

Animal Welfare (*Australian Model Code of Practice for the Care and Use of Animals for Scientific Purposes*) Approval 2005

Disallowable Instrument DI2005—188

made under the

Animal Welfare Act 1992, Section 22 – (Codes of Practice)

EXPLANATORY STATEMENT

Section 22 of the *Animal Welfare Act 1992* provides that the Minister may approve a code of practice relating to animal welfare.

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 7th Edition* (the 7th Edition of the Scientific Code) is prepared by the National Health and Medical Research Council (NH & MRC) in consultation with key stakeholders. It is reviewed every five years. The 7th Edition of the Scientific Code was approved by the NH & MRC in November 2004 and has also been endorsed by the CSIRO, the Australian Research Council and the Australian vice-Chancellor's Committee. The 6th Edition of the Scientific Code is an approved Code of Practice under the *Animal Welfare Act 1992*. This instrument approves the 7th Edition of the Scientific Code.

The provisions of the 7th Edition of the Scientific Code are detailed below:

The purpose of the 7th Edition of the Scientific Code is to guide investigator, teachers, institutions, Animal Ethics Committees (AECs) and all involved in the care and use of animals for scientific purposes. Encapsulated in these principles is the need in scientific and teaching activities to consider:

- the replacement of animals with other methods;
- the reduction in the number of animals used; and
- the refinement of techniques used to reduce the impact on animals

Animal Ethics Committees (AECs)—Institutions that use animals for scientific purposes are required to implement processes so that the governing body of the institution is assured of compliance with the provisions of the Scientific Code and relevant legislation. These processes must include establishing one or more AECs directly responsible to the governing body of the institution or its delegate. AEC's have been a long standing requirement of the Scientific Code.

The primary responsibility of an AEC is to ensure, on behalf of institutions, that all care and use of animals is conducted in compliance with the 7th Edition of the Scientific Code. AECs apply a set of principles, outlined in the Code, that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement.

An AEC must have a membership that will allow it to fulfil its terms of reference. An AEC must comprise at least four persons, including a separate person appointed to each of the following categories:

Category A—a person with qualifications in veterinary science and with experience relevant to the activities of the institution. Veterinarians who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animals used;

Category B—a suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities. This will usually entail possession of a higher degree in research;

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. Veterinarians with specific animal welfare interest and experience may meet the requirements of this Category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and nomination by, such an organisation; and

Category D—a person who is both independent of the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their under-graduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other Category.

Introduction—outlines the purpose and scope of the 7th Edition of the Scientific Code. It identifies that there are difficult ethical judgements to be made regarding the use of animals for scientific purposes and that the 7th Edition of the Scientific Code requires AECs to determine whether the case for animal use is justified and to ensure adherence to the principles of Replacement, Reduction and Refinement (3Rs). The 7th Edition of the Scientific Code covers all live non-human vertebrates and higher-order invertebrates. The 7th Edition of the Scientific Code advises that investigators and teachers should take into account emerging knowledge and ethical values when proposing to use other animal species not covered by the 7th Edition of the Scientific Code.

Definitions—Comprehensive definitions of terms used within the 7th Edition of the Scientific Code are included to ensure there is no confusion over requirements.

Section 1 contains the general principles for the care and use of animals for scientific purposes. This section discusses the justification required prior to any animals being used for research and teaching and outlines the responsibilities of investigators and teachers who use animals for scientific purposes. The principles of Replacement, Reduction and Refinement are outlined in this section.

Section 2 identifies the responsibilities of institutions and their AECs. This section outlines the responsibilities of the institutions and the responsibilities and operation of AECs. Included are the Terms of Reference for AECs, the responsibilities of the Chairperson, membership, written proposals, operating procedures, assessing procedures, monitoring, annual review, reporting of projects, reporting to the institutions, projects involving more than one AEC, non-institutional applicants and AEC responsibilities, projects conducted in other countries in association with Australian institutions and non-compliance with the 7th Edition of the Scientific Code.

Section 3 identifies the responsibilities of investigators and teachers. This section includes general information concerning planning projects, conducting projects, detecting pain and distress, limiting pain and distress, repeated use of animals in activities, duration of scientific activities, handling restraint and confinement of animals, completion of projects, humane killing and euthanasia of animals, autopsies, anaesthesia and surgery, post-operative care, implanted devices, organ and tissue transplantation, neuromuscular paralysis, electro-immobilisation, animal models of disease, modifying animal behaviour, toxicology studies, scientific and teaching activities involving hazards to other animals or humans, animals welfare and animal health research, genetic modification of animals, cloning of animals, induction of tumours, production of monoclonal antibodies, lesions of the central nervous system, withholding of food or water, foetal and embryonic experimentation, research on pain mechanisms and the relief of pain as well the use of non-humane primates.

Section 4 is concerned with the acquisition and care of animals in breeding and holding areas. It outlines the procedures to be followed for obtaining animals from outside the state or territory or from overseas. Information is provided on the transportation of animals, the admission of new animals into holding areas, the care of animals in holding and production facilities, pens cages and containers and the immediate environments of animals. This section goes on to outline issues dealing with the management and personnel in charge of animals and their minimum animal care qualifications, what occurs with routine husbandry procedures, animal identification and the disposal of carcasses and waste material.

Section 5 makes particular reference to free-living native vertebrates and those captured from free living populations, including non-indigenous and vertebrate pest species. It covers the requirements for taking wildlife from natural habitats, appropriate techniques for handling, capture and restraint, transportation, identification and field techniques.

Section 6 provides the minimum standards acceptable in relation to the care and use of animals in teaching activities. It outlines the responsibilities of teachers and how proposals for teaching activities require a proposal to an AEC.

An extensive appendix and a bibliography as a source of reference and further reading is appended in the 7th Edition of the Scientific Code.

Appendix 1— External Review of the Operation of Institutions and their Animal Ethics Committees—outlines the new requirement of ensuring that an external review of the workings of an AEC is conducted triennially. This appendix provides for the scope and outcomes of the external review as well as how the review should be conducted.

The 7th Edition of the Scientific Code recognises that there are many acceptable models for the conduct of an external review, and the approach taken will vary with particular institutional needs.

The external review should represent an informed, broad-based view. Members of the review team must be external to the institution and may include persons who have relevant and appropriate qualifications or experience such as a knowledge of animal welfare matters pertaining to research and teaching institutions, a demonstrated interest in animal welfare or experience in the administration of animal welfare and animal ethics appropriate to the institution.

The ways in which the review team accesses information and conducts its enquiries will vary but could include review of documentation, observation of activities and procedures, and discussions with parties involved.

Appendix 2—Legislation and Codes of Practice—Outlines all relevant Australian legislation and codes of practice that governs the practices and procedures to protect the welfare of animals used for scientific purposes.

Appendix 3—Policies & Guidelines—Outlines a number of authoritative sources to assist investigators, teachers and members of AECs in deciding which practices in light of current knowledge, best satisfy these principles for particular purposes or procedures.

Appendix 4—Information Sources—Outlines bibliographic information sources that have been selected on the basis that they contain information that will be most helpful in the implementation of the principles of the 7th Edition of the Scientific Code, in particular, with regard to ethics, the care and use of animals for scientific purposes and the management of pain and distress. This is not intended to be a comprehensive bibliography but rather to assist in accessing information that would be widely applicable. Investigators and teachers should consult specialist texts, journals and databases for specific information for a particular project. Journal articles have only been included in this list when no other text material is available.

Appendix 5—Alternatives to the Use of Animals—Outlines a number of organisations around the world that are working towards the development and validation of Replacement methods. Many have informative web sites.