

## CHAPTER 16

### CODE OF PRACTICE AND ETHICS COMMITTEES

#### Introduction

16.1 In Chapter 15 the Committee recommended the adoption by all States and Territories and the Commonwealth of a regulatory system for animal experimentation based on the systems operating in New South Wales, Victoria and South Australia. The system is based on legislation, the code of practice, ethics committees and government monitoring. During the course of the inquiry, various issues were raised concerning the Code of Practice and ethics committees. These issues are discussed in this chapter.

#### Code of Practice

16.2 A key element in the regulatory package is the code of practice, within the provisions of which experiments on animals are to be conducted. For the provisions to be enforceable, the code of practice needs to be included in regulations made under relevant legislation. There are always some institutions or individuals who will not comply with the code of practice if it does not have the backing of the law. Not all institutions depend on government funding for their research projects rendering useless the threat of the withholding of grants as a means of ensuring compliance with the code of practice.

16.3 The Victorian Government has included the Code of Practice in its regulations under the Prevention of Cruelty to Animals Act. The South Australian and New South Wales Governments will include the draft revised Code of Practice in their regulations when it has been approved by the sponsoring bodies.

16.4 The New South Wales Government at one stage issued a draft code of practice which varied significantly from the draft revised Code of Practice. The Committee notes that, subsequently, the writing group revising the Code of Practice amended the draft revised Code of Practice by including many key provisions of the New South Wales draft code. The Committee understands that the New South Wales Government will probably now adopt the revised Code of Practice to maintain uniformity with other states.

16.5 It is sensible for there to be a single code of practice applying in all States and Territories and in Commonwealth facilities. That should not prevent a government from imposing extra requirements in regulations to tighten control of animal experimentation. Inevitably, a code of practice is the minimum set of standards which all parties bound by the code are prepared to accept. Some parties may wish to raise the standards within their area of authority. If this improves animal welfare, it should be encouraged.

#### **Revision of the Code of Practice**

16.6 Since 1965 when work was begun on the original Code of Practice, the NHMRC has had the main carriage of the preparation and revision of the Code of Practice. During most of this period, the responsibility for the adoption of an ethical approach to experiments on animals and for the welfare of animals was left to the NHMRC. The CSIRO and later the AAC joined the NHMRC in revising the Code of Practice but it has always been the NHMRC which has provided the administrative support for the Code of Practice.

16.7 The NHMRC has done a good job in establishing the Code of Practice and in carrying out its first three revisions. However, the Committee is aware of difficulties and tensions among the NHMRC, some State Governments and other bodies during the recent revision of the Code of Practice. With the new Code of Practice to be included in regulations in three States and with responsibility for enforcing compliance with the Code of Practice in the hands of those States, a new approach should be taken for conducting future revisions.

16.8 In the past, a new edition of the Code of Practice has come into force when it has received the approval of its sponsoring bodies - the NHMRC, the CSIRO and the AAC. In the future, the State and Territory Governments which will include the Code of Practice in regulations should give it final approval. If the State and Territory Governments were unhappy with a revised Code of Practice, they would withhold their endorsement anyway and not substitute it for the existing Code of Practice. Alternatively, the Governments would simply amend the revised Code of Practice to bring it into line with their policies.

16.9 There are many interested parties in revisions of the Code of Practice - governments, institutions which conduct animal experimentation, experimenters, animal house staff, specialist societies, animal welfare organisations, educational organisations and funding bodies. It would be sensible for all of these interests to have an input into revisions of the Code of Practice. Each party brings a different perspective to bear on the subject matter of the Code of Practice. As with the functioning of ethics committees, it is the mix of these diverse views which will result in a Code of Practice which takes account of all of the interests represented.

16.10 It has been suggested that a national conference be held annually to review the Code of Practice to draw attention to any shortcomings or to technological developments which might impinge on the Code of Practice. The Committee believes that the Code of Practice should be revised about every three years unless there emerges from an annual national conference a clear need to undertake an earlier revision.

16.11 The national conference should have an independent chairman and should include representatives of Commonwealth, State and Territory animal welfare or animal experimentation advisory councils; AVCC; CSIRO; ASLAS; the Australian Association of Animal Technicians; the Australian Research Council; NHMRC; AAC; the Australian Educational Council; ANZFAS; RSPCA Australia; NFF; AVA; experimenters; and the community.

16.12 The national conference should consider and agree on the principles and main points for inclusion in a revised draft of the Code of Practice. It would then select a small writing group to incorporate the changes. When the writing group has completed its task, the revised draft would be considered by the national conference before being submitted to State and Territory Governments for approval. If a Ministerial Council for Animal Welfare were established, the revised Code of Practice would be submitted to it.

16.13 The committee to revise the Code of Practice should draw on the resources of ACCART for technical advice.

16.14 The Committee believes that ACCART should also provide the secretariat for the committee to revise the Code of Practice. ACCART is a neutral body but has many of the interested parties as members.

16.15 The Committee RECOMMENDS that future revisions of the Code of Practice be carried out by a national conference consisting of representatives of governments, institutions which conduct animal experimentation, experimenters, animal house staff, specialist societies, animal welfare organisations, educational organisations and funding bodies and that final approval for those revisions be given by Commonwealth, State and Territory Governments which include the Code of Practice in regulations.

#### Compliance with the Code of Practice

16.16 Until recently, ensuring compliance with the Code of Practice has been the responsibility of funding bodies. Grants were made to experimenters and institutions for projects involving experiments on animals on the condition that they adhere to the provisions of the Code of Practice. Ethics committees were also required to screen proposals for compliance with the Code of Practice.

16.17 In practice, there was little effort made to secure compliance with the Code of Practice by experimenters and institutions. Many ethics committees did not carry out their responsibilities and some institutions did not even have ethics committees in operation. The NHMRC and other funding bodies had no resources to monitor compliance and they depended on statements of compliance from experimenters and institutions. The NHMRC in its original submission dated February 1984 to the Committee stated:

... experience indicates that there is complete compliance with the Code on the part of the medical researchers in Australia.<sup>1</sup>

16.18 By the time that representatives of the NHMRC gave evidence to the Committee on 29 August 1986, the view of the NHMRC about compliance had changed to some extent:

There was no evidence in 1984 of lack of compliance. It would still be difficult to identify whether or not there is lack of compliance. It became clear to the Council that simply asking people to ensure in the submission of their grant application that their proposal had been examined by an ethics committee and that that ethics committee had put a signature on it was not sufficient for the Council to be able to be completely satisfied that compliance was occurring and it was for that reason that Dr Anderson's committee was asked to provide advice, information and input on this matter to the Council.<sup>2</sup>

16.19 The Committee sent out about 50 questionnaires to universities and other institutions which conducted animal experimentation. From the completed questionnaires, it was quite obvious that many institutions were not complying with the Code of Practice in one way or another. The AVCC, with whom the Committee liaised during the preparation of the questionnaire, analysed the returns from the 19 universities. It acknowledged that there were areas in a number of universities that required changes in practice or procedure.<sup>3</sup> In at least two universities, the Committee noticed during its inspections a disregard for the universities' own procedures.

16.20 There is no doubt that the Code of Practice has not been adhered to in all respects. The Committee has noted, however, that during the course of the inquiry, considerable improvements have been made by many institutions in improving facilities and procedures. There has been a growing awareness of the need to adopt a more ethical and careful approach to the use of animals. This has been not just to reflect changing attitudes within the community but also to acknowledge that improvements in animal care and use result in more reliable data.

16.21 In November 1985 the NHMRC decided to take a more active role in monitoring compliance by appointing its own ethics committee. It was given three functions, the third of which was:

With the approval of the Council, to develop and implement ways of ensuring that all animal experimentation funded by the NHMRC is in accord with the current 'Code of Practice'.<sup>4</sup>

16.22 The NHMRC admitted in evidence on 29 August 1986 that it allocated one clerical officer to administer the committee although that officer had back-up support within the then Department of Health. Dr Anderson added that the Baker Institute provided secretarial assistance.<sup>5</sup>

16.23 The budget of the NHMRC ethics committee was limited and membership was originally restricted to people based in Melbourne in order to contain costs.<sup>6</sup>

16.24 It is questionable whether the NHMRC or any other funding body should try to ensure adherence to the Code of Practice. Obviously, it should keep the requirement that funds should only be disbursed to experimenters and institutions which agree to comply with the Code of Practice. Any aspect of a proposal for funding which indicates possible non-compliance with the Code of Practice should be queried and amended if necessary to obtain compliance. However, for a funding body to go beyond these measures requires additional resources and runs the risk of causing other problems.

16.25 The NHMRC funds a small proportion of projects in which experiments are carried out on animals. For the NHMRC to establish a unit to monitor compliance with the Code of Practice means that it would only cover a small proportion of projects anyway. Each funding body would need to set aside resources for this purpose. This would make the system cumbersome and expensive to operate. Different standards or interpretations might apply among the funding bodies to add to the other problems.

16.26 Regulation of animal experimentation is a State responsibility. A State government may decide to impose stricter conditions on experimenters and institutions than those contained in the Code of Practice. The Code of Practice may therefore conflict with regulations made under State legislation. This would create problems for a funding body, if it had to police non-compliance with the Code of Practice. If several States had different regulations, it would compound the difficulties faced by a funding body in ensuring compliance.

16.27 Three States have since 1985 revised legislation and established mechanisms to control and monitor animal experimentation. In all three States the legislation has provided for the appointment of inspectors to carry out this monitoring. There are also moves among the other States and Territories for similar provisions to be put in place.

16.28 The Committee firmly believes that the relevant government authorities in the States and Territories and within the Commonwealth should be responsible for ensuring compliance with the Code of Practice or other regulations made under legislation. These authorities have a legislative responsibility to carry out this task. With government authorities taking over monitoring of compliance, funding bodies should avoid causing confusion by trying to duplicate government efforts in this area, except where non-compliance is obvious from proposals or reports of completed or partially completed projects.

### **Emergencies**

16.29 In the draft revised Code of Practice dated 22 February 1989, there is provision for the nomination of a person to respond to emergencies:

On each site where animals are used, the AEEC should nominate a person who is authorised to respond to emergencies. Where possible, this person should be a member of the AEEC.<sup>7</sup>



16.30 Although an executive committee of an ethics committee may be authorised to deal with emergencies, it may find it impossible to respond to an emergency in a remote facility or even one away from the main campus or headquarters area. The nomination of a person on each site to respond to emergencies enables action to be taken quickly in the event of an emergency. The Committee believes that this is a positive step towards allocating responsibility and authority in the interests of animal welfare. The Committee, however, believes that it should be mandatory rather than optional for such nominations to be made.

#### **Animal Welfare Officers**

16.31 In the draft revised Code of Practice which was distributed for comment in 1988, provision was made for the appointment of an animal welfare officer in institutions. In the draft, it was stated:

Institutions should consider whether an animal welfare officer should be appointed, responsible to the AEEC. An animal welfare officer should have veterinary or other appropriate specialist qualifications, and may act as the executive officer of the AEEC but should not be concerned directly with the day-to-day care or husbandry of the animals. The animal welfare officer must be authorised by the AEEC to ensure compliance with the requirements of this Code and of the AEEC, including the treatment or human killing of any animal.<sup>8</sup>

16.32 The paragraph on animal welfare officers was deleted from the 22 February 1989 draft of the revised Code of Practice. In that draft, it was suggested:

Large institutions with multiple sites of animal care and use should consider whether an Executive Officer with veterinary or other appropriate specialist qualifications should

be appointed. An Executive Officer should be authorised by the AEEC to ensure compliance with the Code and decisions of the AEEC.<sup>9</sup>

16.33 In effect an executive officer has been substituted for an animal welfare officer.

16.34 Few institutions have appointed animal welfare officers although a number have purportedly appointed an animal welfare officer by arranging for a local veterinarian to make periodic inspections of animal houses. Such an arrangement cannot be regarded, however, as the appointment of an animal welfare officer. Animal welfare officers are officers who are appointed on a full-time or part-time basis and who, in the latter case, have other duties within the institution. Apart from carrying out monitoring duties to ensure that the care of animals and experimental projects are carried out in compliance with the Code of Practice and institutional policies, the animal welfare officer has advisory and educational roles to fulfil. The animal welfare officer should be developing standards of care and promoting good animal welfare practice, emphasising the correlation between good animal welfare and reliable experimental data derived from experiments on animals. None of these roles, including the primary monitoring role, can be done by an external officer making occasional visits to the institution. There is nothing wrong in having veterinarians in private practice inspecting facilities but such arrangements do not constitute having an animal welfare officer.

16.35 Under the Code of Practice, the ethics committee has responsibility for monitoring animal breeding and holding areas and for ensuring that experimenters comply with the terms of approved protocols. No administrative arrangements diminish that responsibility although arrangements can be made to enhance it. Members of ethics committees individually and collectively have to fulfil this responsibility by personally inspecting animal

houses and experimentation facilities on a regular basis. It is not enough to delegate this function to an animal welfare officer or executive officer, even though either officer, if one has been appointed, may also monitor those animal houses and experimentation facilities more frequently.

16.36 As it is the ethics committee that has the responsibility for monitoring standards and compliance, the Committee believes that it is appropriate for the ethics committee to appoint an executive officer, with veterinary or other appropriate qualifications, to support it administratively and in its roles of monitoring, development of standards and education. Although it may only be a question of nomenclature, the use of 'executive officer' does reflect the responsibilities of the position and the ethics committee more clearly and it precludes the use of 'animal welfare officer' for public relations purposes only as is the case in a number of institutions at present.

#### Ethics Committees

16.37 The second edition of the Code of Practice required institutions which conducted experiments on animals to establish ethics committees to scrutinise and approve protocols for projects in which animals were involved. Since then, institutions have gradually established ethics committees although the effectiveness of some has been questionable. The Committee is aware of some ethics committees that had not met until recently or that examined protocols in a cursory way to comply with the letter of the 'law' but not its spirit.

16.38 Ethics committees are the lynch pin in the system of responsibility and accountability in the three States with upgraded legislation. The effectiveness of the ethics committees will determine whether the system is successful or not. In the

other States and Territories, they are virtually the only control over animal experimentation. Ethics committees consider all protocols for experiments on animals and they may approve, amend or reject protocols for non-compliance with the Code of Practice. They control, therefore, all experiments on animals and they have the responsibility for ensuring that experiments conform to acceptable ethical principles in accordance with the Code of Practice.

#### **Membership of ethics committees**

16.39 Membership of ethics committees is important because it determines the diversity of views that consider protocols and other business of the committees. A narrow spectrum of views consisting mainly of scientific values would tend to appraise proposals less critically than a membership which reflected both scientific and community attitudes.

16.40 The ethics committee is also a key element in the system for public accountability. By having animal welfare and community views on an ethics committee, the community has more confidence that the ethical attitudes of the community are being reflected in the judgements and decisions of the committee. The Committee believes that it is essential not only for community interests and attitudes to be the basis of decisions of an ethics committee but also for those decisions to be perceived by the community as reflecting its views.

16.41 Under the 22 February 1989 draft revised Code of Practice, the ethics committee must comprise at least four members, including one from each of the following categories:

Category A. a person with qualifications in veterinary science, preferably with experience relevant to the activities of the institution, or a person with qualifications and experience to provide equivalent expertise;

Category B. a person with substantial recent experience in animal experimentation;

Category C. a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. The person should where possible be selected on the basis of membership of an animal welfare organisation;

Category D. an independent person who does not currently and has not previously conducted experiments using animals, and who is preferably not an employee of the institution.<sup>10</sup>

16.42 The Code of Practice provides for additional people to be appointed to an ethics committee. Most ethics committees have a larger membership to reflect the diversity of research which has to be considered by the committees.

16.43 Although the person representing Category D may be appointed from within the institution, it becomes mandatory for two people from Categories C and D to be external appointments if the ethics committee has more than seven members.

16.44 The draft which was distributed for public comment required the person appointed under Category D not to be an employee of the institution.

16.45 The Committee sought the views of a number of people at public hearings on the composition of the ethics committees as set out above. At that stage the draft Code of Practice was subject to public comment. The only reservation about the membership categories that was elicited from witnesses was the requirement for the appointment of two people who have no affiliation with the institution. It was argued that a lay person within the institution, such as a professor of philosophy, would be appropriate to represent community interests. It was not

asserted that two people should not be appointed from outside the institution but that there should be more flexibility so that one of those two might be appointed from within provided that the person was suitable.

16.46 Although a suitable person may be found within an institution to fill the lay person category, the Committee believes that, on balance, it is preferable to appoint from outside of institution two people who have no involvement in animal experimentation. There can be no question then of loyalty to the institution clouding their judgement on sensitive or controversial protocols or other issues. An external appointment under Category D is more likely to ensure that community views and attitudes are reflected than an internal appointment, however well qualified the latter may be for membership of an ethics committee. It also means that the one outside member is not overwhelmed by internal members in meetings of the committee. As most ethics committees require unanimous decisions, there may be pressure brought to bear on a single dissenting member. It may put a single dissenter into a difficult position if he or she is the sole outside member on the committee.

16.47 An eminent philosopher within an institution can still be appointed to the ethics committee when an external appointment is made under Category D as there is no upper limit on the number of people appointed from each category. It has been only a matter of institutional policy that has resulted in the number of non-scientists being kept to a minimum on ethics committees.

16.48 The Committee supports the membership provisions of ethics committees as drafted in the draft revised Code of Practice which was originally published for public comment, that required the community representative to be a person not employed by the institution.

16.49 Under the draft revised Code of Practice, there must be at least one person appointed from each of the four categories. At present, as long as each category is represented, one person may represent more than one category. For example, veterinarians in private practice have often been appointed to ethics committees to represent veterinary science, animal welfare and an external appointment in the one person. This will not be allowed when the revised Code of Practice comes into effect. The Committee supports this change in policy.

16.50 The appointment of a member under Category C 'should where possible be selected on the basis of membership of an animal welfare organisation'. There is an obvious need for flexibility in this provision because in some areas there may not be a suitable person who is a member of an animal welfare organisation available for appointment to an ethics committee. However, the flexibility of the provision should not be used as an excuse not to appoint a member of an animal welfare organisation where one is available. Institutions should make appointments within the spirit and not merely the letter of the provision. In emphasising this point, the Committee believes that members of animal welfare organisations who are appointed to ethics committees must fulfil their responsibilities as members in a way that enables the ethics committees to operate effectively. In other words, there is no place on an ethics committee for people who simply want to obstruct the work of ethics committees because they have a philosophical objection to animal experimentation. The Committee noted that a number of members of ANZFAS and RSPCA have been effective members of ethics committees. By having a different perspective, they have persuaded ethics committees to consider some protocols and issues in a different light.<sup>11</sup>

## Consideration of Protocols

16.51 The manner of considering and approving protocols became a controversial issue during the course of the inquiry. A number of ethics committees have been dealing with protocols by correspondence and not at meetings of the committees. In some cases, consideration and approval of protocols have been delegated to one or a few members of an ethics committee.

16.52 Under the current Code of Practice, the constitution of ethics committees must include provisions to:

... examine written proposals relevant to the use of animals in experiments and approve only those experiments which conform to the requirements of this Code, taking into consideration ethical aspects as well as scientific or educational merit;<sup>12</sup>

16.53 The 19 February 1989 draft revised Code of Practice has four clauses which deal with consideration of protocols. Ethics committees must have terms of reference which include provisions to:

... examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals in experiments and approve only those experiments for which animals are essential and which conform to the requirements of this Code, taking into consideration ethical and welfare aspects as well as scientific or educational value;<sup>12</sup>

Proposals must be considered and approved at meetings of the AEEC.<sup>13</sup>

The AEEC may establish an executive (including at least one member from Category C or D) to approve minor modifications to projects, and deal with emergencies, but any decisions by the executive must be reviewed by the AEEC at its next meeting.<sup>14</sup>

The executive may not approve proposals.<sup>15</sup>



16.54 The above four clauses provide a clear direction to ethics committees for the consideration and approval of proposals. The current Code of Practice is unclear on this point and in many institutions advantage has been taken of this lack of clarity whereby protocols have been considered other than at meetings of an ethics committee.

16.55 Copies of protocols need to be distributed to members of an ethics committee prior to a meeting for their consideration. Members may seek additional information or do their own investigation of a protocol with which they have reservations. However, such preliminary consideration must not be a substitute for consideration at a meeting of the ethics committee. The dynamics of a meeting facilitates the raising of issues and encourages discussion. A point made by one member of a committee will often lead to a chain reaction in the thinking of other members. It is the collective wisdom of a committee, with each member bringing his or her own expertise or perspective to bear on the matter together with the other members, that enables a collective judgement to be made.

16.56 Self-regulation, within or without a legislative framework, requires both responsibility and public accountability. The system of ethics committees provides the opportunity for there to be responsibility on the part of the scientific community and also public accountability. Members representing the community or animal welfare will be, if not already are, a way for community interests to be represented in decisions on the use of animals in experiments. The public attitude towards animal experimentation is of tolerance provided that there is responsibility on the part of the scientific community. The public recognises the benefits that have resulted from experiments on animals in the past and the prospect of further benefits in the future. There is a growing feeling that such animal experiments must take place with the minimum number of animals with the least possible suffering. The use of ethics

committees with members reflecting scientific, veterinary, community and animal welfare interests, enables the public to have some confidence that the interests of the animals are being taken account of in a responsible way. The operations of an ethics committee which do not provide the greatest possible protection of the interests of the animals will, in the end, breed suspicion of the system and bring it into disrepute.

16.57 The Committee acknowledges the benefits of an executive committee making minor modifications to an approved protocol and in making decisions in emergencies, both subject to review by the ethics committee. The executive committee cannot approve protocols in any circumstances. This prohibits the practice being carried out in a few institutions where consideration and approval of some or all proposals have been delegated to one or two members of an ethics committee.

16.58 The Committee supports the system of enforced self-regulation based on ethics committees on the basis that ethics committees operate properly as committees and fully consider and make decisions on protocols at meetings of those committees and not by correspondence or delegation to one or a few members of an ethics committee.

### Guidelines

16.59 The Code of Practice sets out the principles for the care and use of animals for experimental purposes and the administrative procedures to be followed for the control and supervision of animal experimentation. It does not, however, give details of the care and use of specific species of animal. The NHMRC foresaw the need to prepare and publish additional guidelines to supplement the Code of Practice. There are various

and manuals available for scientific procedures done on some specific species and for the husbandry of those species. Not all are up-to-date. Some species, especially Australian native wildlife, are not adequately covered.

16.60 The NHMRC has draft guidelines for use of native mammals in biomedical research and has prepared another set of guidelines for primates. The latter was regarded as totally inadequate by the Australian Primate Society.

16.61 There is a need to prepare guidelines on specific species of animal to assist experimenters and animal house staff in their use and care. The Committee believes that ACCART is the most appropriate organisation to prepare guidelines in many areas of animal experimentation. It already has several monographs in the process of publication. ACCART should liaise with other specialist societies, including the NHMRC and its committees, in drawing up those guidelines. ACCART is more appropriate to undertake this task than the NHMRC because it is a resource centre whereas the NHMRC is primarily a government funding body.

16.62 The Committee RECOMMENDS that the Australian Council for the Care of Animals in Research and Teaching prepare guidelines on procedures and practices in relation to animal experimentation to supplement the Code of Practice.

Senator A.R. Devlin  
Chairman