

## Public participation in decisions relating to the use of animals for scientific purposes: A review of 20 years experience in Australia

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### Abstract

Under the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, as members of Institutional Animal Ethics Committees, community and animal welfare representatives are involved in the ethical review, approval and monitoring of animal use for scientific purposes. These members must be external to the institution and comprise at least one third of the committee membership. By the incorporation of this code into State legislation, these standards are legally enforced.

Two key principles of the NSW Animal Research Act (1985) are to protect the welfare of animals used for scientific purposes and to provide a mechanism to ensure the wider community is involved in decisions as to when and how animals are used for scientific purposes. Not only does this legislation mandate the involvement of the wider community in institutional governance but also, through membership of the Animal Research Review Panel, it requires government monitoring of institutional activities.

This paper will describe the ways by which there is public participation both in the oversight of the use of animals for scientific purposes and in the review of policies in Australia related to such use and discuss issues which could be considered to support and foster public participation in these processes.

**Keywords:** public participation, animal ethics committees, accountability

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### Introduction

In Australia, governance of the use of animals for scientific purpose, including research, teaching and product testing, operates at several levels. Legislative responsibility for animal welfare is vested in the States, consequently there is no overriding, national legislation. However, there is a national code of practice (*vide infra*) which, through various instruments, is incorporated into State legislation and is therefore effectively the national policy and standard.

There has been a national code of practice since the late 1960's which, since that time, has been revised on seven occasions, most recently in 2004. Although initially developed by the scientific community, since the late 1980's there has been involvement of the wider community and animal welfare organisations in the revision process. This code of practice embodies a process of self-regulation with primary responsibility for the welfare of animals invested in the practitioner; this code is a living document and represents, in

effect, an 'agreed contract' between the scientific and the wider community as to why and how animals will be used for scientific purposes.

During the 1980's in Australia, as in several other countries, there were a number of important initiatives by both Federal and State governments in relation to animal welfare. Although the Federal government has limited legal powers in this area, importantly, in 1984 it initiated a national enquiry into animal welfare by a Senate Select Committee. This enquiry, conducted over five years, had animal experimentation as one of its major terms of reference with the *Report on Animal Experimentation* released in 1989 (SSCAW, 1989). This Report set out the goals of public policy which have underpinned subsequent developments. Specifically, the Report identified the need to ensure that the use of animals is justified through ethical review and the application of the 3Rs, Replacement, Reduction, Refinement, and that the welfare of animals is promoted and protected. Further, there needed to be mechanisms to ensure public

participation in this process as well as mechanisms for accountability.

In terms of legislative initiatives, since the mid 1980's State governments have introduced legislation to regulate the use of animals for scientific purposes, incorporating the national code of practice through a model of 'enforced' self-regulation. These developments align with the recommendations of the Senate Select Committee which advocated dual, but reciprocal, responsibility for monitoring animal welfare, arguing a role for both institutions and government. In these legislative developments only New South Wales introduced separate legislation with other States choosing to incorporate the regulation of the use of animals for scientific purposes under general animal protection legislation. Further, NSW legislation specifically mandates a role for the wider community in the oversight of these activities at both an institutional and government level.

The Senate Committee Report also discussed ways by which a code of practice could be incorporated into legislation to optimise animal welfare outcomes when animals are used for scientific purposes. It was argued that, in these circumstances, a code of practice should lay down the general principles and criteria by which practices and procedures can be judged. The Senate Committee concluded that, as the most effective way of promoting good practice and the 3Rs, the incorporation of such a code of practice into a legislative framework should be based on principles of good conduct rather than prescription of practices.

This paper will discuss the various ways by which the public participates in the governance of these activities under the national code of practice and the NSW Animal Research Act (1985).

### **Animal ethics committees**

The Senate Committee Report identified Animal Ethics Committees (AECs) as the 'lynch pin' in any system of accountability. The Committee argued 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 a broadly-based, collective judgement to be made.

The Senate Committee argued 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 recognised that there was a need to reconcile human needs and animal interests and that such decisions should be evidence-based. Another potential benefit of the AEC process was seen as being an interface between scientists and the community and so increasing the awareness of scientists of different perspectives.

### **The Australian code of practice**

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (NHMRC, 2004) (the Code) is the national public policy which governs all use of animals for scientific purposes.

Under the Code, the wider community participates in the oversight of these activities through both the AEC process and the processes for revision of the Code.

The Code establishes a set of principles which govern decisions as to when and how animals are used for these purposes and defines animal welfare outcomes. Through the establishment of institutional AECs, the Code sets out a framework for ethical decision-making with the involvement of the wider community through AEC membership. To be satisfied that a project is justified, the AEC must be convinced there is evidence both of scientific merit and to support the need to use animals (Replacement), using the minimum number of animals to achieve valid data (Reduction) with minimal impact on their wellbeing (Refinement). AECs also have a role in monitoring approved projects to certify compliance with conditions of approval and to review on-going projects to identify opportunities to refine procedures. Thus the Code reinforces and advances the public policy goals advocated in the Senate Committee Report.

The second edition of the Code, published in 1978, required institutions to establish an AEC (at that time called Animal Experimentation Ethics Committees). Membership and operation of these committees were detailed in subsequent revisions of the Code but with minimal change after the fifth edition in 1990 (Rose, 2005). The Code 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, 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 there are 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 importance of public participation is reinforced by the requirement for AEC Executive to have at least one animal welfare or community member.

### **Revisions of the code**

The review of the Code is conducted under the auspices of the National Health and Medical Research Council (NHMRC), Australia's peak body for supporting health and medical research with responsibility for providing advice to the Australian Government on ethical behaviour in healthcare and in the conduct of health and medical research. The Code is sponsored by the NHMRC, together with peak national organisations with responsibilities for the funding, or conduct, of scientific activities, namely, the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council and the Australian Vice-Chancellors' Committee.

The three most recent revisions of the Code (1990, 1997 and 2004) have involved community representation and consultation. In 1997, the Code Liaison Group (CLG) was established to have ongoing 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 for oversight of animal research, the Royal Society for the Prevention of Cruelty to Animals and Animals Australia, the latter two 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 reviews 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.

### **NSW animal research act**

The NSW Animal Research Act was introduced in 1985 as a model of enforced self-regulation, recognising that both institutions and government

have complementary roles to ensure legislative goals are achieved. As noted when introduced into Parliament, this legislation is based on two key principles: to protect the welfare of animals used in research (including product testing) and teaching and to provide a mechanism to ensure the wider community is involved in decisions as to if and how animals are used.

The NSW Animal Research Act pioneered a new approach to considerations of animal welfare in Australian legislation. In developing this legislative framework, the goal was to create legislation which took into account the rights of opposing groups to hold and express differing views and to address and recognise issues on which opinions differed in such a way as to bring a degree of acceptance from all concerned. Thus this legislation sought to provide a balance between accountability for both the decisions to use animals for scientific purposes and the conduct of those activities and the value of freedom of scientific enquiry. Especially where there may be a lack of community consensus, it was seen as important to provide mechanisms for judgements to reflect a balanced view.

The following key issues were identified as foundations to this legislation. A duty of care was identified as a core value, with the investigator having primary responsibility for the welfare of animals involved in an approved project. The role of the institutional AEC was seen as pivotal as was the participation of the wider community. The legislation also recognised the dual responsibilities of institutions, through their AECs and of government to monitor animal welfare outcomes. Under this legislation, the Animal Research Review Panel (ARRP) is mandated as the statutory authority responsible for government oversight.

Public participation in the decisions as to when and how animals are used for scientific purposes and the oversight of those activities is mandated under the Animal Research Act in a number of ways.

The Act requires that any use of animals for scientific purposes must be approved by an AEC in accord with the principles of the Code; community membership of the AEC is mandated. Thus, the Act places community representation at the centre of this legislation. Further, the Act mandates that a third of the twelve members of the ARRP are nominees of animal welfare organisations. The ARRP is responsible for accreditation of institutions, a key part of which involves members visiting institutions and undertaking a comprehensive review of all activities including the operation of the AEC. These activities enable the ARRP to identify areas where policies and guidelines will assist in the implementation of the Act, Regulations and the Code (for details refer [www.animaethics.org.au](http://www.animaethics.org.au)).

Since 1987, the ARRPs have produced an Annual Report to Parliament which, *inter alia*, documents statistics on the use of animals, initiatives to achieve the 3Rs, lists institutional visits and reports on issues identified from these visits as well as other ARRPs activities such as workshops and education programs which are developed to address specific animal welfare issues.

The outcomes sought through this legislation are principally evidence of robust processes for both AECs and ARRPs with public involvement and accountability and demonstrable animal welfare benefits in the advancement of the implementation of the 3Rs.

Although there has not been a formal review of these activities to validate progress in achieving these goals, a key element of the ARRPs site visit program is to obtain evidence indicative of the active involvement of animal welfare and community members in all AEC processes. Progress in animal welfare outcomes is documented in the ARRPs Annual Report. It is also of note that the 2004 edition of the Code has recommended that all institutions should conduct an external triennial review of the operation of their AEC. The recommended process is comparable to that undertaken by the ARRPs but with the difference that under the latter there is a formal mechanism for public accountability.

ARRPs have undertaken site visits of institutions since 1991 and from that experience can identify some key elements to achieving the legislative goals, notably, a commitment to and engagement with the processes by all involved, an acceptance of diversity of views, good communication and evidence-based practice informing decisions. Consequently, the development of education programs for both AEC members and research staff and evidence-based guidelines have been cited as key components of ARRPs's Strategic Plan. The former is seen as particularly important to sustain and progress the role of the AEC and to help maintain public confidence in the ethical review process.

### Effective public participation?

Ethical review committees have had oversight of scientific activities involving either human subjects or animals for at least thirty years. Representation of the wider community on these committees has been argued on the basis that the ethical questions raised are matters for society as a whole and are not the prerogative of the scientific community alone (Warnock, 1984). Consequently, evidence of effective public participation is central to this notion. However, it is only recently that this has been the subject of critical enquiry raising questions not only about the processes of involvement of external members but about fundamental issues related to a shared

understanding of the role of public participation.

These matters were addressed in the only study to date concerning the operation of AECs (Schuppli & Fraser, 2007). The authors identified a number of factors which, they concluded, could lead to bias in the AEC's determinations, including a preponderance of institutional members and potentially an intimidating process from the perspective of a 'minority' member, in particular, non-institutional members possibly without scientific expertise or differing animal welfare views. Similar issues also 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 so as to realise the potential value from their effective participation.

Given the expectations of the pivotal role of public participation in the deliberations about and oversight of these activities, these studies highlight an urgent need to initiate a dialogue around these questions. Engagement with a broader understanding of the social underpinnings of these activities (for example, Kelly, 2003; White & Bourne, 2007) and further critical analysis will better inform effective implementation strategies.

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