

The problems with ethics committees

Presented at the Victorian Animal Welfare Advisory Committee / Bureau of Animal Welfare Scientific Procedures Seminar "Keeping a finger on the pulse – monitoring wellbeing"
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Abstract:

Ask any institution or company whether they use animals in research and their response will nearly always say that all animals are treated humanely and their use is subject to approval by an animal ethics committee which contains an animal welfare rep.

The presence of animal ethics committees, and in particular inclusion of a category C member (animal welfare representative) can therefore be seen to promote a 'clean' image of the research industry to the public - as an assurance that the care and use of animals is sanctioned by those with a concern for their welfare and/or rights.

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 efforts to refine experiments 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.

Thank you for the opportunity to present the views of AAHR here today.

For those of you who are not familiar with the Australian Association for Humane Research, we are a non-profit organization that was formed back in October 1979 and until the last 18 months was based in Sydney.

I'm going to be upfront and confess to you all that we are an abolitionist organization. But don't worry. I haven't brought along any protestors, no placards and I certainly won't be wearing my black balaclava. That's not how we work. We oppose the use of animals in research on both ethical and scientific grounds, but we do this by working with researchers, institutions and funding bodies to encourage the use of more humane, scientifically-valid non-animal methods.

As part of an abolitionist organization I have not served on an ethics committee. The issues that I'll be presenting have therefore been derived from a variety of sources, including overseas studies, discussions with AEC members and some examples taken from our own work.

I do acknowledge and respect the motives of animal welfarists who participate in the process, and appreciate their willingness to become involved in a system they may not necessarily agree with, but consider that their involvement and input may have a positive impact on the welfare of individual animals that are the unconsenting subjects in the system.

General Perceptions:

Ask any institution or company whether they use animals in research and their response will nearly always say that all animals are treated humanely and their use is subject to approval by an animal ethics committee.

I have personally received this standard response from multinational corporations that test their products on animals, from local councils that send pound animals to research institutions and from funding bodies ARC (Australian Research Council) and NHMRC (National Health & Medical Research Council) when I recently challenged their justification of funding vision experiments on marmosets.

The presence of animal ethics committees, and in particular inclusion of a category C member (animal welfare representative), is often used by researchers to promote a 'clean' image of the

research industry to the public - as an assurance that the care and use of animals is sanctioned by those with a concern for their welfare and/or rights. However many category C persons serving on an ethics committee are opposed to the use of animals in research. Their presence is to ensure that the animals are protected as much as possible but can only do so within the scope of the Code of Practice.

"Ethics Committees, however, do not tend to question the 'ethics' underlying experiments, they simply refine experiments. In this way they can be seen to justify experimentation." (Category C member, name withheld.)

Does the existence of AECs and in particular "Category Cs" really provide assurance that animals do not suffer? Ethics committees operate within the constraints of the code. If we look at some extracts of the code we find the following:

"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 animals experiencing the attendant pain or distress of the human disease state" (3.3.43).¹

The nature of many forms of medical research means that animals will suffer pain and distress - from the invasive procedures as well as 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. They may also suffer any adverse reactions the drugs may cause such as vomiting, seizures, stroke etc.

This has been reiterated by *The ethics of research involving animals, Nuffield Council on Bioethics*.

*"..post-operative pain can be controlled by pain relieving medicines, but sometimes they may interfere with experiments on pain and may not be given."*²

The report also states:

*"Regulation can act as an emotional screen between the researcher and an animal, possibly encouraging researchers to believe that simply to conform to regulations is to act in a moral way."*³

*"We conclude that some form of regulation is necessary for good moral practice, but that it is crucial to be aware that it may not be sufficient."*⁴

While the general public are often misled into believing that ethics committees protect animals from pain and suffering, clearly the existence of legislation, codes of practise and ethics committees can only protect animals to a certain degree but certainly do not guarantee there is no suffering.

Failure to exercise ALL the 3R's?

We are all aware that the 3R's serve as complementary rules of thumb to reduce overall suffering and form the framework of the animal ethics system. At conferences I have attended there has been quite some focus on refinement but very little on reduction and specifically on replacement.

My first attendance at the BAW Scientific Procedures Seminar was two years ago when one of the speakers asked the floor whether there was anyone present that would like to see animal experiments banned. I was shocked that only two of us raised our hands at that time. I had assumed that as "Category Cs" there would have been a large number of people present that would

¹ *Australian code of practice for the care and use of animals for scientific purposes*. 7th Edition 2004.

² *The ethics of research involving animals, Nuffield Council on Bioethics, 2005, p.137*

³ *Ibid p.XIX*

⁴ *Ibid p.XXIV*

be looking toward reducing and ultimately eliminating the use of animals for such purposes. This, I believe, should be the ultimate goal of everyone, but particularly of animal welfare representatives.

Even according to William Russell, who co-authored of The 3R's in 1959 (and who sadly passed away just recently), "*Refinement is never enough, and we should always seek further reduction and, if possible, replacement... Replacement is always a satisfactory answer.*"⁵

It's absolutely essential that we 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 you will find that 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.*"⁶

As a local example of the failure to implement replacement, AAHR became aware of the mouse bioassay being used to test water toxicity after algal blooms. The painful test involves intraperitoneal injection (into the abdomen) of the water sample and if 2/3 or 3/3 mice deaths occur within 24 hours then it is determined that toxins are present. The immediate effects on the mice can include them becoming rapidly subdued, unresponsive with bluish extremities and cold to the touch. They can display disorientation, paralysis of hind limbs, breathing difficulties and a violent jumping reaction. These can occur within 30 minutes of injection. No anaesthesia is used and death usually occurs within 5 hours from heart failure.

The mouse bioassay has been criticized for a number of reasons, including inconsistency, its dubious relevance to human hazard and the suffering it causes to laboratory animals.

Our research found that most water authorities use alternatives to the mouse bioassay – mostly high performance liquid chromatography (HPLC) so we now question why this particular water authority continued to use the mouse bioassay when an alternative method of testing not only exists, but provides a more accurate diagnosis? Clearly there was not enough effort put into replacement.

As a further example, a speaker at the most recent ANZCCART conference discussed the use of animals in teaching and justified their use by suggesting that it entuses students to learn more. If we did a cost/benefit analysis, can we honestly say that entusing students is sufficient justification for taking away the lives of sentient beings - particularly when there are other (perhaps a little less stimulating) ways to achieve the desired outcome? Do we really place such little value on the lives of those animals that we dispose of them, not in the pursuit of knowledge, but merely to pass on knowledge to others?

Teaching is an area in which we CAN replace animals and yet they are still being used. I recently corresponded with the Department of Anatomy and Cell Biology at Monash University who I learned are implementing programs to teach anatomy through anatomical models and e-learning programs such as ADAM, Anatomedia and Primal. However they are continuing to support dissection. I queried this and was pleased when they responded that their dissection program is limited to human cadavers.

Similarly, in September, Murdoch University WA completely eliminated some of its core terminal veterinary surgical teaching laboratories. Instead of killing pigs and sheep the students neutered shelter animals instead.

⁵ Quoted in *ATLA* 34, 271-272, 2006.

⁶ 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*

If there is anyone in the audience that considers the use of animals in teaching to be justified then I sincerely hope you are not an animal welfare representative.

Overseas studies:

There has been a number of studies conducted overseas that address the problems that occur within animal ethics committees.

A Study by Catharine A. Schuppli and David Fraser, University of British Columbia, Vancouver was titled "Improving the Effectiveness of Research Ethics Committees" and was presented at the 5th World Congress for Alternatives in Berlin 2005.

The authors identified the following concerns:

1. **Committee composition creates bias towards institutional/research interests versus interests of animals.**
 - Institutional members make up the largest proportion
 - Chairpersons were often scientists
 - Community members reported they had limited power as they were outnumbered.
2. **Committee dynamics prevent full participation of members.**
 - Community members felt intimidated by scientists
 - They had insufficient expertise
 - They were 'outsiders'
3. **Recruitment strategies create bias towards institutional/research interests versus interests of animals.**
 - Community members were recruited as friends, relatives or neighbours of AEC.
 - Word-of-mouth recruitment runs the risk of recruiting members who are perceived to 'fit in'
4. **Motivation for joining is to pursue agendas other than committee mandate.**
 - Some scientists joined the AEC to promote their own or their department's agenda, in some cases to limit the committee's actions.
 - Concern about recruiting animal right advocates
5. **Excessive workload or inadequate participation for adequate review.**

While this study was conducted overseas, I believe a number (but maybe not all) of the problems identified would be applicable to the Australian system and I will consider some of these further.

Committee composition creates bias towards institutional/research interests versus interests of animals.

"...those who oppose the use of animals in research may also argue that animal ethics committees are stacked against the animals and in favour of the research. They may argue that a Category C person is unlikely to effectively make their voice heard for three reasons. First, they are often outnumbered; secondly, they may not be confident to speak up when in conference with doctors and professors, and finally, they are unlikely to have the scientific ability to understand the detail of the protocol before them and come up with an effective counter argument." - Siobhan O'Sullivan⁷

I and the other animal welfare representative have never succeeded alone in stopping an experiment. Recently, for example, we challenged on ethical grounds, the provision by our institution of transgenic pigs for research into organ transplantation. We did this on the grounds that the NH&MRC has placed a five-year moratorium on animal to human organ transplantation. The remainder of the committee opposed us and the experiments went ahead. – (Category C member, name withheld.)

Committee dynamics prevent full participation of members – (insufficient 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?

⁷ "Introduction to the Politics of Animal Protection", anzccart news, Volume 18, Number 1, 2005.

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.)

As AEC members:

- Are you capable of being able to question the design of the protocol?
- Can you critically evaluate the number of animals used in order to reduce that number, but in order to ensure that a sufficient number is used in order to statistically justify the research and not cause it to be repeated?
- Can you be assured that the right species has been chosen to validate the work? This is particularly important because different species can produce vastly different outcomes.
- Is there an over-reliance on researchers to have sought alternatives?

Excessive workload.

I haven't sought data on this area but have been informed by several colleagues that large numbers of protocols are often received shortly before the meeting with little time to read and evaluate the procedures. I also believe it is often difficult to recruit category C reps and therefore those that do perform this task do so for a number of institutions.

Other problems have been identified within the Australian system not included in the above-mentioned study. These seem to relate mainly to the fact that ethics committees are part of a self regulatory system.

Inconsistency

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.*"

No sharing of information

"Presently there is no system in place to make AECs aware of the development of new alternatives. This means that AECs may be approving protocols which use animals when non-animal methods are available. The development of a database of alternatives designed to make AECs aware of new advances could effectively reduce the number of animal based projects approved each year." – Siobhan O'Sullivan

It might also be advantageous if there was a central database maintained to record what research is being conducted on animals. However while this may seem like a reasonable approach to avoid the huge amount of duplication that occurs, the NHMRC would not agree to this even specifically for xenotransplantation research. Their reasons: Who would assume responsibility? Who would fund it? Commercial-in-confidence.

Unannounced inspections

Nobody I have spoken to is aware of any prosecutions of cruelty within the Australian research industry. In the UK problems have only been identified through undercover investigations. I'm not aware that any such undercover work has occurred in Australia – at least within the research industry.

What is the point of announcing an inspection that is intended to identify problems? The need for unannounced inspections of research facilities – will be more likely to identify statutory breaches or animal welfare problems.

Lack of Transparency

“..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’.”⁸

We recently contacted both the funding bodies and ethics committees concerned with an experiment conducted on marmosets to enquire how this particular protocol was given approval to proceed.

The research was titled “Spatial coding and response redundancy in parallel visual pathways of the marmoset *Callithrix jacchus*” and was published in “Visual Neuroscience” 2005.

Basically, the protocol involved eighteen marmosets which were anaesthetised and had their heads mounted in a stereotaxic head device. Their skulls were subsequently sawn open so that brain recordings could be made while the eyes of the marmosets received visual signals. Typical recording sessions lasted 72 hours, during which the animals received intravenous fluids as well as a muscle paralysing drug. At the end of the recording session all the animals were killed with an overdose of barbiturates.

We had this research critiqued by a scientific consultant. He concluded that *“the authors do not present any clear-cut conclusion at the end of the paper. Instead, they present a long discussion, which raises more questions than it answers.”* The experiment does not appear to be applicable to human or animal health and could certainly not be considered life-saving research.⁹

There are many in the community that would find this sort of research unacceptable, particularly as it was funded with public money. We therefore queried the justification of this experiment. The responses we received were that the protocol was approved by an ethics committee and it conformed to the requirements of the code. I have since asked for a copy of the protocol, Minutes of the meeting at which it was approved and the names and roles of those present. I guess this will serve as an interesting test as to whether researchers are really open to transparency!

Finally – A compromise on one’s own moral principles.

It has been suggested that being part of a collective, decisions may be made that are not necessarily consistent with the individuals moral beliefs:

“Committee decisions, as compared with individual ones, can spread the responsibility. A committee can make a decision that no one person – in particular, no committee member – acting alone would make.”

“Might [this involvement] have allowed the caring team to implement decisions that their moral intuitions were indicating were unethical? While these decisions may have been ethical, we must always be aware that we ignore such intuitions at our ethical peril.”¹⁰

“There is indeed comfort in allowing ourselves to be relieved of having to think about the implications of our actions, especially when the research dollar is concerned.”¹¹

⁸ Ibid.

⁹ Dr Andre Menache, Scientific Consultant, Animal Aid UK, 22 June 2006. (Personal correspondence)

¹⁰ Somerville, MA. *Raising our ethics awareness is a good start* [editorial] Med J Aust 2004; 181:180-181, quoted by Bebe Loff and Black, Jim, *Research Ethics Committees: what is their contribution?* MJA 2004; 181 (8): 440-441.

¹¹ Bebe Loff and Black, Jim, *Research Ethics Committees: what is their contribution?* MJA 2004; 181 (8): 440-441.

So we can indeed question whether the same decision would be made if it were up to an individual rather than a collective group of people, all with differing perspectives.

Possible solutions (and why they are unlikely to work):

It was suggested at the most recent ANZCCART conference that one of the indirect responsibilities of the AEC system is to accelerate cultural change.

If we look at a summary of the problems identified we can then consider possible solutions.

Ethics committees are 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.

However as quoted from the Bulletin:

*"Many scientists and funding administrators often simply choose to ignore a promising avenue of research until pressured to do so; careers are more easily advanced by sticking with accepted paths even when they may be wrong."*¹²

Bebe and Black have suggested the following:

"Perhaps the most essential preparation for members of research ethics committees is not studying the content of the Statement or the relevant law, but undertaking a week of intensive training in critical thinking....."

*Many researchers are unaccustomed to thinking through the broader implications of their work. However, they are capable of doing what is necessary in order to fill out a form."*¹³

A few years ago I participated in the NHMRC's animal issues sub committee to the working party on xenotransplantation. We looked at the animal welfare concerns in using animals for organs, cells and tissue transplants. There seemed to be a huge concern that responsibility for decisions remain at the ethics committee level at individual institutions. No one at the time could explain to me why this was so important and to be honest I still don't understand why this is so crucial.

Why can it not be centralised? A group of experts could be specifically trained to ensure consistency in decision-making, would have expert knowledge about ethics, scientific knowledge about the available alternatives and how to identify them, and would also avoid the duplication of work between institutions.

While this approach may address *some* of the problems identified, and improve the *effectiveness* of ethics committees however, I'm reminded of an interesting quote I heard at a seminar. *Should we be polishing a stone that's fundamentally flawed?* While it was quoted to an unrelated topic, I thought it was particularly relevant to the AEC system.

Australian authorities, including NHMRC, ARC, ANZCCART (Australian and New Zealand Council for the Care of Animals in Research & Teaching) and ANZSLAS (Australian and New Zealand Society for Laboratory Animal Science) promote the welfare of laboratory animals. Indeed Australia boasts high standards of lab animal legislation (incidentally, so does the UK – despite undercover footage suggesting otherwise!) but is this focus on welfare doing more damage than good? Instead of changing our approach to research and seeking alternatives, are we instead inadvertently promoting animal use?

My strong belief is that we should shift our focus to the promotion of alternatives research – an area that is flourishing in the UK through the NC3R's (National Centre for the Replacement, Refinement and Reduction of Animals in Research), in Europe through ECVAM (European Centre for the

¹² 'Chasing Cancer' The Bulletin, 19 September 2006.

¹³ Bebe Loff and Black, Jim, *Research Ethics Committees: what is their contribution?* MJA 2004; 181 (8): 440-441.

Validation of Alternative Methods), in the US through ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods) and ZEBET (Centre for Documentation and Evaluation of Alternatives to Animal Experiments) in Germany.

By ignoring this vital field of research Australia is sadly lagging behind and merely deviating from the direction we should be taking in order to be at the forefront of real scientific progress.

As members of animal ethics committees you carry an enormous moral responsibility. What may seem to you to be a tedious meeting and piles of paperwork means a great deal more to the research animals – maybe even life or death! It's therefore up to you whether or not you continue to polish that flawed stone.

Helen Rosser
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