

HUMANE RESEARCH AUSTRALIA INC.
Suite 205, 19 Milton Parade, Malvern 3144
SUBMISSION TO NHMRC
(Also sent via post)

28 November 2011

Project Officer – *Australian code of practice for the care and use of animals for scientific purposes*
Health & Research Ethics Section
Research Translation Group
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Dear Sir/Madam,

Re: Public Consultation on the *Australian code of practice for the care and use of animals for scientific purposes*.

Humane Research Australia opposes the use of animals in research and teaching on both ethical and scientific grounds. We do not in any way condone the use of animals for scientific purposes regardless of whether or not their use is in accordance with any code of practice. We do however wish to comment on the following major areas of concern in the draft code:

The code relies on self regulation and whilst the governing principles contained within the code seem to be generally protective of animals, there is extreme weakness in its enforceability.

On page 12 for example (Responsibilities of Institutions) implementation of policies and procedures is left to individual institutions, which means inconsistency throughout the research community. Similarly, animal ethics committees operate on the institutional level and studies have shown lack of consistency.

In July 2002, the journal *Science* featured a study of the role of Institutional Animal Care and Use Committees. The study involved a comparison of judgements on 150 protocols made by randomly selected committees to assess the consistency of the decision-making process. The results showed that decisions were inconsistent, with experiments approved by one committee being rejected by another. The author commented "*As an animal researcher I was surprised by the results. These committee members are smart, dedicated people. If the reliability of their proposal reviews is at chance levels – literally – a coin toss, then the review system needs to be fixed.*"

An independent body would enable the oversight, consistency and regulation of all aspects of animal research. This group of experts could be specifically trained to ensure uniformity in decision-making, would have expert knowledge about ethics, scientific knowledge about the available alternatives and how to identify them, and would also serve to avoid the duplication of work between institutions. Such a body however, should be part of a separate government department charged specifically for consideration of animal welfare. The priority of the National Health and Medical Research Council is to promote human health and medical research. There is clearly a conflict of interest when considering the welfare of non-human animals.

Governing principles (page 5) specifically states “using animals only when it is justified”.

The attached ‘Case Studies’ clearly demonstrate that this principle is NOT being adhered to. HRA questions why any of these government-funded experiments were ever permitted to proceed.

Point 1.9 (page 6) acknowledges that “animals may perceive and respond to circumstances via different neurological and sensory mechanisms...” however these ‘species differences’ should also be considered in respect to their unsuitability as models for human disease. This needs to be reinforced under the heading “Replacement” (page 8).

It is now becoming increasingly acknowledged by medical experts that reliance on data obtained from animals and extrapolated to human conditions is often misleading. Species differences – anatomic, genetic and metabolic differences mean that a drug, a surgical procedure or a genetic modification can result in vastly different outcomes from one species to another. Consider for example that according to Food and Drugs Administration (the regulatory authority in the United States) nine out of ten drugs deemed successful in animal tests fail in human trials.¹

As stated by WMS Russell, *The Principles of Humane Experimental Technique*, 1959
*“Refinement is never enough, and we should always seek further reduction and, if possible, replacement... Replacement is always a satisfactory answer.”*²

Lack of transparency has always been a concern surrounding animal research. Point 2.1.11 (page 14) reads that institutions “should consider making publicly available” annual reports and summaries of external reviews. HRA considers such data MUST be made publicly available.

Considering that research funded by the NHMRC is essentially paid with public funding it seems incongruous that such information be withheld from the public.

An opinion poll commissioned by Humane Research Australia in 2009 revealed that the majority of Australians are opposed to animal experiments and call for more funding to be allocated to seeking scientific alternatives. Key findings from the survey include:

- Only 62% of the general public is even aware that animals are used in experimental research in Australia these days.
- 58% of respondents do not believe that humans have the moral right to experiment on animals.
- Only 18% of respondents indicated that they would donate to health or medical research charity if they knew it were funding animal experiments.
- More than half the population (53%) do not believe that it is always safe to transfer results from animal research to apply to humans.
- When reminded/informed about the drugs ‘successfully’ tested on animals that had caused harm to humans (such as Thalidomide, Vioxx, DES), 78% indicated they were concerned.
- 87% consider that the number of animals used for research and teaching in Australia is unacceptable or is capable of reduction.
- 71% support the use of scientific alternatives to the killing of animals in research.

¹ *FDA Issues Advice to Make Earliest Stages Of Clinical Drug Development More Efficient. Press release / FDA 12jan2006*

² WMS Russell, *The Principles of Humane Experimental Technique*, 1959 (Quoted in ATLA 34, 271-272, 2006.)

- 79% support allocating a proportion of medical research grants to funding scientific alternatives to animal experiments.

Clearly, the Australian community has an interest in animal research. They should be entitled to know how public funding is spent, how animals are used and on what basis medical research is conducted. For too long this industry seems to have been shrouded in secrecy with few people actually being aware of the extent of animal research in Australia.

*“..those who sit on the Animal Research Review Panel and on ethics committees are bound by strict confidentiality, meaning that even if there were a problem, that problem could not be brought to the attention of the general public. This means that animals used in research and education are not afforded the protection which may flow from ‘the court of public opinion’.”*³

Composition of AEC’s (page 19) includes Category C and D which denotes the animal welfare and ‘public’ representatives. Neither category requires any formal qualification however, and it is unlikely that such persons would have sufficient scientific knowledge to challenge the justification of the protocols presented to them nor have much understanding of the available alternatives.

Ethics committees are currently the only real level at which the validity and justification of the research can be challenged and so it’s imperative that they are used for maximum impact.

A core responsibility of these committees, and one that is often given little emphasis, is to consider the *ethics* of the protocol. They must take measures to ensure that all avenues have been explored relating to the replacement of animals with alternative methods of research.

In the absence of alternatives, the committee must further determine whether the protocol is justified at all. It’s absolutely essential that they ask the question, “Can the aims of the research be achieved in ways that do not involve animals?” And “Will the scientific outcome of this research justify the lives it will take and the suffering it will cause?” In many cases it will not.

The House of Lords Select Committee 2002 has said: *“We are not, however, persuaded that enough effort is always made to avoid the use of animals. We are similarly not persuaded that where this is possible, sufficient effort is always made to minimize the number of animals used, and to minimize the pain and suffering inflicted on each animal.”*⁴

Another major concern is lack of expertise. AEC members are able to insist on more bedding, more appropriate food and cage sizes. Those with a greater understanding may also insist on higher dosage of analgesic, but do they have the scientific knowledge to challenge the legitimacy of the actual protocol itself?

“I certainly don’t understand all the protocols. The scientists who develop the experiments are often specialists and have advanced knowledge in specific fields. Sometimes all members of the committee, even the scientists, admit that they don’t fully grasp what the experiment is about. I tend to concentrate on specific areas such as animal housing, monitoring and pain relief..... I am certain that my lack of knowledge prevents me fully comprehending what the animals involved in experiments are going through.” – (Category C member, name withheld.)

Are AEC members:

- Capable of being able to question the design of the protocol?
- Able to critically evaluate the number of animals used in order to reduce that number, but to ensure that a sufficient number is used in order to statistically justify the research and not cause it to be repeated?

³ *“Introduction to the Politics of Animal Protection”*, anzccart news, Volume 18, Number 1, 2005

⁴ House of Lords Select Committee 2002 *Animals in Scientific Procedures (Norwich:TSO)*, quoted in *The ethics of research involving animals, Nuffield Council on Bioethics, 2005, p.206*

- Assured that the right species has been chosen to validate the work? This is particularly important because different species can produce vastly different outcomes.
- Over-relying on researchers to have sought alternatives?

The Monitoring of Animal Care & Use (page 26) requires that AEC's inspect all animal housing and laboratories however it does not specify a need for unannounced inspections.

It is unlikely that any problems are recognized by the AEC if those responsible for animal care are given prior notice to 'clean up' before the scheduled visit. Unannounced inspections of research facilities will be more likely to identify statutory breaches or animal welfare problems.

Applications to AEC's (page 31, 2.4.17 vi) should include evidence of what resources/databases have been sought in order to seek alternatives.

Clearly this should be the responsibility of the researcher to ensure that alternatives are sought prior to submitting any application to conduct research. The ethics committee must be satisfied that sufficient effort has been made to find such alternatives, however AEC members (particularly Category C and D) are unlikely to have sufficient scientific knowledge of these alternatives. The earlier suggestion of a central overseeing body should therefore have access to an international database to ensure that alternatives are identified wherever available and that there is no duplication of animal use between institutions.

Production of monoclonal antibodies using Ascites mice (page 31, 2.4.17 xi e) must be prohibited.

The procedure has already been acknowledged by the NHMRC to cause significant pain and distress and alternative in vitro methods are both available and are better or equal in terms of antibody quality.

One such alternative is Phage Display – a technology which involves taking the part of a human gene which generates antibodies and transplanting them into viruses that infect bacteria. The viruses are programmed to grow the antibody fragments on their coats, so they will stick to anything that the antibody sticks to. This technology has been around since at least 1994.

Use of non-human primates (page 31, 2.4.17 xi f) should specify that the importation of such animals for research is prohibited.

The importation of non-human primates for research is much cause for concern – involving the conservation status of the species, tearing apart of family units and immense suffering for the individuals involved during capture, in holding pens and during transportation. The attached briefing paper provides more information about this issue. HRA calls for an immediate ban on the importation of non-human primates for research – particularly as there already exists three government-funded primate breeding facilities in Australia.

The use of animals for education (page 64) is unjustified considering it involves the passing on of information already known. No 'new' information is to be discovered and therefore the use of or killing of animals for this purpose is unjust – particularly when such alternatives as DVDs and computer models are plentiful and readily available.

There is already a huge number of alternative teaching methods available, which makes such use of animals unjustified and these alternatives should therefore be promoted rather than allowing the continuation of animal use.

InterNICHE (International Network for Humane Education) provides an extensive resource of alternatives to animals in teaching. This resource is provided free of payment to schools and students.

The use of animals in teaching also has the potential of desensitising students to the needs of animals. Dissection and behavioural studies reinforces the view that animals are mere subjects from which to obtain information and have no intrinsic worth in their own right.

Point 4.4.2 iii on page 67 considers breeding of animals and welfare of offspring. This point MUST rule out 'hatching projects' in primary schools. Around 50% of the resulting offspring are roosters which continue to create problems with rehoming.

The fact that many councils do not allow roosters is often not considered when a student takes home chicks at the conclusion of the 'lesson'. Animal shelters are already over run with unwanted pets and they too cannot keep pace with the increasing number of unwanted roosters.

Children often form strong bonds with their chick and are greatly distressed to learn that they are unable to keep the pet they have become so attached to.

Several alternatives already exist for this activity.⁵

Terminal surgery labs must not be used for veterinary training (page 68).

Many non-harmful alternatives now exist, including computer simulations, high quality videos, 'ethically-sourced cadavers', preserved specimens, models and surgical simulators, non-invasive self-experimentation and supervised clinical experiences.⁶ Well designed educational software can encourage a high conceptual level of understanding as well as increase understanding of the specific topics being addressed. In a virtual dissection or anatomy program, students can perform tasks at their own pace, repeating as necessary.⁷

Students do of course need the experience of handling animal tissue and living animals, including learning to perform invasive surgery and other clinical procedures. This training can and should be achieved by fully replacing conventional animal experimentation or other harmful procedures with the alternative of neutral or beneficial work with animals. As well as helping to meet practical teaching objectives, alternatives to harmful animal use also ensure that students do not acquire undesirable attitudes towards animals, such as indifference to animal life and/or a disrespectful attitude towards animals as patients. Moreover, some necessary elements of veterinary education, such as training in patient care and understanding species-typical behaviour, are likely to be undermined if there is harmful use of animals in the students training.⁸

Some evidence indicates that terminal surgery labs in veterinary education may result in the decreased likeliness of students to view animals as sentient, in decreased empathy towards animals, in decreased propensity to administer peri-operative analgesics (surgical painkillers) and an impedance of moral reasoning ability.^{9, 10, 11, 12} Consequently, the replacement of

⁵ <http://www.edgarsmission.org.au/chickenfacts.htm#alternative>

⁶ Knight, Andrew, *The Effectiveness of Humane Teaching Methods in Veterinary Education*, ALTEX 24, 2/07

⁷ Martinsen, Siri, Jukes, Nick, *Towards a humane veterinary education*, JVME 32(4) 2005 AAVMC

⁸ Martinsen, Siri, Jukes, Nick, *Towards a humane veterinary education*, JVME 32(4) 2005 AAVMC

⁹ Self, D.J., Schrader, D.E., Baldwin, D.C. Jr, Root, S.K., Wolinsky, F.D., and Shaddock, J.A. (1991) *Study of the influence of veterinary medical education on the moral development of veterinary students*. Journal of the American Veterinary Medical Association, 198(5): 782-87. Quoted by Knight, A. *Humane teaching methods in veterinary education*. Veterinaryreview April 2007.

¹⁰ Hellyer. P., Frederick, C. Lacy, M., Salman, M.D., and Wagner, A.E. (1999) *Attitudes of veterinary medical students, house officers, clinical faculty, and staff toward pain management in animals*.

harmful animal use with humane teaching methods is likely to result in veterinarians with more positive attitudes towards animal welfare, which is likely to directly benefit their animal patients.¹³

Point 4.4.14 (page 69) states “Institutions must ensure that tertiary-level students are informed if their choice not to participate in the use of animals as part of a course would prevent them from achieving the educational outcomes due to the lack of suitable alternatives to the use of animals.” It should also state that such a choice must not impact on their overall assessment if they can demonstrate that the teaching objectives have been met by another means.

As stated by Animal Behaviorist Dr Jonathan Balcombe, “A basic ethical principle asserts that if we have a choice between two ways of achieving something – one that causes pain, suffering, and death and the other that does not – then ethical conduct dictates using the latter method. Using animals in education presents such a choice.”¹⁴

The key question is not whether one method is equal to the other but, rather, how well a given method promotes learning. A conservative conclusion based on [several] studies is that alternative methods are pedagogically equivalent to traditional animal dissections.¹⁵

Studies of veterinary students were reviewed comparing learning outcomes generated by non-harmful teaching methods with those achieved by harmful animal use. Of eleven published from 1989 to 2006, nine assessed surgical training – historically the discipline involving greatest harmful animal use. 45.5% (5/11) demonstrated superior learning outcomes using more humane alternatives. Another 45.5% (5/11) demonstrated equivalent learning outcomes, and 9.1% (1/11) demonstrated inferior learning outcomes.¹⁶

Of the eleven studies comparing veterinary student learning outcomes, eight were more than a decade old (published prior to 1996). Hence, a considerable number of these studies examined humane teaching methods such as films, interactive video discs, and early compute simulations which have been largely superseded by more advanced alternatives, particularly in the field of computer simulations.¹⁷

All curricular design involves combining tools from many different sources, and alternatives will almost always be used in combination to meet teaching objectives and to achieve a comprehensive learning experience. Nerve-muscle physiology practicals may combine computer simulation with student self-experimentation, and surgery courses may offer a range of different simulators in conjunction with clinical apprenticeship.¹⁸

Such an investment in alternatives will benefit all the groups concerned – not only the students, the teachers, and the animals, but also the veterinary profession and society in

JAVMA 214: 238-44. Quoted by Knight, A. *Humane teaching methods in veterinary education*. Veterinaryreview April 2007.

¹¹ Paul, E. and Podberscek, A. (2000) *Veterinary education and student's attitudes toward animal welfare*. Vet Rec 146:269-72. Quoted by Knight, A. *Humane teaching methods in veterinary education*. Veterinaryreview April 2007.

¹² Levine, E.D., Mills, D.S. and Houpt, K.A. (2005) *Attitudes of veterinary students at one US college toward factors relating to farm animal welfare*. Journal of Veterinary Medical Education 32 (4): 481-90. Quoted by Knight, A. *Humane teaching methods in veterinary education*. Veterinaryreview April 2007.

¹³ Knight A. *Humane teaching methods in veterinary education*. Vet Rev 2007; 126: 16-21.

¹⁴ Balcombe, J. *Dissection: Case for Alternatives*.

¹⁵ Balcombe, J. *Dissection: Case for Alternatives*.

¹⁶ Knight, Andrew, *The Effectiveness of Humane Teaching Methods in Veterinary Education*, ALTEX 24. 2/07

¹⁷ Ibid

¹⁸ Siri, Jukes, Nick, *Towards a humane veterinary education*, JVME 32(4) 2005 AAVMC

general. These students will have not, during their education, gone against the creed of 'first, do no harm'.¹⁹

Conclusion

While it might be considered necessary to retain a system that monitors and polices the use of animals in research, the system is far from flawless. In particular, our continued focus on improving the welfare of animals may be detracting our efforts to reduce and replace animals by actively seeking alternatives.

Overseas studies of the ethics committee system and discussions with Australian AEC members have revealed serious concerns and raise questions as to whether this system is doing more damage than good. It therefore begs the question of whether we should be trying to resolve these problems or whether we should be re-evaluating the entire system, including our attitudes and approach to the use of animals in research.

Humane Research Australia maintains its imperative to increase the focus on the development and validation of alternatives – for both the sake of non-human animals and for genuine medical progress.

Yours sincerely,

Helen Marston
Chief Executive Officer

¹⁹ Ibid