatives to Animal Testing Web Site, was created to serve as a gateway to alternatives news, information, and resources on the Internet and beyond and is based in Johns Hopkins University in the United States of America

http://www.**nc3rs**.org.uk/ - website of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)