Part 6: Animal Experimentation and Research

Human Exceptionalism and the Use of Non-Human Animals in Scientific Research

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“Models”, “test systems”, “research tools”, “products”; euphemisms for animals. They are called anything but living, feeling, sentient creatures.”

1 Introduction

The utilisation of non-human animals in scientific and medical research is controversial terrain; there are myriad differing, and opposing, viewpoints in terms of the justification for

same. As such, the following discussion will consider the assumptions that inform the justification for the use of non-human animals in research with reference to the regulatory frameworks in place in New South Wales and the effectiveness of such regulation in protecting the interests of animals.

2 The Regulatory Framework

2.1 The Research Code

The central form of regulation of the use of non-human animals in research is that provided by the National Health and Medical Research Council (NHMRC) in the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code). The Code ‘provides an ethical framework and governing principles to guide decisions and actions of all those involved in the care and use of animals for scientific purposes’ and details the responsibilities of all people involved in the care and use of animals including investigators, institutions, animal carers and animal ethics committees. Importantly, in the Introduction of same, the Code indicates that it is underpinned by an obligation to respect animals.

The Code has been incorporated into the *Animal Research Act 1985* (NSW), thus ensuring that all animal use for scientific purposes is conducted in compliance with the Act and, therefore, the Code.

At first glance, the Code seems to be a comprehensive document dealing with all aspects relevant to the use of animals in research. It ‘appears to require a reasonable ethical assessment of proposed research protocols, appears committed to the implementation of the

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3 National Health and Medical Research Council (2013) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, 8th ed.
4 Ibid.
5 Ibid.
8 National Health and Medical Research Council (2013) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, 8th ed.
3Rs, and its scope appears broad’. 9 In addition, Section 3 of the Code is entitled ‘Animal Wellbeing’ 10 and thus appears to regulate issues affecting the wellbeing of animals in research. 11

‘This code of practice acts as a practical guide for institutional animal ethics committees (AECs)’ 12 in approving, modifying or rejecting research proposals put to them. 13

Deeper analysis of the Code reveals, however, that the Code is unlikely to amount to adequate protection of the welfare and interests of non-human animals as there are several shortcomings within same. Firstly, the Code specifies at clause 1.5 that ‘evidence to support a case to use animals must demonstrate that… the project has scientific or educational merit, and has potential benefit for humans, animals or the environment’. 14 It is not difficult to draw from this statement the conclusion that there would be few research projects determined to have not advanced scientific knowledge to some extent- except perhaps where, for example, results are not obtained from the experiment or the results are unreliable. 15 Accordingly, it seems that this requirement falls short of demonstrating adequate protection for the interests of animals given little justification is truly necessary for research to meet this criterion.

Moreover, whilst clause 1.10 of the Code successfully confirms the necessity to recognise that non-human animals experience pain and suffering alike humans, and indicates that decisions relating to an animal’s wellbeing must consider the animal’s capacity to experience

9 Peter Sankoff, Steven White and Celeste Black, above n 7, 279.
10 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed, Section 3.
13 Ibid.
14 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed, 1.5.
15 Peter Sankoff, Steven White and Celeste Black, above n 7, 280.
pain and distress,\textsuperscript{16} it is important to also consider whether animals are relieved of pain and distress in accordance with clauses 1.11 to 1.14 and 3.3.8 to 3.3.15 of the Code.\textsuperscript{17}

Despite the guidelines of the Code providing for the alleviation of pain and suffering of animals, it has been reported that ‘analgesic and anaesthetic modalities remain under-utilised, partly due to concerns… that their use may alter experimental outcomes’;\textsuperscript{18} Literature has confirmed that whilst ‘post-operative pain can be controlled by pain relieving medicines… sometimes they may interfere with experiments on pain and may not be given’.\textsuperscript{19} This is not only problematic in terms of protecting the wellbeing of animals but, in addition, where the wellbeing of animals is compromised, a plethora of issues become prevalent in terms of the usefulness and reliability of the data sourced from such research;\textsuperscript{20} it has been reported that physiological and behavioural responses to distress or pain (which are not those responses being tested) can lead to greater variability in data sourced, the absence of data points, reduced credibility of information and can result in the data obtained being unpublishable.\textsuperscript{21} Thus, where this occurs, not only is the wellbeing of animals compromised but, additionally, there is little justification for the research given the possible effects on the data produced. Clearly this is a significant issue that needs to be rectified, and rectification will be addressed in a later part of this discussion.

In terms also of animal welfare, the Code lacks regulation relating to environmental enrichment which is vital to promoting the wellbeing of animals held for the purposes of research.\textsuperscript{22} Environmental enrichment is also central to the avoidance of physiological and behavioural responses of animals which, as has already been discussed, can result in issues with data obtained.\textsuperscript{23}

\textsuperscript{16} National Health and Medical Research Council (2013) \textit{Australian Code of Practice for the Care and Use of Animals for Scientific Purposes}, 8th ed, 1.10.
\textsuperscript{17} Ibid, 1.11 to 1.14, 3.3.8 to 3.3.15.
\textsuperscript{18} Peter Sankoff, Steven White and Celeste Black, above n 7, 284.
\textsuperscript{19} Nuffield Council on Bioethics, \textit{The ethics of research involving animals} (Nuffield Council on Bioethics, 2005), 137.
\textsuperscript{20} National Health and Medical Research Council, \textit{Guidelines to Promote the Wellbeing of Animals used for Scientific Purposes – The Assessment and Alleviation of Pain and Distress in Research Animals} (Australian Government, 2008).
\textsuperscript{21} Ibid.
\textsuperscript{22} Peter Sankoff, Steven White and Celeste Black, above n 7, 284.
\textsuperscript{23} National Health and Medical Research Council, above n 20.
2.2 Animal Ethics Committees

Furthermore, there are problems associated with the use of Animal Ethics Committees (AECs) which are provided for in the Code, which are to some extent explored by Andrew Knight. Knight states that the requirement by the Code for an AEC to comprise of Category A-D members ‘should lead to a reasonably balanced committee’ although, as Knight purports, there should still be measures in place to fix the proportion of members of each category in order to promote this balance. Other authors, however, have explored problems inherent in the idea of AECs, including the presence of confidentiality agreements put to members of AECs, which limits outsiders’ understanding of the deliberations involved, so ‘neither the institution nor the public can be sure that the committees really are working to approve only that research which is essential and justified’. Without much analysis here it is not difficult to determine that this causes there to be a limited ability to perform checks and balances on the operation of AECs.

Moreover, whilst the Code specifies that the Category D member/s must not be ‘employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities’ it has been reported that it is common for the Category D members to come from the institution running the committee for reasons such that such members can be found within the institution with greater ease. The practice of appointing truly independent members is not widespread and accordingly, it can be considered that bias and reluctance to make judgement on issues is likely to be present in many AECs. Furthermore, the inclusion of additional members who are ‘responsible for the routine care of animals within the institution’ as well as any other members the AEC sees fit further induces the aforementioned issues of a loss of partiality. Clearly this is

24 Peter Sankoff, Steven White and Celeste Black, above n 7, 281.
25 Ibid.
26 Ibid, 282.
28 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed., 2.2.4.
29 Denise Russell, above n 27, 127-142.
31 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed, 2.2.5.
32 Ibid, 2.2.6.
detrimental to the interests and welfare of animals as issues prevalent within AECs discredit the justification process which is expected to be thoroughly conducted by such committees.

Additionally, even where Category D members are in fact independent of the AEC institution, there can be no guarantee that such members bring 'a completely independent view to the AEC'34 given the presence of personal viewpoints based on experience and knowledge35 and, in fact, bias is indeed a founded issue within AECs internationally.36 Thus, the independency of the independent members of AECs is not a measure that can be assumed to offer adequate protection of the interests of animals.

Whilst the Code recognises the need to replace the use of animals with other means of gaining scientific knowledge37 the Code does not promote the replacement principle to a significant extent in that there is no provision in the Code for scientists who are not animal researchers to form part of the AECs; Category B members must be have ‘substantial and recent experience in the use of animals for scientific purposes’.38 Therefore, the Code through this part does not promote the replacement principle or an understanding among members of AECs as to the alternative methods of research and, hence, does not afford adequate protection to the interests of animals.

It must be recognised that, despite the above critique, the Code does go some way in protecting the interests of non-human animals in that it provides a framework which appears to have the interests of animals as one important factor. It is in practice, however, that the current regulatory framework fails to address the current issues facing animals in research, such as their wellbeing or the necessity for them to be involved in such research.

33 Peter Sankoff, Steven White and Celeste Black, above n 7, 282.
34 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed, 2.2.4.
35 Denise Russell, above n 27, 133.
36 C Schuppli and D Fraser, ‘Factors influencing the effectiveness of research ethics committees’ (2007) 33(5) Journal of Medical Ethics 294-301.
37 National Health and Medical Research Council (2013) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th ed, 1.1.
38 Ibid, 2.2.4 (ii).
3 Assumptions informing the regulatory framework

The Australian Association for Humane Research Inc. (AAHR) considers that '[t]he major problem with legislation, codes of practice, ethics committees and the 3Rs principal is that they serve to endorse the belief that animal experiments are necessary, rather than challenge its validity.' The AAHR has suggested that the reason that animal research is viewed as a necessary evil is because of the superiority placed on humans by humans; ‘we are dismissed as caring more for animals than for people’.  

This viewpoint resonates within the approach of Tzachi Zamir, who contends that the regulatory framework in this area is be based on the overriding assumption ‘that humans are more valuable than non-human animals’. This assumption clearly informs the regulatory framework, being the Code, as well as many other frameworks where regulation of animal related activities occur.

Some have come to identify this theory as the human superiority complex but really; this notion parallels utilitarian philosophical theory. Whilst literature and society has shown some acceptance of this notion, in political and moral debate surrounding this issue there is some reluctance to declare human superiority ‘and thus that animal experimentation to advance medical science is not a necessary evil, but a moral good.’

Whilst this assumption of human superiority is based on utilitarian theory, the balancing of human and non-human animal interests with respect to scientific experimentation on animals for human benefit clearly does not adhere strictly to the theory: it is ‘only possible to conclude that such research is ethically justified if a profoundly unequal weighting is applied in which relatively minor or infrequent human benefits are considered more important than the

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39 Helen Rosser, Animal Experimentation – a "necessary evil"? (Australian Association for Humane Research Inc, 2007) 11.
40 Ibid, 3.
42 Ibid, 17.
significant adverse impacts commonly experienced by laboratory animals’.\textsuperscript{45} Consideration of this in light of Singer’s utilitarian theory which recognises that humans and non-human animals are sentient beings and are thus entitled to \textit{equal consideration},\textsuperscript{46} it becomes evident that the regulatory framework is plagued by the assumption of human superiority which has become embedded in a present day approach to utilitarianism.

This must be considered in light also of evidence which suggests the inapplicable nature of animal \textit{models} given the many intricate differences between human and non-human species.\textsuperscript{47} ‘Thus, it makes no logical sense to test a theory about humans using animals’\textsuperscript{48} and so the balancing of costs and benefits will rarely justify research in any event given the limitations of such benefits.

Given that utilitarian theory generally, along with the assumption of the greater value of humans, also informs societal norms and many other areas of regulation, it is difficult to see the subject regulatory framework shifting to a point where same is informed by alternative theories, such as a rights based approach, although this would be ideal.

\section*{4 A better way forward: Options for reform}

The preceding discussion has revealed many problematic features of the current regulatory framework governing the use of non-human animals in research. It is evident, upon analysis of these problematic features, that reform is not only desirable, but is necessary if the framework is to protect the interests and wellbeing of animals to the extent that the Code proposes to.\textsuperscript{49} Accordingly, the issues currently evident within the framework have been considered in light of options for reform to change the face of the framework.

It has become evident that there are few circumstances where animal research could be said to have no scientific merit and accordingly, there is often little justification needed for such

\begin{flushleft}
\textsuperscript{45} Peter Sankoff, Steven White and Celeste Black, above n 7, 276.
\textsuperscript{46} Ibid, 40.
\textsuperscript{47} Choose Cruelty Free, above n 1.
\textsuperscript{49} National Health and Medical Research Council (2013) \textit{Australian Code of Practice for the Care and Use of Animals for Scientific Purposes}, 8th ed, Introduction.
\end{flushleft}
research. In order to address this problem and provide a more even basis on which scientific merit is determined, it is suggested that guidelines and/or factors to be considered when determining scientific merit should be inserted into the Code. In this way, scientific justification would no longer be evident merely where there may be some benefit which results from research, but where, for example, certain thresholds of potential benefit are met. Of course, there may be some issues in determining the factors which carry greater weight or the extent of a threshold of benefit, however same should be considered in light of the fact that the current regulation is far from sufficient in protecting the interests of non-human animals.

Also prominent is the under-utilisation of analgesic and anaesthetic medication for animals in research, which it is reported is due to the potential problems associated with the reliability of data obtained where such substances have been administered. In turn, it has been recognised that where animals suffer pain or distress, this too can result in issues with the usefulness of data obtained. Clearly, either way, there is the potential for both animal suffering and a resultant lack of credibility of information so there is much need for reform in this issue. Accordingly, it is suggested that the Code should explicitly state that such substances should be administered wherever possible where pain and distress are likely to result from the subject experimentation.

Moreover, the lack of regulation in the Code relating to environmental enrichment for animals in research leaves much room for improvement of same. ‘Environmental enrichment is an important component of the animal’s physical, nutritional and social environment and contributes to meeting their physiological and psychological needs’ and is thus vital in promoting the wellbeing of animals used for research purposes. Accordingly, environmental enrichment should be more prominent in the Code and such provisions should also be more explicit in the standards required for housing and husbandry. For example, the Guidelines to Promote the Wellbeing of Animals used for Scientific Purposes provides explicit

50 Peter Sankoff, Steven White and Celeste Black, above n 7, 280.
51 Nuffield Council on Bioethics, above n 19, 137.
52 National Health and Medical Research Council, above n 20.
53 Peter Sankoff, Steven White and Celeste Black, above n 7, 284.
54 National Health and Medical Research Council, above n 20, Part 3 (E).
55 Peter Sankoff, Steven White and Celeste Black, above n 7, 285.
56 National Health and Medical Research Council, above n 20, Part 3(E).
guidelines for the environmental enrichment of various species of animals, and the
components of the environment are divided into social, human-animal, food, physical
environment, olfactory stimulation and provision for natural behaviours so that all aspects of
environmental enrichment are addressed. In this report, the National Health and Medical
Research Council has recognised that different species have specific requirements that
ensure the promotion of their wellbeing, and a strategy to ensure these are implemented
into the Code might exist by including such information as standards in a Schedule annexed
to the Code. In this way, the Code would provide specific rather than general standards and
thus non-compliance with such standards would be simple to identify.

As previously addressed, there exist various problems with the way that AECs are currently
comprised and currently operate - and these issues need to be addressed given the centrality
of AECs to the regulatory framework.

Firstly, as Knight has suggested, fixed and equal numbers in each membership category
must be fundamental to AEC composition to eliminate obvious potential for bias. Clearly,
though, bias can never be eliminated but this strategy should serve to minimise same. As
such it is suggested that the Code contain provisions regulating the balance of the members
within an AEC.

Despite the introduction of such measures, however, given there are issues with the
independency of Category D members in that they often come from the AEC institution, it is
suggested that this practice be explicitly prohibited by the Code. Also, the Code should not
allow additional members to be appointed as an AEC sees fit as this simply allows for greater
bias and partiality. It is hoped that such changes would attempt to promote an independent
viewpoint within AECs. There may be some difficulty associated with monitoring compliance,
however, given the limited checks and balances available for AECs.

The limitations of checks and balances for AECs is also problematic; due to confidentiality
agreements, and limitations in the Code in that all complaints are to be resolved within AECs

57 Ibid.
58 Ibid.
59 Peter Sankoff, Steven White and Celeste Black, above n 7, 282.
60 Ibid.
with the exception of referring a complaint to an external person or agency,\(^\text{61}\) people outside of the AEC have no way of monitoring compliance with the Code to ensure that animals’ interests are being protected. Thus, the NHMRC should establish a body within the Council which has the role of providing this checking function of the practices of AECs. Providing this method of monitoring is the only way the framework can improve without abolishing AECs and establishing a new model, because improvements in the Code are to some extent useless whilst ever there is no monitoring of compliance.

Furthermore, reform is required in terms of promoting the 3Rs, particularly replacement as it has been reported that there are several replacement options often available for research, including ‘the use of less - (or non-) sentient organisms… the use of in vitro techniques… the use of non-biological replacement alternatives… [and] human studies’.\(^\text{62}\) It is considered that reform by way of solidly reinforcing consideration of the 3Rs within AECs given would be most successful, as it is within AECs that decision-making process comes to the ultimate decision. Additionally, it has been evidenced that there is currently little room within AECs for members who specialise in research not involving animals, but instead by other means.\(^\text{63}\)

In response to this flaw in the current composition of AEC members, it is suggested that the Code be amended to provide for members of Category E, being members who specialise in the utilisation of alternative methods for research. It is expected that the inclusion of such members will allow these members to provide significant input into the decision-making process of the approval of research in terms of replacement options, and in the long term it would be desirable for all committee members to come to a better understanding about replacement techniques and their usefulness in avoiding the use of animals in research.

Whilst the above suggestions for reform would likely improve the current regulatory framework with a view of promoting the interests and wellbeing of animals, the ultimate method of reform would be to adopt an *equal consideration* approach to the balancing of costs and benefits in justifying animal research. Such reform would truly change the face of this important issue, and would likely afford animals the greatest form of interest and

\(\text{61}\) National Health and Medical Research Council (2013) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, 8th ed, 5.8.  
\(\text{62}\) Vaughn Monamy, above n 8, Chapter 6.  
\(\text{63}\) Denise Russell, above n 27, 133.
wellbeing protection available to them. This option for reform, however, is unlikely to become a reality given the prevalence of the human superiority complex in modern society and in regulatory frameworks relating to animals.

5 Conclusion

Conclusively, the current framework regulating the utilisation of animals in research - despite its intentions to afford animals some protection - is somewhat problematic in several ways. The assumption of human superiority, however, is the most prominent issue with the framework, although rectification of this issue is unlikely to occur in modern day society. Thus, reforming the other flaws of the framework is vital for the purpose of attempting to afford adequate protection to the interests and wellbeing of non-human animals.
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