



22 March 2006

Secretariat
Animal Welfare Committee
NHMRC (MDP 33)
GPO Box 9848
Canberra
ACT 2601

Dear Sir,

Minimising pain, distress and suffering in animals in research.

Thank you for the invitation to comment on the above draft document.

As you will be aware, the Australian Association for Humane Research Inc. is an abolitionist organization. We oppose all use of non-human animals in research on both ethical and scientific grounds and therefore wish to stipulate that any comment contained within this submission does not in any way support the use of animals in research. We do nevertheless feel it appropriate to comment on a number of points within your draft document.

1. General principles for using animals in scientific research.

Introduction:

One of the ethical issues raised in your introduction is “how far should researchers go in pursuing alternatives..” Anyone intending to use animals in research should use every means possible to find replacements to animals. Taking the life of an animal, or harming it in any form cannot be justified if an alternative already exists.

Your reference to Monamy’s “Animal Experimentation: A Guide to the Issues” as further reading is a poor example of how readers can obtain a balanced overview of this subject. The author’s arguments display a bias toward pro-animal research. For example, chapter five discusses existing regulations that are intended to protect animals used in research, presumably to reassure the reader that ethics committees and animal welfare Acts safeguard animal wellbeing. However, the animal welfare movement is well aware that such regulatory bodies are unable to effectively protect animal interests and to provide reassurance that animals used in research will not suffer.

The author also suggests that animal experimentation is under tight public scrutiny, yet fails to recognise that the public is usually (unknowingly) prevented from making

informed judgements about the use of animals in research due to the level of secrecy and misinformation surrounding specific research activities.

Monamy credits animal-based research as contributing to some medical advancements. However, he does not attempt to measure how the perceived 'successes' compare with the numerous delays and disasters attributed to animal-based research. For instance Monamy suggests that pre-clinical research using monkeys was integral in the cure of human poliomyelitis, despite Dr Sabin (inventor of the polio vaccine) stating under oath that the development of the vaccine was long delayed due to the misleading results from primate experiments¹. By emphasising history's examples of how animal experimentation has ultimately benefited human health, Monamy justifies the use of animals in medical research as an 'inescapable necessity'.

Monamy states 'science demands professional objectivity from its adherents - little, if any, room is available for subjectivity, sentimentality and **value judgements**' (emphasis added). The conflicting philosophies of Schweitzer, Singer and Regan are also criticised as causing the ethical/moral argument to 'drift further and further away from the day-to-day reality of modern experimental procedures'.

Rather than providing balanced views to enable students to reach their own conclusion, *Animal Experimentation: A Guide to the Issues* is more of an attempt to encourage students to display respect for their 'sacrificial' subjects and prepare them for the scrutiny and criticisms that their work will attract from those who oppose it.

Laws and regulations:

The laws and regulations pertaining to animals in research are grossly ineffective. It is widely believed within our community that animals used in research are protected through legislation and the presence of ethics committees. This is a misconception. Whilst animal welfare legislation does exist, as do various Codes of Practice, there are loopholes that will still allow suffering to occur. Furthermore, researchers are provided with legal protection to carry out manipulations on laboratory animals which would otherwise cause them to be prosecuted for animal cruelty.

Prevention of Cruelty to Animals (POCTA) Act and Codes of Practice

Codes of Practice often work against the animals' best interests, as some acts of cruelty are exempt within the Act as they are in accordance with the Code of Practice. Without Codes exempting certain actions many animal industries (including research institutions) would be unable to operate as the confinement and treatment would otherwise constitute cruelty.

Codes therefore serve a dual purpose – to address specific needs of animals through providing guidelines for their treatment, but also to allow animal industries to continue certain procedures and practices without breaking the law.

The "Australian Code of Practice for the Care and Use of Animals for Scientific Purposes" states "*The scientific validity of animal models of human disease rests in part on how closely a given model resembles a particular disease, which may include the*

¹ Dr Ray Greek MD, Proof of Evidence supplied to University of Cambridge in response to their planning appeal for a proposed primate research facility.

animals experiencing the attendant pain or distress of the human disease state”
(3.3.43).

The nature of many forms of medical research means that animals will suffer pain and distress - from the induced conditions themselves, from the invasive procedures and from the effects of many drugs. For example, during research into arthritis the research animals would need to experience the arthritic pain associated with the condition. It may also suffer any adverse reactions the drugs may cause such as vomiting, seizures, stroke etc. Furthermore, induced disease is not an accurate reflection of disease in its natural state. Producing artificial effects to mimic a human disease defeats the purpose of the research as it alters the state.

“If animals develop signs of severe pain or distress ..., the pain or distress must be alleviated promptly or the animals must be euthanased without delay. Alleviation of such pain or distress must take precedence over continuing or finishing the project.” (3.3.9)

Whilst this statement seems at first glance to protect animals, it would not always be adhered to. As per above statement no. 3.3.43, such suffering will be justified by researchers as being necessary to study and understand the disease or condition being studied.

“Scientific activities using animals may be performed only when they are essential... [incl.] for the improvement of animal management or production.” (1.1)

Farmed animals already produce to their capacity. Current farming practices do not and cannot cater to the welfare needs of these animals. Striving to achieve higher yields will only lead to further intensive farming and further welfare problems.

Justification:

Currently the weighing of predicted scientific or educational value of a project against the potential effects on the welfare of animals falls heavily in favour of the researchers with non-human animal lives carrying little value.

Teaching, for example, is the passing on of information that is already known. No further knowledge is obtained by using animals for this purpose. There is 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 in this area.

A great majority of research using animals does not result in any medical progress. It would be deemed impossible to estimate the number of animals that have been used to research cancer, and yet we still have no cure for this disease.

With regard to drug testing, it has been estimated that around 85% of drugs tested on animals fail to reach general distribution. This would suggest that 85% of those animals used have been sacrificed for no human benefit whatsoever and the research has proved fruitless.

Considering these points it seems impossible to justify the use of animals on the grounds that their use is likely to benefit mankind.

Replacement:

Together the replacement, reduction and refinement of animal use are intended to tighten the regulation of animal research and lessen the overall level of animal suffering. Unfortunately however, reduction and refinement do not address the fact that results from animal experiments can be dangerously misleading when applied to human health. It is therefore pointless to use fewer animals or refine the procedure when it is the wrong procedure to follow. Replacement is therefore the only one of the R's that remains a credible objective.

Whilst researchers are encouraged to seek alternatives wherever possible there seems to be no provision for policing this requirement. This is likely to be because of competition within the research industries and the subsequent reluctance for sharing information. The lack of a central register or database for sharing this information means that many thousands of animals are likely used for research that has already been conducted elsewhere – probably unpublished, making a search for this information difficult.

2. How pain, distress and suffering affect research.**Pain:**

Your draft acknowledges that ‘the inability to communicate verbally does not negate the possibility that an individual is experiencing pain..’ It should be noted however, that this inability to communicate effectively could suggest such suffering may likely be even greater for non-human animals due to confusion and lack of understanding on their part.

Suffering:

We commend the inclusion of your statement “The possibility also exists that some species may suffer from states that are not experienced by humans.” Many species have a far greater scope of sensory abilities than humans – the heightened sense of smell and hearing by dogs, the increased range of light and colour experienced by birds, and maybe others that we are not yet even aware of. These greater capacities to experience sensory stimuli would likely mean that non-human animals are more susceptible to environmental changes and conditions than humans envisage and may therefore suffer more.

Effects of an animal's wellbeing on research outcomes:

A number of factors have been identified in your draft that may affect a research outcome. There are many other factors however that must also be considered. Results can differ between different sexes of the same species, different strains, and even due to different housing conditions or levels of stress within the same species. This of course questions how we can reasonably expect to extrapolate data from one species to another.

There have been recent reports that even routine handling of animals in laboratories, such as picking up animals, cleaning their cages, can result in significant changes in stress indicators.² The findings indicate that even standard laboratory practices result in stress and that animals do not readily habituate to them.

² Balcolombe J, Barnard N, Sandusky C, Laboratory routines cause animal stress. *Contemporary Topics in Laboratory Animal Science*, Nov. 2004;43(6):42-51

3. How to predict and minimize pain, distress and suffering in animals.

Your draft document identifies the difficulty in measuring pain due to the inability of animals to communicate their experiences directly to humans. This lack of ability to communicate further compounds suffering as it means that we cannot communicate to them whether the suffering is only short-term and that pain relief will be provided.

4. Planning new research protocols.

Choosing the right animal:

As stated on page 52 of your document (fact sheet on Anaesthesia, analgesia and anxiolytics) "*It is unwise to extrapolate from one species to another. In addition, direct extrapolation from humans to animals is as faulty as is the reverse.*" This statement is a major scientific argument against the use of animals in research and is in direct contradiction to the information you provide on page 75 (fact sheet on Animal models)

It has already been widely acknowledged that extrapolation from animals to humans can and does result in dangerously misleading outcomes. Species differences occur in respect of anatomy, the structure and function of organs, metabolism of toxins, rates of detoxification and protein binding, absorption of chemicals, mechanisms of DNA repair and lifespan, and more. So if such differences can occur between similar species then it's negligent to extrapolate from say a rat to a human – two totally different species with a totally different genetic make-up.

Another major difference is in the regulation of our genes. A mouse and a human for example, may share 99% of the same genes, however they are regulated differently. Both a mouse and a human have the same gene that enables us to grow a tail. In the case of a mouse that gene is "turned on", but in humans that gene is "turned off." The argument that we share a large proportion of genes with another species cannot therefore be used as a reason for selecting a particular animal model.

Researchers often claim that animals are used because they need to test in a living system rather than on isolated cells or tissue, however an entire living system creates more variables which can further affect the outcome of any results.

Another problem is that more often than not a disease that is being researched does not appear in its natural state but instead is artificially induced in the research animal. This can result in the same symptoms being expressed but the underlying illness is not the same as in its human form. Treatments then try to cure the symptoms of the falsified illness but are not addressing nor curing the real problem, which may have been caused, or further affected, by social and environmental factors rather than biological factors alone.

Species differences mean that no other species is a suitable model for human disease/research. This has been highlighted by the recent UK drug trial that resulted in a disastrous outcome for the volunteers.

The most famous example of this argument is of course Thalidomide - intended to prevent morning sickness and resulted in tens of thousands of children born with severe deformities such as missing limbs. It has been claimed that had it been tested on pregnant animals we would have seen malformations. That however is not the case. After thousands of malformed babies were born researchers started conducting

teratogenicity tests and failed to produce similar malformations in numerable other species. Finally, the White New Zealand rabbit also gave birth to deformed offspring, but only at a dose between 25 to 300 times that given to humans. It also eventually occurred in monkeys, but only at ten times the normal dose. The bottom line is that more animal testing would not have found the side effects, and even if they had tested on the White New Zealand rabbit, Thalidomide would still have gone to market since the vast majority of species showed no ill effect. It is only possible to produce specific deformities in specific species, and chances are the right species would never have been used.³

Transporting animals:

Your draft document suggests that researchers must take all steps to minimize distress and pain when transporting animals, including to “ensure all personnel responsible for handling and transportation are skilled and able to recognize signs of distress and pain.” We question how this can be adhered to during air travel.

According to Gateway to Hell, “Undercover exposés show that the animals suffer horrifically whilst in transit. They are often deprived of the basic necessities of food, water and space. There is no care or sensitivity for the animals already terrified by their experiences. Many do not make it through alive.”⁴

5. Approval for new research protocols.

Submitting a proposal to the animal ethics committee:

Proposals to animal ethics committees must include “how the principles of reduction, replacement and refinement are being applied.” There appears to be no formal policing of this and we encourage a more stringent adherence to this requirement. The researcher should provide sufficient evidence that a thorough literature search has been conducted to ensure that the work has not been conducted previously, and that no alternatives to animals exist for their specific protocol.

Animal ethics committees:

The only person that represents the interests of animals on an animal ethics committee is the category C representative. Whilst this person may make minor suggestions to improve the welfare of individual animals (in terms of improved housing or use of analgesics), generally speaking they are not sufficiently qualified to challenge the justification of the research protocol itself. This alone is a major concern.

Several category C’s have also informed the author (in confidence) that in many cases they do not fully understand the protocol, nor the actual impact it will have on animals. Often this is due to them receiving a large number of protocols just prior to an ethics meeting without sufficient time to analyse them sufficiently, or their inability to understand the scientific explanations provided to them.

Under these conditions we do not consider that animal ethics committees serve their intended purpose. This has been reiterated in the Medical Journal of Australia⁵ which states: “*One or two of the most senior members know they can nearly always sway the*

³ Specious Science, Drs Ray Greek and Jean Swingle Greek. p.108

⁴ gatewaytohell.net/gateways/gateways_index

⁵ Loff Bebe and Black, Jim, Research Ethics Committees: what is their contribution? MJA 2004; 181 (8): 440-441

committee to their point of view.”

6. Minimising and managing pain, distress and suffering.

Record observations:

Many laboratory animals are nocturnal and therefore more active at night, when most observations would be most beneficial. Is there any provision for night time monitoring?

Fact Sheets

Animal models

As mentioned elsewhere in this submission, we do not consider animals to be relevant models for human research. This fact sheet states “*Genetic make-up, housing, husbandry, diet and disease can all affect test results, making them invalid and therefore wasting research animals.*” These variations will ALWAYS differ from humans, making all animals invalid models for human research.

We also note with interest your statement “*Most animal models used in toxicity testing have never been formally validated...*” Regulatory bodies often argue that alternative non-animal tests cannot be relied upon due to them not having been validated. This of course raises the question of why animal experiments (tests that are unreliable as they have been conducted on a different species) should be accepted while the humane alternatives (which are based on human data) are not?

Blood collection:

Retro-orbital bleeding is an extremely invasive procedure and should not be permitted under any circumstances – particularly when alternative, and less invasive, forms of blood collection exist. As your fact sheet mentions “*this method is controversial, and there are reports that it causes histological damage to structures around the eye even in anaesthetized rats...*”

Humane killing and euthanasia:

Your definition of euthanasia, “*the humane killing of an animal, in the interests of its own welfare, to alleviate pain and distress*” is inconsistent with your list of when euthanasia is used.

“*At the end of studies, to provide tissues for scientific purposes*”; “*when animals are no longer used for breeding*”; and “*when stock are not required for certain reasons*” are certainly not in the interests of the animals own welfare.

We also question why euthanasia must “*be aesthetically acceptable to the operator*”? If a researcher finds the process of killing an animal to be unpleasant then they should question their own actions as to whether they consider the use of that animal to be genuinely justified.

Surgical procedures:

Your section on **personnel** suggests that surgeons unfamiliar with particular procedures or anatomical approaches should:

- *Perform an anatomical dissection using cadaver specimens to become familiar with the anatomical landmarks, to evaluate the feasibility of the proposed procedure and the optimal surgical approach, and to identify surgical risks*

- *Perform the surgery as a non-recovery procedure in a sufficient number of animals to be confident of being able to manage the animal through the recovery stage: this step will also enable an evaluation of the anaesthetic technique and supportive therapies.*

Both points encourage the wastage of animal lives and are in direct conflict with the concept of the 3R's which the NHMRC and researchers are supposed to promote. If a surgeon is insufficiently qualified to perform a procedure then they should obtain experience through either simulation models or via field experience – operating in a veterinary practice for genuine therapeutic purposes on real animal patients.

Conclusion

While our organization is strongly opposed to the use of animals in research we commend your efforts to reduce the suffering of those animals that are being used. We do urge the NHMRC however, to take a much firmer stance on the promotion of using alternatives. If researchers and the NHMRC are genuinely committed to hastening medical progress and exploring all avenues to replace animals with more humane and scientifically-valid options then we can only expect to see a massive reduction of both human and animal suffering.

Yours sincerely,

Helen Rosser
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Australian Association for Humane Research Inc.