

2009 - A Year of Animal Welfare Milestones

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The year 2009 marks the 50th anniversary of the publication of the book by Russell and Birch entitled "The Principles of Humane Experimental Technique", which introduced the principles of 'Replacement', 'Reduction' and 'Refinement' – now commonly known as the 3Rs. 2009 also marks the 40th anniversary of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, which is now in its 7th Edition.

Earlier this year, while speaking at a number of training days for new investigators (as well as many far more experienced researchers), I was asked by one member of an audience "Why has the Code suddenly been overtaken by a passion for the 3Rs and why this suddenly interest in them?" Another member of a separate audience (in response to my mentioning that this was the 50th anniversary of the 3Rs) asked "What progress - if any - has been made towards implementing the basic principles of the 3Rs and why have we achieved so little in this regard during these past 50 years?" Thinking back, it seems such a shame

that these questions arose in separate institutions on different days, as together they effectively highlight two quite distinct perspectives that in reality are so inextricably linked. They also may possibly help to answer both questions at the same time.

The first inquisitor was a little surprised, but never the less, quite reassured by the knowledge that the principles of the 3Rs were not merely a product of the wine consumed at a recent ANZCCART conference, but a rather well thought out set of principles that had now certainly stood the test of time. I am not so sure however, that the person who asked the second question was completely won over when I explained that the 3Rs had not only achieved very broad acceptance and adoption by many among the scientific community, but they were also the underlying principles upon which the Australian Code of Practice is based.

While I accept that these two questions may represent minority perspectives in Australia today, I think they do highlight the important role that Institutions, Animal Ethics Committees (AECs),

Researchers, Teachers and ANZCCART must all accept and share. It is imperative that anyone with even a passing interest in the care and use of animals for research and teaching be aware of the checks and balances that are in place to ensure that all such animals are cared for in the best possible way. We must ensure that all these people are aware of the Code and the make up of AECs and the responsibilities that everyone who is involved must accept. The fact that in 2009 we have both a huge disparity in opinions about the scientific use of animals and at the same time, we find there are still people who are unsure if they even need to seek approval from a duly constituted AEC before they can undertake a project of some kind that may (even peripherally) involve direct interaction with animals, indicates that there is still a lot of educative work to be done.

Interestingly, this 40th anniversary of our Code of Practice sees the process of review and presumably the writing the 8th edition starting. Once again, opinion will inevitably be divided among those that believe we are still getting used to the 7th edition and others who may be hoping for more guidance in some areas or a major revamp of part or all of the Code. Fortunately, the committee charged with the responsibility of reviewing and revising the Code is – like any AEC, made up of a very diverse group of people who represent different perspectives and opinions. We should also be reassured by the fact that the process of review and revision includes ample opportunity for comment through the public consultation process it undergoes.

The Australian Code of practice has come a long way during its 40 year life. It has evolved from a voluntary code that was written by a group of forward thinking scientists, to a Code of Practice that is enshrined in the animal welfare legislation of every Australian State and Territory that has been written by a large and diverse group, which in itself mimics the constitution of an AEC. While it may still be underpinned by the basic principles of the 3Rs, this evolution has helped to ensure that it also does a pretty good job of reflecting what most believe to be the collective attitude of Australians and hopefully some of the highest international

standards as well. The fact that the Australian Code of Practice has been adopted by a number of other countries around the world as the basis of their own governing regulations would certainly offer strong support in this regard.

So as we celebrate two important milestones this year and we acknowledge that we live in an imperfect world where we do still unfortunately need to use animals in research and teaching, perhaps it might be worth stopping to think how far we have come in implementing the principles of the 3Rs and how far we still have to go.

Dr Geoff Dandie
CEO, ANZCCART

In Memorium – Dr John Barnett

While the recent Black Saturday bushfires resulted in a horrifying toll of death and destruction – both human and animal, for the Australian animal welfare community it became all the more personal and significant when news emerged that the toll included people like Dr John Barnett and his wife Jenny both of whom died when the fires hit their Steels Creek home.

John was a member of the Animal Welfare Science Centre in Victoria and known internationally as an outstanding researcher whose work had enhanced the welfare of domestic animals, particularly poultry and pigs over a number of years.

The profound effect this tragedy has had on so many people around Australia and the world is possibly best exemplified by the tributes that have been posted in the months since. The Animal Welfare Science Centre has received many messages of condolence and tributes to John's professional and personal life and has encouraged John's many friends and colleagues to forward their messages to them so that they can put together a permanent record of their thoughts. (If you would like to send in your message please email it to

awsc-info@unimelb.edu.au). Similarly, The Victorian National Parks Association has set up a page for dedications to Jenny. Visit: http://www.vnpa.org.au/subssubsection.php?subsection_id=5&subsubsection_id=277

Tributes have been received from friends and colleagues the length and breadth of Australia as well as many from New Zealand, USA, The Netherlands and Sweden. They represent the many facets of John's working life and include representatives from many leading researchers and research institutes, industry groups, animal welfare groups and organizations, professional bodies and governments. Not surprisingly, Jenny's passing has also effected wildlife care groups and environmentalists in a very personal way and resulted in a number of tributes.

While the care of farm animals and continual improvement in their welfare was the prime focus of John's work throughout his career, he was also able to apply his findings in the area of the use of animals in research and teaching and it was in this capacity that he had most contact with ANZCCART. This is perhaps best exemplified by the excellent article John wrote for ANZCCART News in June 1997. His article "The use of pigs for research and examples of research on housing and handling" (*ANZCCART News Vol 10 number 2, June 1997*) clearly demonstrated his outlook and commitment.

It goes without saying, that everyone associated with ANZCCART mourns the loss of John and Jenny Barnett and the contribution to animal welfare that they should still be making.



Animals Used for Research and Teaching

A Category D Perspective, or Ds Matter a Lot

Dr John Hatch, Adelaide University

Background

1985 was an important year. It was the date of the South Australian Prevention of Cruelty to Animals Act, and I joined the already quite experienced, but informal University of Adelaide AEC. Since then I have been a 'D' on one or more AECs continuously. Once a D always a D!

In the early days there were no Ds, but the Code of Practice which rapidly became the 'Bible' refined and reorganised the membership of AECs and in its fifth incarnation (dark green, 1989), the Code defines a compulsory category D as follows,

"An independent person who does not currently and has not previously conducted experiments using animals, and who is preferably not an employee of the institution."

The current Code, (Edition seven, blue and white) basically uses the same definition but with the additional comment that,

"Category D members, (note the plural) should be viewed by the wider community as bringing a completely independent view to the AEC , and must not fit the requirement of any other category"

A residual? No.

The Role of the D

Consider the definition of the D. It stresses **Independence. The D carries none of the baggage of the researcher, the Animal Welfarist or even the veterinarian.** I say this not to denigrate the role of other members but to point out an advantage that the D has. It points up their wider public role and make no mistake about it, the public does care about how we use animals

in research. We have a constituency, which is the concerned and informed public.

I sometimes describe myself as the ignoramus on the committee, but I see ignorance as almost a virtue in this context. Ethics is about the way things '...ought to be' and therefore requires imagination as well as information.

In the collective interactive discovery process which is mandated for AECs the freedom of the D is often crucial. Together with the Cs, but even more so, the D can be ignorant of technical matters without shame. We are not expected to know a whole raft of scientific knowledge and I view with some apprehension overzealous attempts to train us.

My old colleague on the Adelaide University AEC, Professor Graham Nerlich wrote an excellent long letter in the June 1997 ANZCCART News where he discussed the value of the Lay Description and in doing so the implicitly the importance of the Lay Members. I commend the piece to you. Lay members can often 'smell a rat', pun intended, because they have to think harder about the protocol. Often they bring to the surface things which are ill-defined or ill-understood by the experts. As Graham Nerlich points out, if you cannot explain something broadly to an interested and educated layman, then you probably do not really understand it yourself.

Problems for the D

The D is often isolated having no regular colleagues and no apparently relevant discipline or training. This can lead to a very passive role. It should not since your interpretation of community values is vital to the process. Start by insisting that the **lay descriptions** are just that. **Send them back if they are not.**

Almost certainly some of the experts will thank you. After all, scientists have an enormous range of backgrounds. A good start is to believe in yourself and your role. **You do matter a lot and you can often change a decision or even more importantly in the long run change the way a committee works.**

Editors Note: The following article is an excellent summary of the New Zealand operating environment. Australian readers are reminded that both the nomenclature used and significant portions of the content do not apply in Australia, but this article provides an interesting perspective on other systems.

Regulation of animal use in research, testing and teaching in New Zealand - the black, the white and the grey

*Linda A Carsons, Animal Welfare Directorate
MAF Biosecurity New Zealand*

This article updates one that appeared in Surveillance in 1998.⁽¹⁾

The law requires those who manipulate live animals for the purposes of research, testing or teaching to do so in accordance with an approved code of ethical conduct and with the approval of an animal ethics committee established under that code. Deciding which activities are encompassed by this requirement, and which are not, is not always straightforward.

Historical background

In 1983 the Animals Protection Act 1960 was amended to remove the exemption from the provisions of the Act previously enjoyed by 'bona fide research workers'. The amendment provided for regulations to be made to control the use of live animals in research, experimental, diagnostic, toxicity or potency testing work and teaching. It was the result of submissions made by the Royal Society of New Zealand to the Minister of Science.⁽²⁾ The regulations, the Animals Protection (Codes of Ethical Conduct) Regulations 1987, came into force in early 1987 and took effect from 1 September that year. The scope of the regulations was later extended to include work for the purposes of producing antisera or other biological agents (from 1 July 1988).

The 1983 amendment also required the Minister of Agriculture (the Minister responsible for administration of the Act), to establish a committee to advise the Minister on matters related to the use of animals in research, testing and teaching and in particular, the content of codes of ethical conduct. Thus, the National Animal Ethics Advisory Committee (NAEAC) was created.

This legislation was replaced, from 1 January 2000, by the Animal Welfare Act 1999. Part 6 of the Animal Welfare Act, although similar to the previous statutory and regulatory regime, is more comprehensive and provides greater clarity as to process and procedure. New features included:

- a statutory requirement for animal ethics committees to be established and to approve projects;
- greater ethical guidance for animal ethics committee members on the factors that they must take into account before deciding whether to approve a project, including the promotion of the Three Rs;
- a stronger focus on monitoring projects to ensure compliance;
- requirements for independent reviews of code holders and their animal ethics committee(s) by a MAF-accredited reviewer.⁽³⁾

Issues

The Animal Welfare Act contains definitions of the terms 'animal', 'manipulation' and 'research, testing and teaching' (see appendix 1).

In trying to determine whether an activity needs animal ethics committee approval, it is useful to use a three step test:

1. Is the activity being performed on a live animal (as defined)?
2. Does the activity constitute a manipulation (as defined)?
3. Does the reason that the activity is being performed fall into the category of research, testing, or teaching (as defined)?

If the answers to all three questions are 'yes' then the activity must be performed in accordance with

an approved code and with the approval of the animal ethics committee. If the answer to any of the questions is 'no' then animal ethics committee approval is not necessary.

A flowchart has been developed by NAEAC to assist in such deliberations (see appendix 2).

The black ...

Some examples of activities which clearly require animal ethics committee approval are:

- basic biological, biomedical, veterinary and agricultural research using live animals;
- non-recovery surgery carried out by veterinary students as part of their training;
- testing animal vaccines on laboratory rodents.

Although it may not be the first legal issue which springs to mind when considering rabbit calicivirus disease (RCD), the spreading of the RCD virus by injecting caged rabbits with the virus mixture for the production of additional virus material and releasing them into the wild is also an activity which requires ethical approval. The decision-making process for this example is as follows:

- rabbits fall within the definition of animal;
- injecting them with a viral mixture is exposing them to a micro-organism, and is therefore a manipulation;
- the purpose of the activity is the production of biological products, which falls within the definition of research, testing and teaching.

Note, however, that harvesting dead rabbits for the same purpose does not require ethical approval.

... the white

There are other activities which definitely do not require a code of ethical conduct. For example, keeping animals in kindergartens/classrooms as pets or for purely observational purposes does not involve a manipulation and thus does not require a code.

Dissections on carcass material do not require ethical approval either. The Act is specifically restricted to live animals. An exemption is provided for the killing of animals in order to undertake research, testing or teaching on dead animals or 'prenatal or developmental' tissue provided the animal is killed humanely.

For the same reason, farming practices which involve surgical procedures (such as tailing or castration) when done in the context of routine farm management are not manipulations, because they are not being performed for the purposes of research, testing and teaching. However, it is worth noting that the same procedures do require ethical approval in some circumstances. One example would be where the procedures were being carried out as part of a research programme to compare different methods of castration.

There are other exemptions for veterinarians carrying out trials on animals in their immediate care for clinical diagnostic purposes, for clinical assessment of a proposed treatment regime or for productivity assessment. The veterinarian must believe 'on reasonable grounds' that the animals concerned will not suffer unreasonable or unnecessary pain or distress or lasting harm.

Similarly, certain activities such as assisting the breeding, translocation of animals and the like, carried out under conservation or fisheries legislation is also exempted from the need for approval by an animal ethics committee.

...and the grey

There are a number of activities which fall within a "grey" area i.e. where the answer to one or more of the questions in the three step test is not immediately clear or is a matter of judgement.

One issue that has arisen a number of times over the years is blood harvesting. Given that reference was made to the production 'of antisera and other biological agents', in the Animals Protection Act, blood harvesting was considered to fall within the range of activities requiring a code of ethical conduct. Under current legislation, careful consideration of the precise nature of the harvesting and of the legal definitions is required.

Given that the animals involved in commercial blood harvesting are usually livestock, then clearly they fall within the definition of animal. The purpose of the work is to produce blood, which is a 'biological product', so the activity falls within the definition of research, testing and teaching. However, while harvesting blood simply by insertion of a hypodermic needle into a vein may be insufficient to constitute 'surgical intervention',

the restraint involved in the collection process is considered to meet the criteria specified in the definition of manipulation. Thus blood harvesting by this method requires ethical approval. Furthermore, the collection of blood by indwelling catheter would be regarded as a surgical intervention, and therefore need approval, and situations where substances (eg antigens) are administered to the animal prior to blood collection would also require ethical approval on the basis of exposure to drugs, chemicals, micro-organisms et cetera.

Another grey area relates to what might be termed "incidental" manipulations. Wild animals (eg possums) may be required for research projects so they are captured. In order to ensure that there are sufficient animals to meet any age or sex ratio requirements more animals are captured than are needed for the project. Some surplus animals are euthanased, others may die before being assigned to a specific research project. The question is, should these animals be regarded as having been manipulated? Capture and holding in captivity does not constitute a manipulation. Thus possums which are not actually used in a research project are not manipulated and numbers should not be included in statistical returns.

Prior to the Animal Welfare Act coming into force, the use of foetuses was considered a grey area as it was unclear at what point an animal became an animal. The Animal Welfare Act largely resolved this by specifying that the definition of animal includes marsupial pouch young, mammalian foetuses in the second half of gestation and pre-hatched birds or reptiles in the second half of development. Thus an inquiry regarding the need for ethical approval for a teaching project involving embryonic zebra fish elicited the response that ethical approval was not required because a zebra fish embryo does not fall within the definition of animal.

Debate arises regarding training courses. There are a number of courses at the senior secondary school, pre-employment or polytechnic level which teach animal handling/husbandry or veterinary nursing skills. The animals involved are generally livestock or companion animals. Two of the criteria are clearly met - the animals fall within the definition and the activity is

for teaching purposes. The question to resolve is, is it a manipulation? Docking tails certainly interferes with the anatomical integrity of an animal. One may decide that teaching people to dock tails during a training course is a manipulation. The ramifications of this are possible perceptions of 'bureaucracy gone mad', not to mention an argument for saying that every farmer who teaches a new farmhand some animal handling skills needs a code of ethical conduct.

On the other hand, bringing the family pet into a veterinary nursing course so that students can practise injection techniques repeatedly may be an activity that more readily suggests the need for ethical approval.

The rule of thumb developed to cover these types of situations is that if the procedure that is performed in a teaching situation would be performed anyway (eg the trainees are learning how to drench sheep that were due to be drenched) then coverage by a code is not necessary. However, if the procedure is one which would not have been carried out at the time, or if the procedure is repeated a number of times, then careful consideration of the legal definition of 'manipulation' is necessary and a code of ethical conduct may be advisable.

Conclusion

The requirement for codes of ethical conduct have now been in place for 20 years and some 30-odd organisations have a code of ethical conduct which has been approved by the Director-General of MAF. Over 70 additional organisations or individuals have a formal arrangement, in accordance with the relevant provisions of the Animal Welfare Act, to use another organisation's approved code. Such codes ensure that the welfare and humane treatment of live animals used for research, testing and teaching is fully considered by an animal ethics committee (which includes at least three members from outside the organisation) prior to any manipulations being performed.

If anyone is unclear whether particular activities need approval by an animal ethics committee, the flowchart and legal definitions should be the first reference point. If further assistance is required they are advised to contact MAF Biosecurity New Zealand's Animal Welfare Directorate.

Appendix 1: Definitions from the New Zealand Animal Welfare Act 1999

Excerpt from section 2(1)

"Animal"--

- (a) Means any live member of the animal kingdom that is--
- (i) A mammal; or
 - (ii) A bird; or
 - (iii) A reptile; or
 - (iv) An amphibian; or
 - (v) A fish (bony or cartilaginous); or
 - (vi) Any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish); or
 - (vii) Any other member of the animal kingdom which is declared from time to time by the Governor-General, by Order in Council, to be an animal for the purposes of this Act; and
- (b) Includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development; and
- (c) Includes any marsupial pouch young; but
- (d) Does not include--
- (i) A human being; or
 - (ii) Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage:

5 Definition of New Zealand "research, testing, and teaching"--

- (1) In this New Zealand Act, unless the context otherwise requires, the term "research, testing, and teaching" means, subject to subsections (2) to (4),-
- (a) Any work (being investigative work or experimental work or diagnostic work or toxicity testing work or potency testing work) that involves the manipulation of any animal; or
 - (b) Any work that
 - (i) Is carried out for the purpose of producing antisera or other biological products; and
 - (ii) Involves the manipulation of any animal; or
 - (c) Any teaching that involves the manipulation of any animal.
- (2) The term defined by subsection (1) does not include any manipulation that is carried out on any animal that is in the immediate care of a veterinarian,

if--

- (a) The veterinarian believes on reasonable grounds that the manipulation will not cause the animal unreasonable or unnecessary pain or distress, or lasting harm; and
 - (b) The manipulation is-
 - (i) For clinical purposes in order to diagnose any disease in the animal or any associated animal; or
 - (ii) For clinical purposes in order to assess the effectiveness of a proposed treatment regime for the animal or any associated animal; or
 - (iii) For the purposes of assessing the characteristics of the animal with a view to maximising the productivity of the animal or any associated animal.
- (3) The term defined by subsection (1) does not include any manipulation of an animal--
- (a) Which is carried out with the principal objective of-
 - (i) Assisting the breeding, marking, capturing, translocation, or trapping of animals of that type; or
 - (ii) Weighing or taking measurements from the animal; or
 - (iii) Assessing the characteristics of animals of that type; and
 - (b) Which is a manipulation of an animal that-
 - (i) Is carried out routinely; or
 - (ii) Is a minor modification of a manipulation that is carried out routinely; and
 - (c) Which is used to fulfill responsibilities and functions under-
 - (i) The NZ Conservation Act 1987; or
 - (ii) Any Act listed in the First Schedule of the Conservation Act 1987; or
 - (iii) Any other Act or regulations under which the NZ Minister of Conservation or the Director-General of Conservation or the Department of Conservation has responsibilities or functions; or
 - (iv) The NZ Fisheries Act 1996.
- (4) For the purposes of this section, an animal is in the immediate care of a veterinarian if the veterinarian-
- (a) Has accepted responsibility for the health and welfare of the animal; and
 - (b) Is providing the animal with direct and continuing care.

(5) In the other sections of this Act (except section 57(a)(i)),-

- (a) The term "research" means any research work that comes within the term defined by subsection (1); and
- (b) The term "testing" means any testing work that comes within the term defined by subsection (1); and
- (c) The term "teaching" means any teaching that comes within the term defined by subsection (1).

3 Definition of "manipulation"-

(1) In this Act, unless the context otherwise requires, the term "manipulation", in relation to an animal, means, subject to subsections (2) and (3), interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately--

(a) 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 and which involves-

- (i) Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or
- (ii) Enforced activity, restraint, nutrition, or surgical intervention; or

(b) Depriving the animal of usual care;-

and "manipulating" has a corresponding meaning.

(2) The term defined by subsection (1) does not include-

- (a) Any therapy or prophylaxis necessary or desirable for the welfare of an animal; or
- (b) The killing of an animal by the owner or person in charge as the end point of research, testing, or teaching if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress; or
- (c) The killing of an animal in order to undertake research, testing, or teaching on the dead animal or on prenatal or developmental tissue of the animal if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress; or
- (d) The hunting or killing of any animal in a wild state by a method that is not an experimental method; or
- (e) Any procedure that the Minister declares, under subsection (3), not to be a manipulation for the purposes of this Act.

(3) The Minister may from time to time, after consultation with the National Animal Welfare Advisory Committee and the National Animal Ethics Advisory Committee, declare any procedure, by notice in the Gazette, not to be a manipulation for the purposes of this Act.

(4) The Minister must, in deciding whether to publish a notice under subsection (3) in relation to a procedure, have regard to the following matters:

- (a) The nature of the procedure; and
- (b) The effect that the performance of the procedure will or may have on an animal's welfare; and
- (c) The purpose of the procedure; and
- (d) The extent (if any) to which the procedure is established in New Zealand in relation to the production of animals or commercial products; and
- (e) The likelihood of managing the procedure adequately by the use of codes of welfare or other instruments under this Act or any other Act; and
- (f) The consultation conducted under subsection (3); and
- (g) Any other matter considered relevant by the Minister.

Acknowledgements

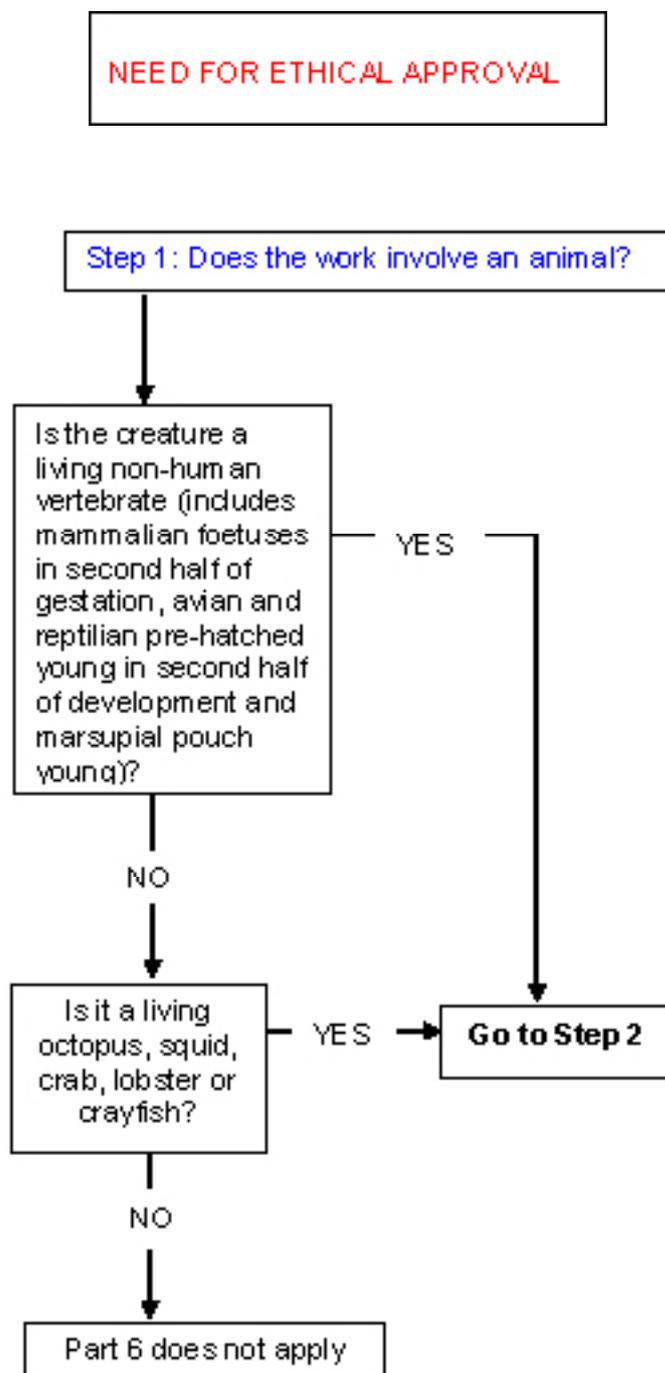
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- (2) Reid CSW. Ethics, animals, science and the Royal Society. In: Royal Society of New Zealand. *The Use and Welfare of Experimental Animals*. Pp 79-82. The Royal Society of New Zealand, Wellington 1990.
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Appendix 2: Need for ethic approval flowchart



Step 2: Is the work research, testing or teaching (RTT)?

Is it research? Is it:
- Investigative work
- Experimental work
- Diagnostic work

YES

NO

Is it testing? Is it:
- Toxicity testing work
- Potency testing work

YES

NO

Is it to produce antisera or other biological products?

YES

NO

Is it teaching?

YES

Go to Step 3

Note: Excluded from this definition are:

- Certain manipulations carried out on an animal in the immediate care of a veterinarian and
- Certain procedures carried out for breeding, marking, capturing, translocation or trapping animals
- See section 5(2) – (4)

Part 6 does not apply. Part 1 applies

Obligation to provide for physical, health and behavioural needs of the animal – section 10

Step 3 Is the work a manipulation of an animal?

Will the procedure interfere with the normal psychological integrity of the animal?

YES

NO

Will the procedure interfere with the normal behavioural integrity of the animal?

YES

NO

Will the procedure interfere with the normal anatomical integrity of the animal?

YES

NO

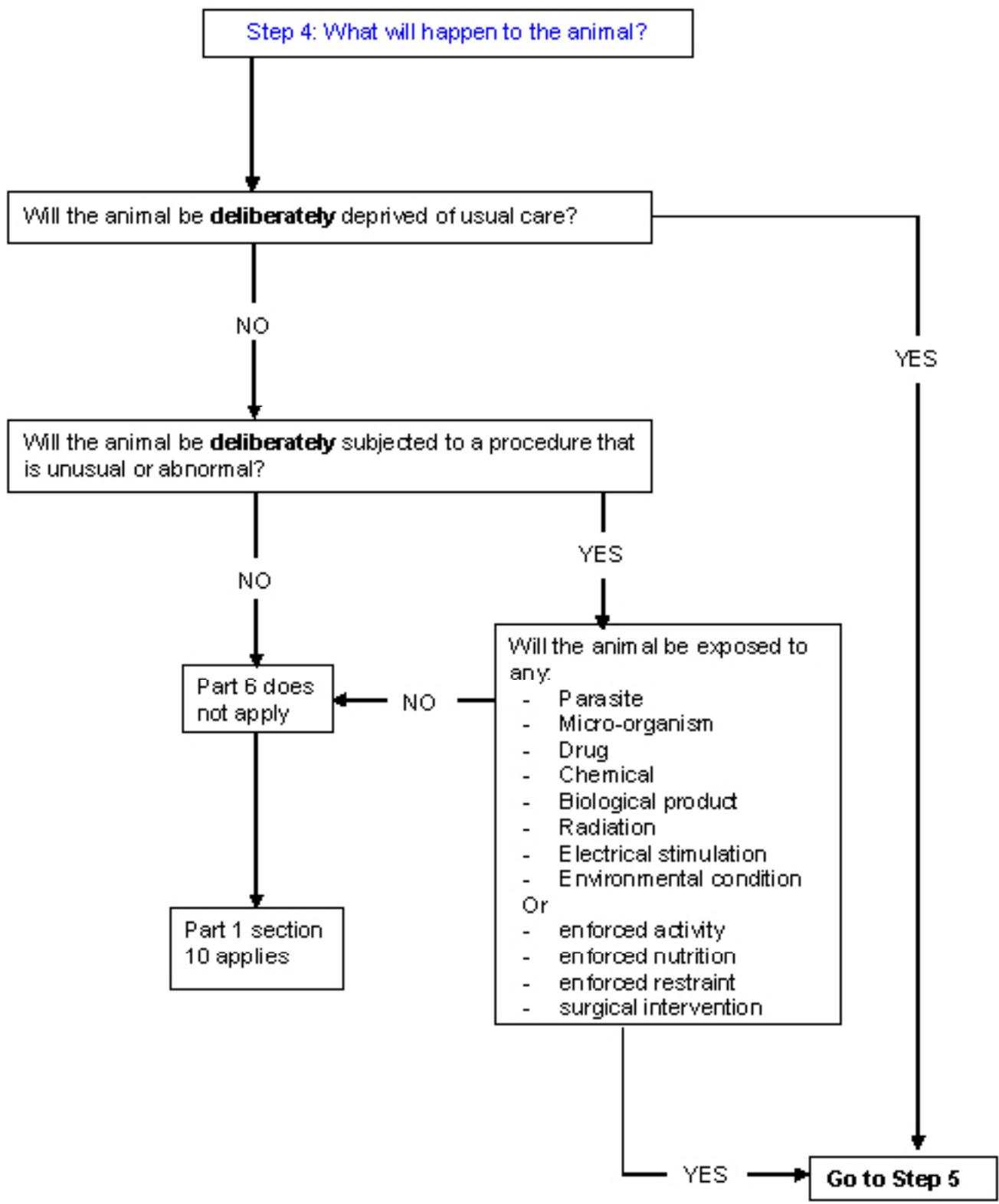
Part 6 does not apply

Part 1 section 10 applies

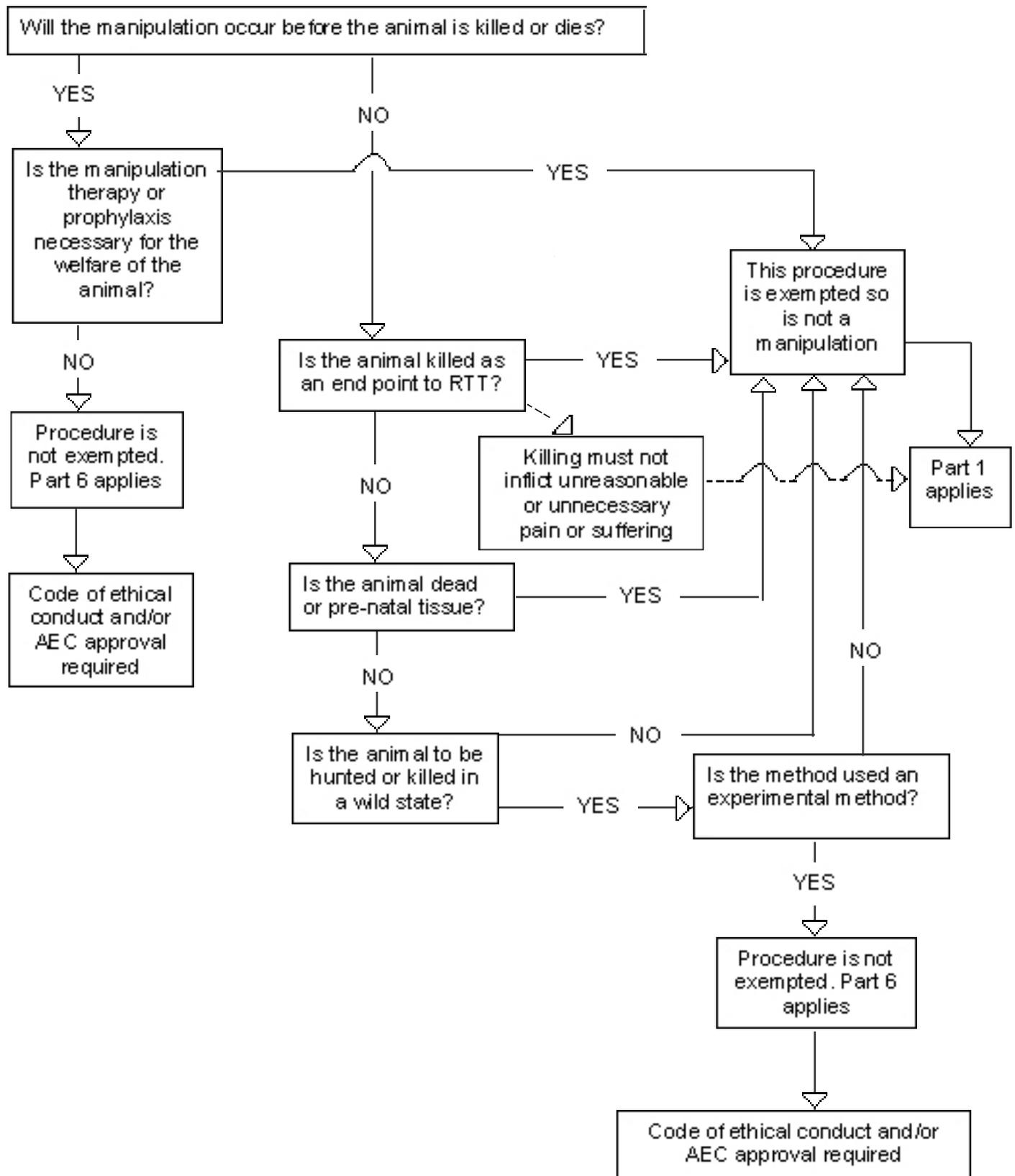
Part 6 may apply

Code of ethical conduct and/or AEC approval may be required

Go to Step 4



Step 5: Is the work an exclusion from manipulation?



Readers are reminded that the above article is an excellent summary of the New Zealand operating environment. Australian readers are reminded that both the nomenclature used and significant portions of the content do not apply in Australia, but provide an interesting perspective on other systems of regulation.

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