

Australia's ethical framework for animals used in research and teaching

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Abstract

There is a long history of public debate as to the acceptability of the use of animals for scientific purposes be that for research, for teaching or for product testing. The basic tenet of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code) is that there is an ethical imperative in our decisions as to if and how animals are used in these circumstances. The Code provides a framework for ethical review which incorporates a set of guiding principles and establishes institutional Animal Ethics Committees with responsibilities for oversight of these activities; the nexus between animal welfare and scientific outcomes and the recognition that such ethical decisions are not matters for the scientific community alone but must involve the wider community are notions central to the effective implementation of the Code.

The Code also identifies the responsibilities of the various parties involved such that the arrangements within which individuals exercise their responsibilities are clarified and processes for accountability are transparent. The framework for ethical review and the governance arrangements which underpin responsibilities and accountabilities are intricately linked and must be so if the aims of the Code are to be achieved.

First published in 1969 as an initiative of the scientific community under the auspices of the National Health and Medical Research Council, the seventh edition of the Code was published in 2004. The Code is a living document with changing community views and scientific developments reflected in each revision. The time course of the development of the Code provides a background to examine the way in which policies governing the use of animals for scientific purposes have evolved in Australia. This paper will provide an overview of these developments and discuss the influences which have shaped the key elements of this approach.

Introduction

Controversy about the use of animals for scientific purposes, be that research, teaching or product testing has been at the forefront of the animal welfare debate from the beginning of the modern animal welfare movement in the mid-nineteenth century. Although, from that time, the primary focus of animal welfare concerns has evolved from matters of cruelty alone to encompass, in recent times, broader issues often identified under the umbrella of the 'Five Freedoms', the fundamental issue with animal research has always been whether or not animals should be used for these purposes.

Such questions arise primarily because when animals are used for scientific purposes accepted animal welfare benchmarks cannot always be met; in limited circumstances, animals may experience discomfort, disease, pain or distress as a deliberate component of an experimental study. Clearly there needs to be special justification for this to occur – we need to decide when and if this is acceptable and, if so, by what criteria. Thus, ethical decisions have been important to our use of animals in science for many years.

Perhaps more than any other animal welfare issue, the use of animals in research and teaching is marked by robust public debate and, on occasion, by conflict. From the anti-vivisection rallies in Britain at the end of the nineteenth century to more recent times where we have seen research laboratories vandalized and scientists attacked, this debate highlights the diversity of views and the depth of feelings in our community about our relationships with and duties towards other animals and the complex cultural, social and personal dimensions of these relationships. We are confronted with a range of competing values and passionately held beliefs which challenge and potentially confound our reaching agreement as to the ethical acceptability of our use of animals in these circumstances.

Countries have responded to these issues in various ways that reflect historical experiences and cultural differences. In so doing, governments have sought to bring about circumstances whereby concerns about the acceptability of the use of animals for research and teaching are addressed but which permit such use in ways which are broadly acceptable to the wider community. As a common principle, we seek to

promote the public good by recognizing, and seeking to balance, the competing claims of animal welfare and of the potential benefits to society from these scientific activities. Ethical considerations are integral to such an approach. Thus, in recent years, processes which support ethical decision-making have evolved so that today in many countries ethics committees play a central role in the governance of our use of animals for scientific purposes.

Despite a common vision, the development of these committees in different countries will be influenced by and so need to respond to local circumstances. This paper will describe the development in Australia of a framework to address the ethical challenges we face when deciding if and how animals are used for scientific purposes. The key elements of and influences in this approach will be discussed and parallels with international initiatives highlighted.

Development of the Australian Code of Practice

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (the Code)* (NHMRC, 2004) defines the ethical framework for making decisions as to if and how animals can be used for these purposes in this country. The Code sets out the general principles which guide these decisions and details processes for ethical review, approval and monitoring. The Code encompasses all aspects of the care and use of animals involved in research, product testing or teaching activities in the fields of medicine, biology, agriculture, veterinary and other animal sciences. The Code concerns the use of all live, non-human vertebrates and higher order invertebrates such as cephalopods.

The Code was first published in 1969 as an initiative of the scientific community and since then has been revised on six occasions, most recently in 2004. An overview of the scope and contents of successive editions of the Code highlights how the key elements of the ethical framework have evolved.

The intent of the Code, as stated in the first edition, was to set down guidelines for the conduct of experiments involving animals to ensure pain or discomfort was prevented or minimized; in so doing, to promote humane conduct of these activities. The 1969 edition highlighted the scientific rationale for inferring that some animals could experience pain and the need to recognize that not only the experience of pain but of suffering, discomfort and distress also needed to be taken into account. The importance of standards of animal care, meeting different species-specific

requirements and the skills of animal care staff in achieving the goals of humane experiments was argued. Notably, the important link between animal welfare and scientific outcomes was highlighted – “*For humane reasons and to ensure minimum variability in experimental methods all laboratory animals should receive every consideration for their comfort and well-being*”.

The second edition of the Code in 1978 continued these themes and sought to emphasize the responsibilities of those involved, the need to limit the level of pain, distress or discomfort which animals may experience and to ensure that “*research is not prejudiced by inefficient experimental techniques and lack of animal care*”. The underlying principle was that “*the lives of animals, especially vertebrates, should be treated with respect and care and their welfare catered for at all times*”; experiments involving animals needed to be justified and use the minimum number of animals. Of note, the Code now required institutions to establish an Animal Experimentation Ethics Review Committee to ensure investigations using animals conformed with accepted standards of animal care as set out in the Code.

In the 1980's there were a number of important international initiatives in relation to the use of animals in science. In the United Kingdom, the Animals (Scientific Procedures) Act was introduced which replaced the 1876 Act which had been the first legislation in the world to regulate animal research, the Council of Europe issued a Directive to protect animals used in scientific procedures (Council of Europe, 1986) and the US Congress commissioned a report by the Office of Technology Assessment on *Alternatives to Animal Use in Research, Testing and Education* (OTA, 1986). These initiatives reflected the level of public discourse on these questions and a growing consensus that such use of animals raised important ethical questions. Further, the publication in 1985 by the Council for International Organizations of Medical Sciences of the *International Guiding Principles for Biomedical Research Involving Animals* (CIOMS, 1985) was evidence of an evolving international agreement on the need to justify such use of animals, to use the minimum numbers and to limit pain and distress and the pursuant responsibilities of researchers.

In Australia, during this time, there were a number of important initiatives by both Federal and State governments. In 1984, the Federal Government initiated a national enquiry into animal welfare by a Senate Select Committee. This enquiry, conducted over five years, included animal experimentation as one of its major terms of reference with the *Report on Animal Experimentation* released in 1989 (SSCAW, 1989). This

Report identified the need to ensure that the use of animals is justified through ethical review and the application of the principles of the 3R's – Replacing the use of animals where possible, and, when this was not so, to use the minimum number (Reduction) with minimum impact on their welfare (Refinement). The Senate Select Committee concluded that there was conditional community support for the use of animals in science but that it was paramount that the welfare of animals was promoted and protected and that transparency of process, public participation in the ethical decision-making as well as mechanisms for accountability were important.

The primary legislative responsibility for animal welfare in Australia is vested in the States and, in this period, Victoria, South Australia and New South Wales introduced new legislative arrangements to regulate the use of animals for scientific purposes.

During the 1980's there were three revisions of the Code in 1985, 1987 and 1990 with the fifth edition in 1990 being an important milestone. This edition brought forward the principles which had been developed in previous editions and detailed a framework for ethical review aligned with the goals set out in the Senate Select Committee Report and published international standards. This framework has withstood the test of time and has been substantially unchanged in subsequent editions of the Code.

The major addition to the Code in the sixth edition in 1997 was a section on wildlife research - an important development and one of the first national policy documents to address these issues.

The most recent edition of the Code in 2004, brought several important developments. A statement on the 'duty of care' of all those involved in the care and use of animals for research or teaching, although inferred in previous editions, was a timely clarification which serves to highlight this core value. The inclusion of definitions of pain, distress and well-being provides a broad and practical conceptual framework within which the impact of circumstances and procedures on the welfare of animals can be assessed and managed. Further, the inclusion of a requirement for external triennial review of an institution's ethical review procedures is a significant development as an additional mechanism to support institutional arrangements and accountabilities.

It is notable that throughout its history of nearly forty years, the foundation principles of the Code have been constant – respect for animals and a commitment to their welfare,

the imperative to only use animals when justified, to promote the 3Rs and to recognize that inextricable link between animal welfare and scientific outcomes.

The Code is sponsored by the peak national organisations with responsibilities for the funding, or conduct, of scientific activities in Australia. From the first edition, the National Health and Medical Research Council (NHMRC) has taken a leading role in the development of the Code having been a sponsor since its inception and supporting its on-going revision and publication. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has been a co-sponsor since the second edition and continues to be so along with the Australian Research Council (ARC) and Universities Australia (formerly the Australian Vice-chancellor's Committee) both of which have co-sponsored recent editions.

The capacity of the Code to deliver its stated goals rests on two key platforms – an ethical framework and effective governance arrangements.

An Ethical Framework

The fundamentals of the ethical framework that is established by the Code are a set of guiding principles that inform a process for ethical review; this review being undertaken by an Animal Ethics Committee (AEC) that must include representatives of the wider community in its membership.

Such a framework is important to facilitate effective ethical review. Although we can agree that our use of animals in these circumstances poses ethical questions that must be addressed, we do not have consensus as to the value we place on the interests of the animals when deciding if such use is acceptable. Consequently, a robust process that supports the expression of differing views, facilitates genuine debate and seeks to reach a conclusion through open and critical examination of argument, is important for there to be confidence in and broad acceptance of the outcomes.

The Code is not a prescriptive document but rather sets out principles which establish the criteria against which, on a case by case basis, the evidence put forward to support a decision to use animals can be tested. This approach permits a set of common principles to be applied to a wide range of circumstances. It provides flexibility and allows an in depth review of the specifics of a particular project so that the potential risks to the animals involved are identified and strategies to manage those risks are developed. Not only is this approach compatible with how science is done - how

research is planned, reviewed and conducted - but, importantly, it promotes an assessment of animal welfare which is focused on the particulars of a project and supports the incorporation of new knowledge relevant to promoting animal welfare on an on-going basis. Further, based on statements of principle, the Code provides criteria to assess animal welfare outcomes for particular procedures, for example, in the choice of methods for anesthesia or euthanasia which are best suited to the species and the circumstances of the proposed study. Thus, a principle-based approach enables animal welfare outcomes in the context of scientific activities that would not be possible using a more prescriptive document.

Animal Ethics Committees

The Senate Select Committee identified AECs as the 'lynch pin' in any system of ethical review arguing that it was the collective wisdom of a committee with each member bringing their own expertise and values to bear on a matter that would enable broadly-based, collective judgments to be made. The Committee concluded that AECs served a major social benefit by bringing together people of differing views and saw a pivotal role for lay/non-scientist members reasoning that their involvement would improve the review process by providing a broader consideration of animal welfare issues. It was recognized that there was a need to reconcile human needs and animal interests and that such decisions needed to be informed by an examination of the evidence. Further, by providing an interface between scientists and the wider community, it was seen that the AEC could increase the awareness among scientists of wider community views.

Under the Code, institutions which use animals for scientific purposes must appoint an AEC whose primary role is to ensure that any use of animals within that institution is in accord with the principles of the Code; the AEC reviews and monitors all activities concerned with the breeding, supply and use of animals in these circumstances. Before approval is given for a specific project to commence, the Code requires AEC members to be satisfied that a case has been made that the proposal is justified taking into account the predicted scientific or educational benefit, the evidence that the use of animals is necessary and that, for those animals used, the study will involve the minimum number compatible with the scientific goals with minimum impact on their welfare – i.e. there is a critical evaluation that the principles of the 3Rs have been rigorously applied. Consequent AEC decisions should, where possible, be on the basis of consensus.

The membership and operation of the AEC are detailed in the Code which requires four categories of membership – a veterinarian with relevant expertise, an active scientist, a person representing animal welfare and a community representative.

Concerning the animal welfare member, the Code requires the appointment of ‘*a person with demonstrable commitment to and established experience in furthering the welfare of animals, who is not employed by or associated with the institution and not involved in the care and use of animals for scientific purposes*’. The community member also must be independent of the institution and not involved in the use of animals in scientific or teaching activities. It is intended that this person will bring to the AEC a wider, independent community view not reflected in the expertise and experiences of other categories of membership.

While there can be more than one person appointed to each membership category, if more than four members, the animal welfare and community members must represent at least a third of the total membership. Approval of projects can only occur at AEC meetings where attendance of members from each category is necessary for a quorum. The AEC Executive must have at least one animal welfare or community member.

AEC membership is drawn from a spectrum of interests, seeking to bring a diversity of views to its deliberations. There will be tensions between competing values and interests; differences that can place particular demands on AEC members. Whilst it is recognised that external members, in particular animal welfare and community members, play a critical role, their engagement with the AEC process can be problematic by virtue of their being external to the organization and, often, with limited scientific knowledge. The AEC process must be inclusive; all members must be involved. Members need to be informed of issues, aware of sensitivities and, when necessary, committed to the resolution of differences. The provision of complex technical information to AEC members in lay language is an essential, and sometimes challenging, aspect of this process.

In the 1980's, there was considerable debate around two issues relative to the operation of AECs. The first concerned whether or not AECs should operate within, or be external to, institutions. The Senate Select Committee supported the argument that had been made in a number of submissions that institutional AECs would be more effective by the close supervision they could bring to the conduct of such research. As

will be discussed below, the placement of the AEC within an institution is integral to the effective governance of these activities.

The second matter concerned the involvement of members of animal welfare organisations – on one hand concern by scientists that they could have a negative influence on the determinations of the AEC, on the other, concerns expressed by members of animal welfare organisations that their involvement in the AEC process was tantamount approval of activities with which they disagreed. Despite these misgivings, as noted by Peter Singer (1991), members of animal welfare organisations play a significant role on AECs.

Public Participation

It is inescapable that questions about our use of animals in science must involve the wider community. In Australia, this occurs at three levels – through AEC membership, through involvement in the external triennial review of AECs and through participation in the revisions of the Code.

Involvement with AECs, as outlined above, is an essential avenue for wider community participation in decisions as to why and how animals are used for scientific purposes. Representation of the wider community on AECs was strongly endorsed by the Senate Select Committee; as argued by Warnock (1984), such ethical questions are matters for society as a whole and are not the prerogative of the scientific community alone. Consequently, evidence of effective public participation is relevant to the successful operation of an AEC.

The only study to date concerns the operation of AECs in Canada (Schuppli and Fraser 2007) and identified a number of factors that, the authors concluded, could lead to bias in the AEC's determinations. They cited a preponderance of institutional members and potentially an intimidating process from the perspective of a 'minority' member - non-institutional members possibly without scientific expertise or differing animal welfare views – as matters of concern. Similar issues have been identified in a number of studies of human research ethics committees (for example, Anderson, 2006). A common theme in all these studies has been an identified need to clarify the role of community members. In a detailed consideration of these questions, Dyer (2004) supported the conclusions of Schuppli and Fraser of the need to better define and understand the role of lay members on ethical review committees so as to fully realise the potential value from their involvement.

The 2004 edition of the Code included details for the external review of the operation of institutional AECs; the aim being to validate that the welfare of animals used by the institution was 'safeguarded in accordance with the Code'. Members of the review team must be external to the institution and may include animal welfare or lay members from other AECs. This review is seen as providing an opportunity for self-assessment by the institution with feedback from the review team bringing new, or different, perspectives and so assisting the institution to evaluate, and if necessary modify, its procedures. Given that, in the course of this review, the AEC process is assessed as to whether it is 'fair and transparent', the important issues identified in the Canadian study can be addressed and remedial action taken as necessary.

The review of the Code is conducted under the auspices of the NHMRC. The three most recent revisions (1990, 1997 and 2004) have involved community representation and consultation. In 1997, the Code Liaison Group (CLG) was established to have on-going responsibility for the revision and oversight of the Code. Membership of the CLG comprises nominees the Code sponsors together with representatives of the State and Territory government departments with legislative responsibilities, the Royal Society for the Prevention of Cruelty to Animals and Animals Australia, the latter being major national animal welfare organisations. Through the processes required under the NHMRC's Policy on Public Consultation (NHMRC, 2002), the Australian community is actively engaged in this process. The review takes into account both scientific and technical developments as well as community views about the ethics of animal use in research, teaching and product testing. All submissions to the review are taken into account in the drafting of the final document.

Analysis of submissions to the Code revisions is one indication of the level of involvement by interested parties. Data for 1990 – 2004 show that whereas animal welfare organisations represented only 6% of respondents in 1990, in 1997 this increased to 22% and was sustained at a comparable level (18%) in 2004. In the same time, the number of individual submissions fell from 12 to 6% and submissions from institutions varying from 69% in 1990 to 38% in 1997 and 66% in 2004. Thus there is evidence of sustained, active involvement by interested parties and on-going participation by the non-scientific community.

Supporting ethical decisions

The Code is a living document; to be relevant and influential it needs to respond to emerging community concerns and to reflect advances in scientific knowledge whether that be procedures which present specific ethical dilemmas or information concerning animal welfare. Further, as argued above, it is important that ethical decisions are informed by evidence in support of claims to justify the use of animals. Thus, over the course of Code revisions there have been changes in detail and content concerning specific matters and, in areas where more detailed information would be helpful, policies and guidelines have been developed to supplement the Code and to provide contemporary information as a resource for researchers, teachers and AEC members in their deliberations. The following examples highlight these kinds of initiatives.

The avoidance and minimisation of an animal's experience of pain and distress has been a guiding principle of the Code since its inception. In the 1969 edition it was noted that pain is *a subjective and, as yet, poorly understood phenomenon ... but that ... the only defensible position is to assume that procedures known to cause pain in ourselves will do so in animals with a comparable neural apparatus* – an approach which we still use today. Our knowledge of pain and distress in animals and our ability to assess and treat such pain and distress is rapidly evolving but, over the period in which the Code has existed, only recently have these phenomena been subjected to critical enquiry; the first textbook on laboratory animal anaesthesia was published in 1982, major publications on animal pain did not occur until the late 1980's and the concept of 'pain management' in animals has been a very recent development. Nevertheless, in each edition of the Code, increasing attention has been given to the recognition and management of pain and distress and to ways to limit the possibility of these experiences – concepts of pain, distress and pain management being modified to align with developments in the scientific literature. The 2004 edition of the Code broadened the concept of animal welfare to encompass an animal's experiences ranging from a positive state of wellbeing to a negative state of distress. Subsequently, the NHMRC has published a *Guideline to Promote the Wellbeing of Animals Used for Scientific Purposes* (NHMRC, 2008) as a comprehensive and practical guide based on current scientific knowledge. An animal's state of wellbeing is the benchmark and any circumstance that negatively affects that needs to be identified and, if possible, eliminated; the exception being where this is integral to the research plan when, if approved, the impact must be managed and limited.

The use of genetically modified (GM) animals or of non-human primates for scientific purposes raises particular ethical concerns. Both these activities are addressed in

current guidelines (NHMRC & OGTR, 2006; NHMRC 2003). Compliance with the policy on the use of non-human primates is mandatory to undertake such research in Australia and the GM guidelines have been recognized by the International Council for Laboratory Animal Science as a benchmark international document. Further, Australian researchers are active in the development and evaluation of ways to improve how we house and handle primates and so contribute to the body of evidence which will better inform our decisions (Homes et al., 1996; Cross et al., 2004; Pines et al., 2007; O'Brien et al., 2008).

Finally, issues around improving the living conditions of laboratory animals have been raised for many years (for example, Singer, 1990). Today, as a general principle, the Code requires us to provide animals with living conditions that meet species-specific physiological and behavioral needs. The need to develop evidence-based guidelines to inform this principle is acknowledged and is the subject of on-going international activities; an important strategy to achieve improvements in animal welfare (Dawkins, 2006). The NSW Animal Research Review Panel (ARRP), in co-operation with NSW Department of Primary Industries, has developed a series of evidence-based guidelines on the housing and care of animals used in research and teaching - rats, mice, guinea pigs, rabbits and sheep. These are comprehensive documents that undergo peer review by international experts prior to publication. Recently the Canadian Council on Animal Care has sought agreement to use these guidelines and to partner with ARRP in the further development of documents.

Effective Governance

It is expected that research and teaching are conducted to high ethical standards. Thus, institutions involved have in place mechanisms to be able to demonstrate that there is effective over-sight of these activities, and that standards of quality, safety, and ethical acceptability are being met. Not only are researchers, teachers and institutions responsible for meeting these standards but they need to be able to demonstrate that they are doing so. Notions of responsibility and accountability are central to effective governance.

The Code details the responsibilities of all involved in the care and use of animals when they are used for scientific purposes. The responsibilities of researchers and teachers, of institutions and of AEC members are clearly set out; the AEC processes for approval, monitoring and reporting provide mechanisms for accountability.

The primacy of the responsibility of the researcher (or teacher) is a cornerstone of the Code. The Code assigns to the researcher “*direct and ultimate responsibility for all matters relating to the welfare of animals they use*”. As noted by Professor Warwick Anderson (1990) “*No matter how many people are involved ... the scientist must accept that the buck stops here.*” The SSCAW contended that assigning this responsibility to the researcher or teacher would achieve more for animal welfare than the most stringent monitoring or supervisory system - an argument that is endorsed by many commentators (for example, Britt, 1984).

Notions of responsibility and accountability are complementary but the processes used to achieve accountability have implications for how responsibility is exercised. If accountability is sought through a system of control, this will devolve responsibility from the practitioner to the review authority and distance the practitioner from responsibility for his or her actions. When accountability is achieved through a process of authentication this will act to enhance the responsibility of the practitioner.

Thus there are significant implications for achieving the goals of the Code in relation to effective ethical review and animal welfare outcomes depending upon the governance arrangements (Rose, 1996). The Code is clear as to the relationship between the AEC and researchers and teachers and their respective responsibilities; the role of the AEC is to verify the case to use animals and to monitor approved activities - it is a process of authentication which supports, but holds accountable, the actions of researchers and teachers and, in so doing, seeks to optimize achieving animal welfare outcomes.

As noted above, legislative responsibility for animal welfare in Australia is vested in the States and Territories and, today, each have enacted legislation that regulates the use of animals in research and teaching. Although there are some differences, in all cases, the Code has been incorporated into legislation and so is the national policy that sets the standards for such use of animals. This legislation provides a formal mechanism for institutions to be accountable to the wider community for the governance of these activities but, importantly, has been crafted to support the governance framework established under the Code; institutions and governments have complementary responsibilities in the oversight of these activities.

Conclusions

Under the Code, Australia has developed a strong ethical framework based on a system of ethics committees and supported by effective governance arrangements.

These arrangements ensure both the involvement of and accountability to the wider community and, by placing primary responsibility for the welfare of animals used on researchers and teachers, seek to achieve the best possible outcomes for the welfare of those animals. To be sustainable this must be a flexible and responsive process. Key to this will be to ensure there are robust and effective procedures, in particular, to identify and address barriers to participation and to review animal welfare standards so that decisions are based on contemporary scientific evidence.

The Code is closely aligned with the goals of the Australian Animal Welfare Strategy - it underpins a national approach to ensure high ethical and scientific standards when animals are used in research and teaching; it involves the wider community in its development and implementation and, by responding to changing community views and incorporating scientific advances, it seeks to achieve sustainable improvements in animal welfare.

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