Australian Government
National Health and Medical Research Council

Australian code of practice for the care and use of animals for scientific purposes

7th Edition 2004

INVESTING IN AUSTRALIA'S HEALTH

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representatives of the:
State and Territory governments of Australia; Animal welfare organisations (RSPCA and Animals Australia); and

endorsed by the:
National Health and Medical Research Council; Commonwealth Scientific and Industrial Research Organisation; Australian Research Council; and Australian Vice-Chancellors' Committee.

The strategic intent of the NHMRC is to work with others for the health of all Australians, by promoting informed debate on ethics and policy, providing knowledge based advice, fostering a high quality and internationally recognised research base, and applying research rigour to health issues.

Documents for the NHMRC are prepared by panels of experts drawn from appropriate Australian academic, professional, community and government organisations. The NHMRC is grateful to these people for the excellent work they do on its behalf. This work is usually performed on an honorary basis and in addition to their usual work commitments.

Revision of the Code
The 7th edition of the *Australian code of practice for the care and use of animals for scientific purposes* (the Code) is endorsed by the NHMRC, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australian Research Council (ARC) and the Australian Vice-Chancellor's Committee (AV-CC). It was revised by representatives of these organisations together with representatives of the State and Territory governments of Australia, animal welfare groups and with input from the public. The first Code was produced by the NHMRC in 1969 with revisions undertaken in 1979, 1982, 1985, 1989, 1997 and 2004. Periodic revisions take into account changes in the biological sciences and in community attitudes.

Comments on the Code
Comments on the Code are invited and should be addressed to The Secretariat, Animal Welfare Committee NHMRC, MDP 100, GPO Box 9848, Canberra ACT 2601

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INTRODUCTION

PURPOSE OF THE AUSTRALIAN CODE OF PRACTICE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES (THE CODE)

The purpose of the Code is to ensure the ethical and humane care and use of animals used for scientific purposes as defined in the Code. The principles set out in the Code are for the guidance of investigators, teachers, institutions, Animal Ethics Committees (AECs) and all people involved in the care and use of animals for scientific purposes.

The Code emphasises the responsibilities of investigators, teachers and institutions using animals to:

- ensure that the use of animals is justified, taking into consideration the scientific or educational benefits and the potential effects on the welfare of the animals;
- ensure that the welfare of animals is always considered;
- promote the development and use of techniques that replace the use of animals in scientific and teaching activities;
- minimise the number of animals used in projects; and
- refine methods and procedures to avoid pain or distress in animals used in scientific and teaching activities.

There are difficult ethical judgements to be made regarding the use of animals for scientific purposes. The 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). AECs apply a set of principles that are outlined in the Code and that govern the ethical conduct of people whose work involves the use of animals for scientific purposes.

SCOPE OF THE CODE

The Code encompasses all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes the use of animals in research, teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.

The Code provides general principles for the care and use of animals, specifies the responsibilities of investigators, teachers and institutions, and details the terms of reference, membership and operation of AECs. It also provides guidelines for the humane conduct of scientific activities, and for the acquisition of animals and their care, including their environmental needs.

The Code covers all live non-human vertebrates and higher-order invertebrates. Investigators and teachers should take into account emerging knowledge and ethical values when proposing to use other animal species not covered by the Code. Animals at early stages in their development, that is in their embryonic, fetal and larval forms, can experience pain and distress but this occurs at different stages of development in different species and thus decisions as to their welfare should, where possible, be based on evidence of their

neurobiological development. As a guide, when embryos, fetuses and larval forms have progressed beyond half the gestation or incubation period of the relevant species, or they become capable of independent feeding, the potential for the experience of pain or distress should be taken into account.

DEFINITIONS OF TERMS USED IN THE CONTEXT OF THE CODE

Animal: any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid.

Animal Ethics Committee (AEC): a committee constituted in accordance with the terms of reference and membership laid down in the Code.

Animal welfare: an animal's quality of life based on an assessment of an animal's physical and psychological state as an indication of how the animal is coping with the ongoing situation as well as a judgment about how the animal feels (see also 'Animal wellbeing' and 'Distress').

Animal wellbeing: an animal's present state with regard to its relationship with all aspects of its environment, both internal and external. It implies a positive mental state, successful biological function, positive experiences and freedom from adverse conditions.

Biological product: biological products are products derived from animals to be used for scientific purposes which can include blood products, vaccines, antisera, semen, antibodies and cell lines.

Clone: a genetic copy of another living or dead animal. It is not a twin derived by the fertilisation of an egg by a sperm (see Somatic cell nuclear transfer).

Compliance: acting in accordance with the Code.

Conflict of interest: a situation in which an AEC member has an interest that may either influence or appear to influence their objectivity in the exercise of their duties as a member of the AEC.

Consensus: the outcome of a decision making process whereby the legitimate concerns of members of the AEC are addressed, and as a result all members accept the final decision, even though it may not be an individual's preferred option.

Death as an end-point: when the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects. That is, where the investigator or teacher will not intervene to kill the animal humanely before death occurs in the course of a scientific activity.

Distress: the state of an animal, that has been unable to adapt completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Ethics: a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when animals are proposed for use, or are used, for scientific purposes.

Euthanasia: the humane killing of an animal, in the interests of its own welfare, to alleviate pain and distress (see Humane killing).

Facilities: places where animals are kept including yards, paddocks, tanks, ponds and buildings.

Genetic modification (of animals): the use of any technique for the modification of genes or other genetic material, but not including the use of natural processes such as sexual reproduction.

Humane killing: the process of killing an animal with minimal pain and distress (see Euthanasia).

Investigator or teacher: any person who uses animals for scientific purposes.

Livestock: animals that are used in commercial agriculture and aquaculture.

Monitoring: measures undertaken to assess the wellbeing of animals in accordance with the Code. This occurs at different levels. *For example, at the level of the researcher and animal facility manager, monitoring is undertaken to assess the wellbeing of animals that are used and cared for, and at the level of the AEC, monitoring is undertaken to assess the adequacy of standards of animal care and use.*

Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project: a scientific activity or activities that form a discrete piece of work. A project cannot commence until it has been approved by an AEC.

Proposal: a written application to carry out a project for consideration by an AEC.

Scientific activity: an activity required to achieve the scientific purposes.

Scientific purposes: all those purposes which aim to acquire, develop or demonstrate knowledge or techniques in any area of science including teaching, field trials, environmental studies, research, diagnosis, product testing, and the production of biological products.

Somatic cell nuclear transfer: the technique of inserting a nucleus of a cell from one of the body's tissues, other than a germ cell (a somatic cell) into an egg that has had its nucleus removed.

Standard Operating Procedure (SOP): detailed description of a standardised procedure.

Teaching: developing, imparting or demonstrating knowledge or techniques in any area of science.

Vertebrate pest animals: animals, including non-indigenous (introduced and feral) and native species, that are generally regarded, or have been declared under State or Territory legislation, as a 'pest species'.

Voucher specimen: any specimen, usually but not always a dead animal, that serves as a basis of study and is retained as a reference. 'Type' specimen is a particular voucher specimen that serves as a basis for taxonomic description of that subspecies.

Xenotransplantation: the transplantation of living organs, tissues or cells from one species to another. It includes xenotransplantation for therapeutic purposes.

Wildlife: free-living animals of native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations.

SECTION 1 GENERAL PRINCIPLES FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES

The Code emphasises the responsibilities of all those involved in the care and use of animals. This embraces a duty of care that demands a genuine commitment to the welfare of the animals, a respect for the contribution the animals make to research and teaching and a desire to promote the animals' wellbeing.

Encapsulated in the Code 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 adverse impact on animals.

JUSTIFICATION

1.1 Scientific and teaching activities using animals may be performed only when they are essential:

- to obtain and establish significant information relevant to the understanding of humans and/or animals;
- for the maintenance and improvement of human and/or animal health and welfare;
- for the improvement of animal management or production;
- to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment; or
- for the achievement of educational objectives.

1.2 Projects using animals may be performed only after a decision has been made that they are justified, weighing the predicted scientific or educational value of the projects against the potential effects on the welfare of the animals.

1.3 Investigators and teachers must submit written proposals to an AEC for all animal projects which must take into account the expected value of the knowledge to be gained, the justification for the project, and all ethical and animal welfare aspects taking into consideration the 3Rs.

RESPONSIBILITIES

1.4 Investigators and teachers who use animals for scientific purposes have personal responsibility for all matters relating to the welfare of these animals. They have an obligation to treat the animals with respect and to consider their welfare as an essential factor when planning or conducting projects.

1.5 Institutions using animals for scientific purposes must ensure, through an AEC, that all animal use conforms to the standards of the Code.

1.6 Scientific and teaching activities must not commence until written approval has been obtained from the AEC.

1.7 The acquisition, care and use of animals for all scientific purposes in Australia must be in accordance with the Code and with Commonwealth, and State or Territory legislation.

REPLACEMENT

1.8 Techniques that totally or partially replace the use of animals for scientific purposes must be sought and used wherever possible.

REDUCTION

1.9 Each project must use no more than the minimum number of animals necessary to ensure scientific and statistical validity.

1.10 The principle of reducing the number of animals used should not be implemented at the expense of greater suffering of individual animals.

1.11 Scientific and teaching activities involving the use of animals must not be repeated unless essential for the purpose or design of the project.

1.12 Teaching activities must involve no more than the minimum number of animals required to reach the educational objectives.

1.13 Overproduction of animals bred for scientific purposes should be avoided so that the need to kill healthy animals is minimised.

REFINEMENT

1.14 Animals must be suitable for the scientific purpose taking into account their biological characteristics including behaviour, genetic attributes and nutritional, microbiological and general health status.

1.15 The design and management of animal accommodation should meet species-specific needs. Special consideration is required where this is precluded by the requirements of the project.

1.16 Animals should be transported, housed, fed, watered, handled and used under conditions that meet species-specific needs. The welfare of the animals must be a primary consideration in the provision of care, which should be based on behavioural and biological needs.

1.17 Wildlife should not be taken from natural habitats unless animals bred in captivity are not available or are not suitable for the specific scientific purpose.

1.18 Investigators and teachers who use animals for scientific purposes must employ the best available scientific and educational techniques and be competent in the procedures they perform or must be under the direct supervision of a person competent in the procedure.

1.19 Projects should be designed to avoid both pain and distress in animals. If this is not possible, pain or distress must be minimised.

1.20 Pain and distress cannot be evaluated easily in animals and therefore investigators and teachers must assume that animals experience these in a manner similar to humans unless there is evidence to the contrary. Decisions regarding the animals' welfare must be based on this assumption.

1.21 An animal with signs of pain or distress not predicted in the proposal, must have the pain or distress alleviated promptly. Alleviation of such pain or distress must take precedence over completing a project. If this is not possible the animal must be euthanased without delay.

1.22 Scientific and teaching activities that may cause pain or distress of a kind or degree for which anaesthesia would normally be used in medical or veterinary practice, must be carried out using anaesthesia appropriate to the species and the procedure.

1.23 Pain management appropriate to the species, the procedure and the circumstances must be provided.

1.24 The use of local or general anaesthetic, analgesic or tranquillising agents must be appropriate to the species, and should at least parallel their use in current medical or veterinary practice.

1.25 Where it is established that the purpose of the project precludes the use of anaesthetic or analgesic agents to alleviate pain, the planned end-point of the project must be as early as feasible to avoid or minimise pain or distress in the animals.

1.26 Neuromuscular blocking agents must not be used without appropriate general anaesthesia, except in animals where sensory awareness has been eliminated. If such agents are used, continuous or frequent monitoring of paralysed animals is essential to ensure that the depth of anaesthesia is adequate to prevent pain or distress.

1.27 'Death as an end-point' (see definition) must be avoided wherever possible.

1.28 Scientific and teaching activities involving the use of animals must be of minimum duration compatible with the objectives of the project.

SECTION 2 RESPONSIBILITIES OF INSTITUTIONS AND THEIR ANIMAL ETHICS COMMITTEES

2.1 RESPONSIBILITIES OF INSTITUTIONS

2.1.1 Institutions that use animals for scientific purposes must implement processes so that the governing body of the institution or its delegate is assured of compliance with the Code and relevant legislation. These processes must at least include:

(i) establishing one or more AECs directly responsible to the governing body of the institution or its delegate. Where there is little use of animals for scientific purposes, institutions may consider accessing an external AEC or sharing an AEC with another institution;

(ii) ensuring through the AEC, that all scientific and teaching activities involving the use of animals comply with relevant legislation and the Code;

(iii) ensuring that investigators and teachers are aware of their responsibilities under the Code, including by the provision of educational programs, continuing training and workshops;

(iv) responding promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code;

(v) addressing concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC (see 2.2.48);

(vi) seeking comment from the AEC on all matters that may affect the welfare of animals used for scientific purposes by the institution, including the building or modification of animal facilities;

(vii) ensuring that the AEC approves guidelines for animal care and use within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively;

(viii) providing the AEC with the resources required to fulfil its terms of reference and operate as set out in Section 2.2. This includes provision of resources for orientation and education of AEC members, administrative assistance and, where appropriate, the reimbursement of out-of-pocket expenses and/or payment of an allowance to AEC members;

(ix) conducting an annual review of the operation of the AEC, including an assessment of the AEC's Annual Report (see 2.2.40) and a meeting with the AEC chairperson;

(x) providing all relevant personnel including AEC members with details of the institution's policy on the care and use of animals, confidentiality, Freedom of Information legislation, legal requirements, privacy policy and commercial considerations;

(xi) establishing mechanisms to respond to enquiries or complaints concerning the use of animals within the institution and ensuring that personnel and

students may voice concerns without jeopardising their employment, careers or coursework;

(xii) establishing and making known procedures for the fair resolution of disagreements between AEC members, between the AEC and investigators or teachers, or between the AEC and the institution (see 2.2.14);

(xiii) providing personnel and AEC members with information on potential disease hazards and other Occupational Health and Safety (OH&S) issues associated with the care and use of animals;

(xiv) ensuring that there are adequate numbers of appropriately trained and skilled personnel to care for the animals; and

(xv) ensuring that appropriate veterinary services are available and that there is access to diagnostic services.

2.1.2 To enable the institution to assess whether the care and use of animals by the institution complies with the Code, an external triennial review should be undertaken (see Appendix 1).

2.2 RESPONSIBILITIES AND OPERATION OF AECs

The primary responsibility of AECs is to ensure, on behalf of institutions, that all care and use of animals is conducted in compliance with the 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.

Terms of reference

2.2.1 AECs must have terms of reference that are publicly available and include provisions to:

(i) approve guidelines for the care of animals that are bred, held and used for scientific purposes on behalf of the institution;

(ii) monitor the acquisition, transportation, production, housing, care, use and fate of animals;

(iii) recommend to the institution any measures needed to ensure that the standards of the Code are maintained;

(iv) describe how members are appointed, re-appointed, or retired, according to procedures developed by the institution in consultation with the AEC;

(v) require that all members declare any conflict of interest;

(vi) deal with situations in which a conflict of interest arises (see 2.2.10 (vi));

(vii) examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals for scientific purposes;

(viii) approve only those studies for which animals are essential and justified and which conform to the requirements of the Code. This should take into consideration factors including ethics, the impact on the animal or animals and the anticipated scientific or educational value;

(ix) withdraw approval for any project (see 2.2.33);

(x) authorise the emergency treatment or euthanasia of any animal (see 2.2.36);

(xi) examine and comment on all institutional plans and policies that may affect the welfare of animals used for scientific purposes;

(xii) maintain a record of proposals and projects (see 2.2.24);

(xiii) comply with the reporting requirements of the institution and the Code (see 2.2.40); and

(xiv) perform all other duties required by the Code.

Membership

2.2.2 An AEC must have a membership that will allow it to fulfil its terms of reference. It 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.

2.2.3 In addition to the prescribed membership Categories A to D, the institution should appoint to the AEC a person responsible for the routine care of animals from within the institution. This membership is not mandatory.

2.2.4 To assist the AEC to function effectively, institutions may appoint as members, people with skills and background of value to the AEC. These members may be additional to the members required by Categories A to D.

2.2.5 The AEC may invite people with specific expertise to provide advice as required.

2.2.6 The Chairperson should either hold a senior position in the institution or, if an external appointee, be given a commitment by the institution to provide the necessary support and authority to carry out the role. It is recommended that the Chairperson is an additional appointment to Category A to D members. To perform a key role in the successful operation of the AEC, the Chairperson should possess the following attributes:

(i) an ability to bring impartiality to the task;

(ii) the skills to manage the business of the AEC;

(iii) an ability to communicate, negotiate and to resolve conflict; and

(iv) an understanding of the ethical and animal welfare issues involved in the use of animals for scientific purposes.

2.2.7 If the committee has more than four members, Categories C plus D should represent no less than one third of the members.

2.2.8 Before appointment, all members of the AEC should acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the institution, including how advice may be sought without breaching confidentiality.

Responsibilities of the Chairperson

2.2.9 The Chairperson must:

(i) ensure that the AEC operates in accordance with the principles and requirements of the Code; the relevant policies of the institution, and the agreed AEC procedures (see 2.2.10);

(ii) ensure that proposals are considered by the AEC and the outcomes conveyed to investigators and teachers in a timely manner;

(iii) advise institutional management regarding the level of resourcing required by the AEC;

(iv) represent the AEC in any negotiations with management;

(v) oversee all requirements of the AEC to report and review its operation, as outlined in the Code (see 2.2.40); and

(vi) ensure AEC records are maintained and made available for review by the institution and authorised external reviewers.

Operating procedures

2.2.10 AECs must establish and document procedures that will enable compliance with the provisions of the Code and where relevant the policies of the institution. In particular, such procedures should cover:

(i) the assessment of proposals in a manner that is fair to applicants and acceptable to all members including the need to provide AEC members with information in a timely manner;

(ii) the presence at meetings of at least one member from each of Categories A, B, C and D to establish a quorum. If more than four AEC members are present, Categories C plus D should represent not less than one third of those members present;

(iii) the conduct of quorate AEC meetings in exceptional circumstances where a face-to-face meeting is not possible (for example, through the use of video-linking or teleconferencing);

(iv) the delegation of authority to inspect sites and monitor projects at remote sites;

(v) dealing with non-compliance with the Code to ensure that the processes are fair and effective and that there is appropriate reporting to the institution (see 2.2.48);

(vi) resolution of any conflict of interest that may arise, that is, any situation where a member of an AEC has an interest that may be seen to influence the objectivity of a decision;

(vii) approval, in advance, for the immediate use of animals should that be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people; and

(viii) appointment of, and delegation of functions to, an AEC executive if established.

2.2.11 The AEC may establish an executive that must include at least one member from Category C or D who:

(i) may approve minor modifications to projects for review at the next AEC meeting;

(ii) may not approve new proposals.

2.2.12 Minutes must be maintained that record decisions and other aspects of the AEC's operation.

2.2.13 Meetings should be held at least quarterly to allow interaction of AEC members and effective functioning of the AEC (see 2.2.1).

2.2.14 Irreconcilable differences between the AEC and an investigator or teacher must be referred to the governing body of the institution for review of the due process (see 2.1.1(xii)). The ultimate decision of an AEC after such review must not be over-ridden.

Proposals

2.2.15 Proposals – general

Information provided in proposals must be sufficient to satisfy the AEC that the proposed use of animals is justified by weighing the predicted scientific or educational value of the proposal against the potential impact on the welfare of the animals (see 1.2). An essential component of this assessment by the AEC involves consideration of the steps taken by the applicant to comply with the principles of the 3Rs specified in the Code (see Section 1 under Purpose).

It is important that all AEC members are provided with sufficient information to participate in the assessment of proposals. This can only be achieved by the use of plain English in the proposal. Applicants must ensure that where the use of scientific language is deemed unavoidable, it is supported by a suitable lay description or a glossary of terms.

2.2.16 Proposals – detailed

Proposals should contain the following information as appropriate:

Information required	Why the information is required
(i) The project title.	To set the scene and for administrative purposes.
(ii) The expected commencement and completion dates.	
(iii) The names of all personnel involved with the project, their role and details of the experience and training that qualifies them to perform specific procedures using animals.	To inform the AEC who is responsible for the work with animals and whether individuals have the necessary skills or require supervision.
(iv) The source of animals and any permits required, details of where the animals will be housed and where procedures will be performed.	The AEC needs to know that the source of animals and specified facilities are appropriate.
(v) Potential benefits of the project A plain English description of: • the broad context of the project; • maintaining or improving human or animal health and welfare; • the expected benefits in: - increasing our understanding of humans or animals; - improving animal management or production; - achieving educational objectives; or • achieving environmental objectives.	
(vi) Overview of the project An outline of how the project is designed in relation to its aims.	To assist AEC members in understanding the reasons behind the request for approval to use animals and the potential benefits of the project.
(vii) Reduction A clear description of: • the number, species and strain of animals required, by treatment groups, where appropriate; • the reasons why this number is necessary, including whether the proposal is for a repeat of an earlier project and if so, why repetition is necessary; and • whether there is an opportunity for the sharing of tissues or animals.	AECs and animal users are required by the Code to consider the principle of Reduction to minimise the number of animals used for scientific purposes. Excessive use of animals can result from users overstating the number of animals required to achieve a statistically valid result or requesting too few animals which may lead to needless repetition or a failure to achieve outcomes. Justification for the number of animals required may include: • teacher:student and student:animal ratios in teaching activities, and • statistical consideration in experimental design with regard to prior experience, and/or advice from a biometrician.

Information required	Why the information is required
(viii) Replacement Explanation of why animals are needed for the project, including: • a list of any potential alternatives to animal use; • whether any of these alternatives would be used, and if not; • why alternatives are unsuitable.	AECs, investigators and teachers are required by the Code to consider the principle of Replacement of animals with alternative models where possible. Applicants have responsibility to inform AECs about the suitability of alternatives.
(ix) Refinement Proposals must identify and justify the impact of all aspects of the project on an animal's wellbeing from the time it is obtained until the project is completed and detail how that impact will be minimised. The assessment of potential impact should include: 1. A step-by-step description of what will happen to each animal including: (i) transportation, acclimatisation and conditions of housing and handling; (ii) experimental and other procedures, including dose and route of any substance or treatment given and method, volume and frequency of samples collected; (iii) surgical and related procedures including dose of anaesthetic, analgesic and tranquillising agents and methods of monitoring their adequacy and side-effects; (iv) the sequence and timing of events from start to finish for individual or groups of animals; and (v) the arrangements for the animal or animals at the completion of the project, including, if applicable, the method of humane killing. 2. Identification of all aspects of animal use and management, including handling and housing, that may adversely impact on the animals' wellbeing, and how this impact will be minimised. The information provided should include details of: (i) the Refinement of procedures that reduce the adverse impact on animals; (ii) how any impact will be monitored, assessed and managed; and (iii) procedures to identify and quickly respond to unforeseen complications.	AECs, investigators and teachers are required by the Code to consider the principle of Refinement to minimise the adverse impact of the intended project on animals. This can only be achieved if all activities involving animals are described in full. To assist in the understanding of the use of animals in the project. An animal-use flowchart may assist in this process.

Information required	Why the information is required
(x) Monitoring of animals Details of how the wellbeing of animals will be assessed throughout the project, including: • method and frequency of routine monitoring of animals; • method and frequency of monitoring animals during and after procedures; • what will be done if a problem is identified including criteria for intervention, treatment, or withdrawal of the animals from the project; and • names and contact details of personnel responsible for day-to-day monitoring and for dealing with any emergencies.	To inform AECs of the extent to which the monitoring of animals and their care has been considered in the project design.
(xi) Justification Investigators and teachers must provide justification for the use of animals in the project weighing the predicted scientific or educational value against the potential impact on the welfare of the animals. In addition, particular justification must be given for potentially severe or ethically contentious procedures. For example: • unrelieved pain and distress including where the planned end-points will allow severe adverse effects to occur (see 3.3.10); • death as the end point (see 1.27 and 3.3.5 (vi)); • reuse of animals (see 3.3.11); • prolonged restraint or confinement (see 3.3.16); • production of monoclonal antibodies by the ascites method (see 3.3.69 and 3.3.71) and • the use of non-human primates (see 3.3.79).	This is the opportunity for the investigator or teacher to present their case for the justification of the project on the basis of the proposed benefits, sound experimental design, and the potential adverse impacts on the animals described in the proposal. The AEC is then able to decide whether it agrees that the project is justified.
(xii) Practical considerations to assist AECs and animal carers Specify any special risks to other animals or humans arising from the project (see 3.3.50 - 3.3.54).	
(xiii) Declaration The proposal must include a statement signed by the responsible investigator(s) or teacher(s) stating that they and all others involved in the project are familiar, and will comply, with relevant Commonwealth and State or Territory legislation and the requirements of the Code. The applicant must assure the AEC that adequate resources will be available to undertake the project.	

2.2.17 Where appropriately applied, Standard Operating Procedures (SOPs) may facilitate the preparation of proposals by investigators and teachers. There is a risk that the use of SOPs may reduce the rigour with which procedures are considered by the AEC and, therefore, SOPs should only be referred to in proposals under the following circumstances:

(i) new SOPs must be approved by the AEC before implementation;

(ii) SOPs must include in the title the date on which they were last approved or reviewed and be reviewed regularly by the AEC at least every three years;

(iii) AEC members must have ready access to copies of all current SOPs;

(iv) investigators or teachers named on a proposal must have the necessary skills to implement a SOP; and

(v) variations to a SOP must be detailed in the proposal.

Assessing proposals

2.2.18 Only those scientific and teaching activities that conform to the requirements of all relevant sections of the Code and of legislation may be approved.

2.2.19 Pilot studies, where proposed, should be regarded as integral to the overall project, especially to enable assessment of the feasibility of the project and the potential for Refinement and Reduction. They should be assessed by the AEC according to the usual criteria applied to project approval.

2.2.20 New proposals and the renewal of existing projects must be considered and approved only at quorate meetings of the AEC.

2.2.21 Decisions must be made as promptly as possible.

2.2.22 Decisions by the AEC with regard to approval, modification or rejection of a proposal, or withdrawal of approval for a project, should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still unachievable, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

2.2.23 AECs must advise investigators and teachers of their decisions in writing as promptly as possible. Projects must not commence until written approval has been received.

2.2.24 A register of all proposals to the AEC, including the outcomes of the committee's deliberations, must be maintained.

2.2.25 In determining the duration of approval for individual projects, AECs should take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any Deeds of Agreement between the institution and the funding bodies.

Monitoring

2.2.26 Once an animal is allocated to a project, the investigator or teacher is responsible for the day-to-day monitoring of its wellbeing (see 3.3.1). Prior to this allocation, it is the responsibility of the animal facility manager (see 4.5.3). The AEC monitors these activities during the inspection of animal housing and laboratories and in the review of reports (see 2.2.37 – 2.2.39 and 3.1.12).

2.2.27 The records maintained by investigators and teachers (see 3.3.2) and animal facility managers (see 4.5.8) will enable the AEC to verify that the welfare of animals has been monitored as agreed. Such records also enable a critical investigation of the cause(s) of unexpected adverse events as a basis for future prevention strategies.

2.2.28 Investigators, teachers and animal facility managers should promptly notify the AEC of any unexpected, adverse events that may impact on the wellbeing of an animal in their care.

2.2.29 Members of the AEC should inspect all animal housing and laboratory areas regularly and record their findings. Records of inspections should include the names of those who attended, observations, any identified problems, follow-up and outcomes. Inspections of fieldwork conducted at extremely remote sites, or where access is difficult, may be performed by an agent or delegate and can be facilitated or corroborated with photographic or video imaging (see 2.2.10 (iv)).

2.2.30 Where possible, a member of the AEC who is external to the institution should participate in inspections.

2.2.31 Any projects likely to cause pain or distress, such as the study of pain, responses to stressors, certain animal models of human diseases or attempts to change behaviour by physical or chemical means, should be subject to early inspection by the AEC as a condition of approval.

2.2.32 The frequency and timing of inspections will be determined by factors such as the number and accessibility of sites, the amount, type and variety of scientific and teaching activities, and whether inspections can be combined with scheduled AEC meetings. As a guide, AECs should routinely inspect animal holding areas at least annually and preferably more frequently. In addition, certain projects may necessitate more frequent inspections of animals and animal use.

2.2.33 Where inspections detect activities that are non-compliant with the Code, the AEC must ensure that such activities cease immediately and remedial action is initiated.

2.2.34 Institutions should consider appointing an officer with veterinary, or other appropriate, qualifications who is authorised by the AEC to ensure that projects are proceeding in compliance with the Code and the decisions of the AEC.

2.2.35 On each site where animals are used, including the location where fieldwork is undertaken, the AEC should authorise a person to respond to emergencies, including unexpected adverse outcomes, in the absence of the investigator or teacher.

2.2.36 In cases of emergency before an animal is treated or euthanased, all reasonable steps must be taken to consult with the responsible investigator or teacher. Any treatment or euthanasia must be reported promptly to the responsible investigator or teacher and the AEC with reasons for the action taken, and confirmed in writing.

Reporting of projects

2.2.37 All projects must be the subject of written reports to the AEC. Regardless of the duration of approval, the continuation of all projects must be subject to the receipt of written annual reports by the AEC that should advise on:

(i) what progress has been achieved;

(ii) any problems that may have interfered with progress of the project;

(iii) how many animals have been used;

(iv) whether the wellbeing of the animals is consistent with that anticipated in the proposal;

(v) whether any changes are envisaged; and

(vi) whether the project is meeting its aims.

2.2.38 Following a review of the annual progress report, the AEC may determine on the basis of the report and further consultation with the investigator, that a the project may continue, be suspended, require modification or be discontinued.

2.2.39 For projects that have been completed or discontinued, a report should be submitted to the AEC as soon as practicable. This report should advise on:

(i) whether the stated aims were achieved;

(ii) whether the number of animals used varied from the number approved and if so, why any major discrepancies occurred;

(iii) whether the wellbeing of the animals was consistent with that anticipated in the proposal;

(iv) conclusions as to how procedures in future projects could be modified to reduce any impact on animal welfare; and

(v) details of publications and presentations that have resulted from the project.

Reporting to the institution

2.2.40 The AEC must submit a written report on its activities at least annually to the governing body of the institution(s) for which it acts. The report should include information on:

(i) numbers and types of projects assessed and approved or rejected;

(ii) the physical facilities for the care and use of animals by the institution;

(iii) activities that have supported the educational needs of AEC members, and of personnel involved in the care and use of animals;

(iv) administrative or other difficulties being experienced; and

(v) any matters that may affect the institution's ability to maintain compliance with the Code and if necessary the provision of suitable recommendations.

Projects involving more than one AEC

2.2.41 Where projects are to be conducted at more than one institution, procedures must be in place to ensure that:

(i) animals will be well cared for in all phases of the project;

(ii) the responsible AECs are in a position to inspect the animals during all phases of the project;

(iii) before any work commences each AEC approves, or delegates approval of, scientific and teaching activities being conducted by members of its institution;

(iv) clear communication channels are established between all involved AECs and investigators and teachers; and

(v) such arrangements between institutions should be as a formal agreement that ensures that all parties involved are aware of and can meet their respective responsibilities under the requirements of the Code and relevant legislation.

2.2.42 Where parts of a project take place at different institutions, each AEC may choose to approve and monitor only those parts that take place at their institution. Notwithstanding this arrangement, it is essential that each AEC is cognisant of all aspects of the project and ensures that any cumulative impact of procedures on animals is considered. Such arrangements should be part of a formal agreement between the institutions involved.

Non-institutional applicants and AEC responsibility

2.2.43 AECs may be approached by individuals who, or organisations that, do not have direct access to an institutional AEC, yet require AEC approval before proceeding to use animals for scientific purposes. The AEC must decide on an individual case basis whether it is prepared to assess the proposal and oversee the project. In such cases, proposals from non-institutional applicants must clearly address the points below, in addition to the information normally required (see 2.2.15 - 2.2.16):

(i) who is liable and responsible for the project;

(ii) how the impact of the project on the animals will be monitored and by whom; and

(iii) the qualifications and experience of applicants.

2.2.44 Arrangements between an institutional AEC and a non-institutional applicant must be a formal agreement between the institution and the applicant. This arrangement should enable the institution to withdraw from the agreement if the non-institutional applicant fails to comply with the directions of the AEC.

Projects conducted in other countries in association with Australian institutions

2.2.45 The welfare of animals used for scientific purposes in countries not subject to the Code or Australian law should be considered by the AEC on a case-by-case basis. The AEC should take into account the requirements of the Code and seek evidence that the welfare of the animals will be suitably monitored. Evidence will include compliance with codes, laws and practices equivalent to those in Australia. The final decision by an Australian AEC on the use of animals in other countries in association with an Australian institution(s), may take into consideration the acceptance of an approval granted by a local AEC, or equivalent body, where the Australian AEC is satisfied that the standards defined in the Code are met.

2.2.46 In the case where an Australian institution operates facilities that use animals for scientific purposes in another country, projects at those facilities should be compliant with the Australian Code.

Non-compliance with the Code

2.2.47 Institutions, AECs, investigators and teachers have responsibility for compliance with the Code.

2.2.48 The institution and the AEC should prepare written procedures, which are agreed to by the institution, (see 2.1.1 (v)) to deal with non-compliance and any grievance related to the AEC process (see 2.2.10 (v)). The written procedures must clearly define the reporting mechanisms and the responsibilities of all parties to ensure fair and effective processes.

SECTION 3 RESPONSIBILITIES OF INVESTIGATORS AND TEACHERS

3.1 GENERAL

3.1.1 Investigators and teachers have personal responsibility for all matters related to the welfare of the animals they use and must act in accordance with all requirements of the Code. This responsibility begins when an animal is allocated to a project and ends with its fate at the completion of the project.

3.1.2 In order to ensure the wellbeing of animals used in their projects, investigators and teachers must ensure that the level of supervision of personnel involved in the care and management of the animals in their projects takes into account the levels of competence of each person and the responsibilities they are given.

3.1.3 Before any scientific and teaching activities involving the use of animals begin, investigators and teachers must submit a proposal to the AEC that complies with Clauses 2.2.15 and 2.2.16 of the Code, and that indicates that the design of the project complies with the Code and relevant legislation.

3.1.4 Investigators and teachers must not begin a scientific or teaching activity involving the use of animals before written AEC approval is obtained, and must adhere to all requirements of the AEC.

3.1.5 When seeking approval for a project, investigators and teachers must inform the relevant AEC of other scientific and teaching institutions participating in the project (see 2.2.41).

3.1.6 Investigators and teachers must notify their institutional AEC in writing when seeking approval to participate in scientific and teaching activities at another institution through that institution's AEC (see 2.2.41).

3.1.7 Investigators and teachers must make arrangements so that they, or other responsible persons, can be contacted in the event of emergencies.

3.1.8 In choosing animals, investigators and teachers must ensure that the choice of species is appropriate for the scientific purpose. Requirements for known genetic constitution, freedom from specific diseases, documented health, nutritional and environmental histories and other relevant factors should be taken into account.

3.1.9 Investigators and teachers must ensure that records of the use and monitoring of animals used for scientific purposes are maintained. Under a particular AEC approval, records should include the origin and fate of issued animals, how animal welfare was assessed, any unexpected negative impact on animal wellbeing and notation of procedures. The AEC should advise investigators and teachers of any additional information to be recorded. These records should be available for audit by the institution and authorised external reviewers.

3.1.10 AEC approval is required when livestock are used to acquire, develop or demonstrate knowledge and techniques for scientific purposes. This requirement covers standard husbandry procedures and normal farming practices, such as mulesing, tail docking and beak trimming, when these activities are performed for a scientific purpose. It includes the use of livestock for the production of biological products other than food or fibre (the only exceptions are defined in clause 6.1.6). AEC approval is not required

when inspectorial personnel are undertaking routine regulatory activities such as examination for lice, disease surveillance, tick control and saleyard work.

3.1.11 When privately-owned animals, such as livestock or companion animals, are to be used for a scientific purpose and when the owner, their staff or other personnel retain day-to-day responsibility for the treatment, care and welfare of those animals, the details and duration of the specific responsibilities of the investigator or teacher, and the owner, must be clearly set out in the proposal.

3.1.12 Investigators and teachers must make reports to the AEC as requested, including prompt notification of any adverse or unexpected effects that impact on animal wellbeing (see 2.2.28), advice when a project is completed or discontinued (see 2.2.39) and the information required for the annual report of any on-going project (see 2.2.37).

3.2 PLANNING PROJECTS

3.2.1 Before submitting a proposal to the AEC, investigators and teachers need to consider the following questions during the planning stages of a project (see 2.2.15, 2.2.16, and 6.3.1):

(i) Do the potential benefits outweigh any ethical concerns about the impact on animal welfare?

(ii) Can the aims be achieved without using animals?

(iii) Has the most appropriate species of animal been selected?

(iv) Is the biological status (including genetic, nutritional, microbiological and general health) of the animals appropriate?

(v) Are suitable animal holding facilities, equipment and personnel available?

(vi) Have all involved personnel been informed of the planned procedures?

(vii) Do these personnel have the skills and experience to perform these procedures?

(viii) Does this project involve students and are they appropriately supervised (see 6.2.2 & 6.2.3)?

(ix) Are the environmental conditions (including type of enclosure, noise, photoperiod, temperature, humidity, ventilation, density of housing, and social structures) appropriate?

(x) Are the studies designed so that statistically valid results can be obtained or educational objectives achieved using the minimum number of animals?

(xi) If the potential impact on the animal is unknown, is it appropriate to incorporate a pilot study into the project design to allow a staged assessment of the impact on animal welfare and how it will be managed? Pilot studies should be regarded as integral to the overall project and should be assessed by the AEC according to the usual criteria applied to project approval (see 2.2.19).

(xii) Will any aspects of the project adversely impact on the wellbeing of animals and if so what will be done to minimise or avoid this?

(xiii) What arrangements will be made for the regular assessment of the animals' wellbeing?

(xiv) Have any of the studies been performed previously? If so, why should they be repeated?

(xv) Have all relevant permits been obtained (including those for the importation, capture, use, treatment, humane killing or release of the animals)?

(xvi) What arrangements have been made for the fate of all healthy animals at the completion of the project?

3.2.2 When the biological status of animals must conform to defined requirements, investigators and teachers must ensure that the supplier can provide documentation of biological status. Where relevant, species and individual animals should be chosen on the basis that the proposed studies will result in the least pain or distress. In making this decision, investigators and teachers should consider all aspects of the biological nature of the animals, including their behavioural characteristics and cognitive development.

3.3 CONDUCT OF PROJECTS

Detecting pain and distress

3.3.1 Investigators and teachers should be familiar with the normal behaviour of the animal species chosen and knowledgeable about signs of pain and distress specific to that species and must assess animals regularly for these signs.

3.3.2 Animals must be observed for deviations from normal behavioural patterns that are often the first indications that animals are experiencing pain or distress. Changes in patterns of sleeping, feeding, drinking, grooming, exploratory behaviour, performance in learning or discriminatory tasks, and social and reproductive behaviour should be recorded and appropriate action taken.

3.3.3 Animals must be regularly assessed for signs of pain or distress. These may include aggressive or abnormal behaviour (some species may become unduly submissive), abnormal stance or movements, abnormal sounds, altered cardiovascular or respiratory function, abnormal appetite, rapid decline in body weight, altered body temperature, vomiting and abnormal defecation or urination. Indicators of sustained pain or distress may include loss of body weight, failure to thrive, impaired reproductive ability and reduced resistance to disease.

Limiting pain and distress

3.3.4 Pain and distress cannot be evaluated easily in animals and therefore investigators and teachers must assume that animals experience pain in a manner similar to humans unless there is evidence to the contrary. Decisions regarding the animals' welfare must be based on this assumption.

3.3.5 Investigators and teachers must anticipate and take all possible steps to avoid or minimise pain and distress including:

(i) choosing the most humane method for the conduct of the project;

(ii) ensuring the technical skills and competence of all people involved in animal care and use;

(iii) checking and assessing animals regularly for evidence of pain or distress throughout the course of the project. The frequency of observations will be determined by the nature of the protocol and must be such that changes in any animal's condition can be detected early;

(iv) acting promptly after appropriate advice to alleviate pain or distress;

(v) using anaesthetic, analgesic and tranquillising agents that are appropriate to the species and the scientific or educational aims;

(vi) determining criteria for early intervention and humane end-points;

(vii) conducting studies over the shortest time practicable; and

(viii) using appropriate methods of humane killing.

3.3.6 Where the condition of an animal indicates that there is a need for intervention to limit pain or distress, actions that may be taken include an increase in the frequency of observation, consultation with a veterinarian, administration of analgesic agents or other appropriate medication, removal from the project and euthanasia.

3.3.7 The use of local or general anaesthetic, analgesic or tranquillising agents must be appropriate to the species, and should at least parallel their use in current medical or veterinary practice.

3.3.8 Scientific and teaching activities that are liable to cause pain of a kind and degree for which anaesthesia would normally be used in medical or veterinary practice must be carried out under anaesthesia.

3.3.9 Distress can sometimes be avoided or minimised by non-pharmacological means. Before commencing a project, investigators and teachers should condition animals to the project environment and procedures and to personnel involved in the project. During and after procedures, appropriate nursing to minimise pain and distress and to promote animal wellbeing must be provided.

3.3.10 If animals develop signs of severe pain or distress despite the precautions outlined above, the pain or distress must be alleviated promptly or the animals must be euthanased without delay. Alleviation of such pain or distress must take precedence over continuing or finishing the project.

Repeated use of animals for scientific purposes

3.3.11 Individual animals must not be used in more than one scientific activity, either in the same or different projects, without AEC approval. However, appropriate reuse of animals may reduce the total number of animals used in a project, result in better experimental design, reduce distress or avoid pain to other animals. When considering approval for the reuse of animals, the AEC must take into account:

(i) the pain or distress and any potential long-term or cumulative effects caused by any previous procedures;

(ii) the total time that an animal will be used;

(iii) the pain or distress likely to be caused by the next and subsequent procedures; and

(iv) whether an animal has recovered fully from the previous procedure before being used in the next.

Duration of scientific activities

3.3.12 Scientific and teaching activities, particularly those that cause any pain or distress, should be as brief as practicable. AEC approval must be sought for the continued long-

term use of individual animals. The decision to continue must be based on the clinical wellbeing of the animal and behavioural evidence of aversion to the situation.

Handling, restraint and confinement of animals

3.3.13 Animals must be handled only by personnel instructed and competent in methods that avoid pain or distress.

3.3.14 When the use of restraint devices appropriate to the animal is necessary for the animal's welfare and the safety of the handler, it should be for the minimum period required to accomplish the purpose of the project (see 3.3.42).

3.3.15 Tranquillising or anaesthetic agents may aid restraint but may prolong recovery from the procedure. When these agents have been used, greater attention may be required in assessing the recovery of animals.

3.3.16 Periods of prolonged restraint or confinement should be avoided. However, where prolonged restraint or confinement of animals is proposed, such as housing livestock in metabolism cages, consideration must be given to the animal's biological, including behavioural, needs. Such animals must be assessed regularly by a veterinarian or other qualified person not otherwise involved in the project. If any negative impact on an animal is detected, the animal must be removed from the restraint or the method of restraint must be modified to minimise the impact.

Completion of projects

3.3.17 Upon completion of the project, animals must be returned promptly to normal husbandry conditions or their natural habitat (see 5.1) if appropriate and permitted, or where necessary, killed humanely.

Humane killing and euthanasia of animals

3.3.18 When it is necessary to kill an animal, humane procedures must be used. These procedures must avoid pain or distress, be reliable and produce rapid loss of consciousness until death occurs. The procedures should also be compatible with the scientific or educational aims.

3.3.19 The procedures must be performed only by personnel approved as competent by the AEC or under the direct supervision of a competent person.

3.3.20 Animals should be killed in a quiet, clean environment, that is away from other animals where possible. Death must be established before disposal of the carcass occurs.

3.3.21 Where practicable, tissue from animals being killed should be shared among investigators and teachers in line with the principle of Reduction (see 2.2.16 (vii)).

3.3.22 Dependent offspring of animals being killed must also be killed or appropriate provision made for their care.

3.3.23 Methods of killing must be appropriate to the developmental stage of the animal. Disposal of fertilised eggs, fetuses and embryos must not occur until death is assured.

Autopsy

3.3.24 When an animal dies unexpectedly, or is euthanased due to unforeseen complications, an autopsy should be performed by a person with appropriate qualifications and/or experience. The AEC should be notified promptly (see 3.1.12).

Anaesthesia and surgery

3.3.25 For any surgical procedure a pain management plan aimed at the prevention or alleviation of pain and which is appropriate for the procedures and the species must be developed, implemented and reviewed, as necessary.

3.3.26 Anaesthesia and surgery must be performed only by personnel with appropriate training and experience and who are approved as competent by the AEC. Training in surgical or anaesthetic techniques must be under the direct and constant supervision of such persons.

3.3.27 Surgical procedures must be carried out under appropriate local or general anaesthesia. The depth of anaesthesia must be adequately monitored throughout the procedure. There must also be appropriate monitoring and management of potential side effects, such as hypothermia, and cardiovascular and respiratory depression. Anaesthetic monitoring records should be kept as appropriate.

3.3.28 The choice and administration of anaesthetic, analgesic and tranquillising agents must be suitable for the species and the purpose of the project. These agents should be used within the context of the pain management plan.

3.3.29 Aseptic procedures are necessary when it is intended that the animal will recover from surgery.

3.3.30 When an animal is to recover from the anaesthetic, surgical procedures must conform to accepted standards in medical or veterinary practice. Analgesic and tranquillising agents must be used when required and should at least parallel their use in current medical or veterinary practice.

3.3.31 When more than one surgical procedure is to be performed on an individual animal, the time between each procedure must allow a recovery to good general health unless otherwise justified.

3.3.32 For non-recovery surgery, the animal must remain unconscious throughout the procedure.

Post-operative care

3.3.33 The comfort of animals must be promoted throughout the post-operative period. Attention should be given to warmth, hygiene, fluid and food intake, and control of infection. The use of analgesic, tranquillising and antibiotic agents may be needed to minimise post-operative pain or distress. Care should be taken to ensure that animals recovering from anaesthesia do not injure themselves by uncoordinated movements, and that conditions are such that they are not disturbed, attacked or killed by other animals in the same enclosure.

3.3.34 Clinical records of an animal's state must be kept, including observations and administration of any drugs, fluids or other treatments, and made accessible to all personnel involved in the post-operative care of the animal.

3.3.35 Investigators must ensure that adequate monitoring, treatment and care of post-operative animals is provided and that they are fully informed of each animal's state.

3.3.36 The duties of all personnel must be clearly defined and procedures must be established for identifying and responding to post-operative emergencies, including management of pain and distress.

3.3.37 Any post-operative animal observed to be in a state of severe pain or distress, which cannot be alleviated quickly, must be euthanased without delay.

3.3.38 Surgical wounds must be inspected regularly for the progress of healing and any problems must be attended to immediately.

Implanted devices

3.3.39 Skilled and specialised attention is required in the care of animals following operations in which recording or sampling devices are implanted, or fistulae created. Animals should be assessed frequently for any signs of pain, distress or infection and treated immediately if these occur.

Organ and tissue transplantation

3.3.40 Skilled and specialised attention is required in the care of animals following organ or tissue transplantation. Animals must be assessed frequently for any signs of pain, distress, infection and tissue rejection and treated immediately if these occur. Special attention should be given to the management of immunosuppression and the disease hazards and adverse outcomes that may be associated with organ and tissue transplantation between species (xenotransplantation). Death as an end-point should be avoided when determining recipient survival times.

Neuromuscular paralysis

3.3.41 Neuromuscular blocking agents may only be used with adequate general anaesthesia or an appropriate surgical procedure that eliminates sensory awareness. When these agents are used, specialist advice on anaesthesia should be obtained. Immobilisation of an animal solely with a neuromuscular blocking agent is not acceptable. When these agents are used in conjunction with general anaesthesia, special care must be taken to ensure the maintenance of an adequate plane of anaesthesia. Since the usual criteria used to monitor this, such as character of respiration and corneal and flexor withdrawal reflexes, cannot be used, continuous or frequent monitoring of physiological variables such as heart rate, blood pressure, pupil size and the electroencephalogram is necessary, together with the effects on these of mild sensory stimuli. Care is required to ensure that drugs used during procedures do not interfere with assessment of the depth of anaesthesia.

Electroimmobilisation

3.3.42 Electroimmobilisation must not be used as an alternative to analgesia or anaesthesia. It should not be used for restraint unless there is published evidence showing that electroimmobilisation causes less distress than traditional methods.

Animal models of disease

3.3.43 The scientific validity of animal models of human disease rests in part on how closely a given model resembles a particular disease, which may include an animal experiencing the attendant pain or distress of the human disease state. Investigators must take steps to minimise such pain or distress. Death as an end-point in these studies should be avoided.

Modifying animal behaviour

3.3.44 Positive reinforcement is the preferred method to motivate an animal to modify its behaviour or to perform specific tasks. However, in some cases the inducement may need to be some form of biological stress, in which case, it must be as mild as possible. Severe deprivation of water, food, social interaction or sensory stimuli must not be used (see 3.3.73). Painful or noxious stimuli should be avoided. If their use is necessary, the level and duration of the stimulus must be minimised and escape from the stimulus must be available.

Toxicological studies

3.3.45 Investigation of the safety of agents intended for use in human beings, animals, the household and the environment, and of naturally occurring toxins, should be performed by personnel with appropriate training.

3.3.46 If suitable non-animal tests are available they must be used. In particular, in vitro methods should be used as initial screening tests wherever possible.

3.3.47 The end-point of toxicological studies must be as early as is compatible with reliable assessment of toxicity, and must minimise the extent of any pain or distress.

3.3.48 Investigators must not allow the painful, distressing or lingering death of animals unless no other end-point is feasible and the goals of the project are the prevention, alleviation, or cure of a life-threatening disease or situation in humans or animals.

3.3.49 When death as the end-point is unavoidable, the project must be designed to result in the deaths of as few animals as possible.

Scientific and teaching activities involving hazards to other animals or humans

3.3.50 Hazards may arise from sources including viruses, bacteria, fungi, parasites, radiation, radioactivity, corrosive substances, toxins, allergens, carcinogens, recombinant DNA, anaesthetic gases and physical injuries.

3.3.51 Any potential pathogenic effects of these hazards when used in projects must be explained as far as possible to all personnel. Tests before, during and after the project may be required for personnel.

3.3.52 The AEC should require evidence that the Institutional Biosafety Committee (IBC) has been consulted and that appropriate measures for containment, disposal and decontamination of biohazardous material have been established.

3.3.53 Procedures for quarantining animals that have had infectious organisms administered should take into account risks to other animals and to humans.

3.3.54 Regarding the end-point of studies involving hazardous agents, 3.3.45 to 3.3.49 apply.

Animal welfare and animal health research

3.3.55 When studying ways of improving the health or welfare of animals, investigators may need to replicate the problem, such as injury, trauma, nutritional disorder, physical exertion, disease or environmental stress. Thus, the attendant pain or distress may also be replicated. When such studies are necessary, investigators and teachers must ensure that:

(i) the principal aim of the project is to improve animal welfare or health;

(ii) the outcome of the project cannot be achieved by alternative methods;

(iii) all possible steps are taken to minimise any pain or distress; and

(iv) the end-point of studies conforms to the requirements for toxicological studies (see 3.3.47 to 3.3.49).

Genetic modification of animals

3.3.56 All projects involving the genetic modification of animals must be conducted in accordance with requirements and guidelines of the Office of the Gene Technology Regulator and the relevant Institutional Biosafety Committee (see NHMRC Guidelines and other references in Appendix 3).

3.3.57 Application must be made to the AEC for the production of a new strain or hybrid of a genetically modified animal. The Prohibition of Human Cloning Act 2002 (the Act) strictly prohibits the combination of human and animal gametes (see Section 21 and the definitions in Section 10 of the Act). The proposal should provide sufficient information to allow the AEC to consider the potential impact of introducing a new gene, or altering the expression of existing genes on all the animals involved in the breeding program, as well as the reason for creating the genetically modified animal.

3.3.58 In the proposal, the investigator must inform the AEC of any potential side-effects of genetic manipulation that may impact negatively on the welfare of the parent animal or offspring and of the means that will be used to deal with such eventualities. The investigator must provide monitoring details for expected and unexpected adverse effects arising from the genetic modification to the AEC.

3.3.59 Proposals for the creation of genetically modified animals that are expected to suffer pain or distress must define any special needs and give details of specialist care that will be provided to minimise these negative impacts (see 3.3.61). Humane end-points must also be defined.

3.3.60 The breeding procedures used to establish a genetically modified animal colony, either from newly-created genetically modified animals or those from an outside source, should be considered as a scientific purpose. This is at least until information regarding data on mortality, morbidity and population health, including the stability of the phenotype of the animals over several generations and any adverse side effects of the genetic manipulation have been documented by the investigator and forwarded to the AEC. The AEC should determine the transition between experimental animals and breeding stock based on this information. A final report should be submitted to the AEC at the completion of the project and/or when the strain is regarded as breeding stock.

3.3.61 The clinical status of genetically modified animals may deviate unexpectedly from the predictions made in the proposal to the AEC. Investigators must assess through detailed monitoring, the welfare and genetic stability of newly created genetically

modified animals and their offspring across a number of generations and forward a summary of these observations to the AEC. The frequency of reporting should be determined by the AEC, taking into account the nature of the genetic modification.

3.3.62 For projects involving the creation or use of genetically modified animals, records of the number of animals bred to support the project must be maintained. The fate of those animals that do not have the required genotype must be considered.

3.3.63 The least invasive collection technique that will provide sufficient tissue for genotyping should be used. Procedures used to determine the genotype of transgenic animals, such as tail-cutting of mice, must be performed or closely supervised by experienced personnel. Proposals should identify who will perform these procedures and include details of their experience. The method for the collection of tissue for genotyping of animals may be approved by the AEC in the form of a SOP (see 2.2.17).

Cloning of animals

3.3.64 The cloning of animals may or may not involve genetic modification. However, as cloning by somatic cell nuclear transfer technique may be associated with unexpected adverse effects, clauses 3.3.56-3.3.63 must apply when such projects are considered. The Prohibition of Human Cloning Act 2002 (the Act) strictly prohibits the combination of human and animal gametes (see Section 20 and the definitions in Section 8 of the Act).

Induction of tumours

3.3.65 The site for induction of tumours must be chosen carefully. Subcutaneous sites on the back or flank should be chosen where possible. Implantation of tumours either in the footpad, tail, brain or eye must not be chosen unless there is no alternative.

3.3.66 Investigators must monitor animals closely for signs of pain and distress, sudden changes in body condition, and other signs of tumour growth and spread.

3.3.67 Animals with induced tumours must be killed humanely before predictable death occurs, wasting becomes advanced, or the tumour becomes large enough to cause ulceration or severely limit normal behaviour. Animals should be euthanased as early as possible when tumours are at the minimum size necessary to obtain valid results.

3.3.68 In tumour therapy studies, end-points compatible with reliable assessment of the therapy must be as early as possible. Weight changes must be monitored closely and death from the tumour must not be an end-point.

Production of monoclonal antibodies

3.3.69 In vitro methods should be used for the routine amplification of hybridomas for the production of monoclonal antibodies (see the NHMRC guidelines and other references in Appendix 3). Investigators wishing to use the in vivo (ascites) method must provide in their proposal to the AEC recent laboratory evidence to show that in vitro methods are unsuitable for the specific monoclonal antibody that is the subject of the proposal.

3.3.70 In the immunisation phase, investigators must ensure the minimisation of pain and distress to animals from factors including:

(i) the type, volume, site and frequency of injection of adjuvants; and

(ii) the method and frequency of blood sampling.

3.3.71 If the ascitic tumour method is to be used, investigators must ensure the minimisation of pain and distress to animals from factors including:

(i) the type and volume of the priming agent;

(ii) accumulation of ascites fluid;

(iii) body weight loss (which may be difficult to discern due to overall weight gain from accumulation of ascites fluid and/or the growth of solid tumours); and

(iv) the removal of ascites fluid.

Lesions of the central nervous system

3.3.72 Projects involving anatomical or chemical lesions of the central nervous system demand special consideration when the lesion produces loss of function; including impairment of limb or trunk movements, loss of sensibility to touch, temperature or pain, impairment of the animal's awareness of its surroundings or impairment of appetite or thirst. Special animal care, caging and other facilities may be needed.

Withholding of food or water

3.3.73 Projects involving the withholding or severe restriction of food or water must be designed to produce no continuing detrimental effect on the animal. In these studies, the changes in fluid balance or body weight must be monitored, recorded and maintained within the limits approved by the AEC.

Fetal and embryonic experimentation

3.3.74 Investigators must assume that fetuses have the same requirements for anaesthesia and analgesia as adult animals of the species, unless there is specific evidence to the contrary.

3.3.75 When fetal and embryonic experimentation, including surgery, compromises the ability of the neonate to survive or there will be unrelievable pain or distress, it must be killed humanely before or immediately following birth.

3.3.76 During surgery to the mother, consideration must be given to any subsequent requirement for anaesthesia of the fetus or embryo.

3.3.77 Eggs must be destroyed before hatching, unless hatching is a requirement of the project. The AEC must approve arrangements made for hatchlings.

Research on pain mechanisms and the relief of pain

3.3.78 If unanaesthetised animals are to be subjected to stimuli designed to produce pain, investigators must:

(i) ensure that the expected level of pain caused by the stimuli is less than that which would be expected to cause distress in humans;

(ii) ensure that the animals are exposed to the minimum pain necessary for the purpose of the procedure; and

(iii) provide treatment for the relief of pain, or where possible, allow self-administration of analgesic agents or escape from repetitive, painful stimuli.

Use of non-human primates

3.3.79 Special ethical and welfare concerns arise in the use of non-human primates for scientific purposes. Investigators must take particular care to demonstrate that predicted outcomes justify the use of these species (see NHMRC Policy and other references in Appendix 3).

SECTION 4 ACQUISITION AND CARE OF ANIMALS IN BREEDING AND HOLDING FACILITIES

Animals should be obtained from breeding and supply facilities that maintain conditions consistent with the Code or relevant industry code. Housing conditions, practices and procedures involved in the care of animals in breeding and holding facilities of scientific and teaching institutions must be approved and monitored by an AEC.

4.1 ANIMALS OBTAINED FROM INTERSTATE OR OVERSEAS

It is the responsibility of the investigator or teacher to consult the relevant Commonwealth, State and Territory authorities to ensure compliance with all requirements governing the import, capture, handling and transportation of animals and to include details of this in the proposal. Some requirements are given below. However, it should be noted that this list is not comprehensive.

4.1.1 Under quarantine and fauna laws and formal agreements, the Commonwealth and States and Territories regulate the movement of animals and animal tissues into Australia and across State and Territory borders.

4.1.2 A Certificate of Health, normally issued by State or Territory Departments of Agriculture or their equivalent, may be required to accompany animals travelling interstate.

4.1.3 For native fauna, the appropriate State or Territory fauna authority may require certification that animals will be taken legally.

4.1.4 Permits must be obtained from Environment Australia for the importation of live animals, except for those species that are specifically exempt. The Australian Quarantine and Inspection Service (AQIS) should also be contacted.

4.1.5 Permits must be obtained from Environment Australia for the export of all specimens of native Australian fauna, whether alive or dead. Prior approval is also required from Environment Australia for export of some animal species not native to Australia (for example, non-human primates).

4.2 TRANSPORTATION OF ANIMALS

4.2.1 Transportation can cause animals distress due to confinement, movement, noise and changes in the environment and personnel.

4.2.2 The extent of any distress will depend on the animals' health, temperament, species, age and sex, the number of animals travelling together and their social relationships, the period without food or water, the duration and mode of transportation, environmental conditions, particularly extremes of temperature, and the care given during the journey.

4.2.3 The conditions and duration of the transportation must ensure that the impact on animal health and welfare is minimal.

4.2.4 Containers must be secure and escape-proof. There should be adequate nesting or bedding material and animals must be protected from sudden movements and extremes of climate.

4.2.5 Food and water must be provided when necessary.

4.2.6 Transportation by air should be in accordance with International Air Transport Association (IATA) regulations and domestic transportation of livestock must be in accordance with the relevant codes of practice (see Appendix 2).

4.2.7 Both suppliers and recipients of animals must ensure that there are satisfactory delivery procedures, with animals received by a responsible person.

4.3 ADMISSION OF NEW ANIMALS INTO HOLDING AREAS

4.3.1 When new animals are admitted into holding areas, they should be held separately, inspected by a qualified person and quarantined if necessary. Their health should be evaluated and treatment instigated, if required. The suitability of the animals for projects in which they are to be used should be assessed.

4.3.2 Animals should be acclimatised to the holding facility and personnel before their use in a project and those that do not adapt satisfactorily should not be kept (see 3.3.17).

4.4 CARE OF ANIMALS IN HOLDING AND PRODUCTION FACILITIES

4.4.1 Facilities are defined as the places where animals are kept including yards, paddocks, tanks, ponds and buildings.

4.4.2 Investigators and teachers, AECs and institutions must ensure that facilities are appropriately staffed, designed, constructed, equipped and maintained to achieve a high standard of animal care and fulfil scientific requirements.

4.4.3 The design and management of facilities will depend on the type of animals to be kept and the studies to be undertaken. The overall condition and management of facilities must be compatible with maintaining animal wellbeing and good health.

Outdoor holding areas

4.4.4 Outdoor holding areas must meet the needs of the species, including access to adequate shelter, food and water, protection from predation, and behavioural and social requirements.

Housing

4.4.5 Buildings should be compatible with the needs of the animals to be housed and the projects in which they are used.

4.4.6 Buildings should be designed and operated to control environmental factors appropriately, to exclude vermin and to limit contamination associated with the keeping of animals, the delivery of food, water and bedding, and the entry of people and other animals.

4.4.7 Buildings must be maintained in good repair. Walls and floors should be constructed of safe and durable materials that can be cleaned and disinfected readily.

4.4.8 Buildings must be kept clean and tidy.

4.4.9 There must be adequate storage areas for food and equipment.

4.4.10 The choice of detergents, disinfectants, deodorants and pesticides must avoid contamination of the animals' environment and should be made in consultation with investigators and teachers.

4.4.11 There should be a reticulated water supply and proper facilities for drainage, if appropriate.

4.4.12 There must be suitable plans to cover any emergencies such as the breakdown of lighting, heating or cooling.

4.4.13 Precautions should be taken to prevent entry of unauthorised people.

4.4.14 Animals must be provided with environmental conditions that suit their behavioural and biological needs unless other conditions are approved by the AEC for a particular project.

4.4.15 Air exchange, temperature, humidity, light and noise should be maintained within limits compatible with animal wellbeing and good health.

4.4.16 Effective ventilation is essential for the comfort of animals and the control of temperature, humidity and odours. Ventilation systems should distribute air uniformly and achieve adequate air exchange.

4.4.17 Noxious odours, particularly ammonia, must be kept to a level compatible with the health and comfort of the animals and personnel. The adequacy of the ventilation system, the design, construction and placement of cages and containers, population densities both within cages and within a room, the effectiveness of cleaning and the frequency of bedding changes, will all influence the level of noxious gases. Attention should be given to the balance between the need for cleanliness and the potential impact of cleaning procedures on the animals.

4.4.18 Environmental factors potentially affect the welfare of animals and may affect the results of scientific and teaching activities. Investigators, teachers and the AEC should be informed in advance of planned changes to the environmental conditions under which animals are held.

Pens, cages and containers and the immediate environments of animals

4.4.19 Animal accommodation should be designed and managed to meet species-specific needs. Pens, cages and containers should ensure animal wellbeing and comfort. Variations to these requirements as part of a project must receive prior AEC approval. The following factors should be taken into account:

(i) species-specific behavioural requirements, including the availability and design of space to enable free movement and activity, sleeping, privacy, contact with others of the same species, and environmental enrichment;

(ii) provision of single housing for animals when appropriate for the species and if necessary for the purpose of the project (for example, during recovery from surgery or collection of samples);

(iii) species-specific environmental requirements, such as lighting, temperature, air quality, appropriate day/night cycles and protection from excessive noise and vibrations;

(iv) the need to provide ready access to food and water;

(v) the need to clean the pen, cage or container;

(vi) protection from spread of pests and disease;

(vii) requirements of the project; and

(viii) the need to observe the animals readily.

4.4.20 Pens, cages and containers must:

(i) be constructed of safe, durable, materials;

(ii) be kept clean;

(iii) be maintained in good repair;

(iv) be secure and escape-proof;

(v) protect animals from climatic extremes;

(vi) not cause injury to animals;

(vii) be large enough for the species and the number of animals held; and

(viii) be compatible with the behavioural needs of the species.

4.4.21 The number of animals in cages, pens or containers and the placement of these should enable social and environmental conditions for the species to be maintained. Where it is necessary to individually house animals of a species that normally exists in social groups, the impact and time of social isolation should be kept to a minimum.

4.4.22 Bedding and litter must be provided if appropriate to the species and should be comfortable, absorbent, safe, non-toxic, able to be sterilised if needed, and suitable for the particular scientific or educational aims. Pregnant animals must be provided with nesting materials, where appropriate.

4.4.23 The AEC, investigators and teachers should be consulted in advance of planned changes to these conditions, since these may affect both the welfare of animals and results of the scientific and teaching activities.

Food and water

4.4.24 Animals must receive appropriate, uncontaminated and nutritionally adequate food of a quantity and composition that maintains normal growth of immature animals or normal weight of adult animals as well as meet the requirements of pregnancy, lactation or other conditions.

4.4.25 Where possible, animals should be given variety in the composition and presentation of food that is suitable for the species. Uneaten perishable food should be removed promptly unless contrary to the needs of the species.

4.4.26 Clean, fresh drinking water should be available at all times as suitable for the species.

4.4.27 Variations to these requirements as part of a project must receive prior AEC approval.

4.5 MANAGEMENT AND PERSONNEL

Person-in-charge of breeding and holding facilities

4.5.1 Animal acquisition, breeding and holding facilities must be supervised by persons with appropriate veterinary or animal care qualifications or experience.

4.5.2 The person-in-charge should be responsible for:

(i) managing the day-to-day care of the animals in holding and breeding facilities;

(ii) supervising the work of personnel in the facility;

(iii) liaising between investigators and teachers and facility personnel; and

(iv) communicating with the AEC on management of the facility and any adverse incidents.

4.5.3 The person-in-charge should be knowledgeable about signs of pain, distress and illness specific to each species kept and ensure that the wellbeing of all animals is regularly assessed. After animals are allocated to a project, investigators and teachers have primary responsibility for ensuring adequate monitoring of animal wellbeing.

4.5.4 The person-in-charge must ensure that ill or injured animals that are not assigned to projects are treated promptly. Animals that die unexpectedly should be subjected to autopsy.

4.5.5 The person-in-charge should contribute to the development and maintenance of the institution's animal care policies and procedures.

4.5.6 The person-in-charge must ensure that personnel receive appropriate protective clothing, maintain high standards of personal hygiene, do not eat, drink or smoke in animal areas, and have all required vaccinations, particularly against tetanus and other zoonoses.

4.5.7 Written procedures must be established for use in the management of holding and breeding facilities. These procedures must be submitted to the AEC for approval, made known to all personnel involved in the care and use of animals and be reviewed regularly. They should take into account the requirements of the species held, the studies being conducted and the health and safety of personnel and include:

(i) transportation, quarantine and disposal of animals;

(ii) routine husbandry;

(iii) prevention, diagnosis and treatment of disease;

(iv) assessment of health status and genetic constitution of the different species; and

(v) physical environmental factors.

4.5.8 The person-in-charge must maintain adequate records to allow effective management of the breeding stock including the detection of the origin and spread of disease. Records should include:

(i) the source, care, allocation, movement between locations, use and fate of all animals;

(ii) details of any diseases;

(iii) the fertility, fecundity, morbidity and mortality in breeding colonies; and

(iv) the health status, genetic constitution and physical environment of the animals.

4.5.9 Records maintained by the person-in-charge must be made available to investigators, teachers and the AEC.

4.5.10 The person-in-charge should ensure that investigators and teachers are informed of any changes to the conditions under which animals are held and that may affect the results of their studies.

Personnel

4.5.11 An important factor contributing to high standards of animal care is the number of well-trained, committed personnel. People working with animals in a holding facility

should be instructed in the detailed care and maintenance of the animals, and in how their actions may affect animal wellbeing and the outcomes of scientific and teaching activities.

4.5.12 Institutions should encourage and promote formal training in animal science or technology.

4.5.13 Personnel employed in the care of animals should be trained to recognise, at an early stage, changes in animal behaviour, performance and appearance.

4.5.14 New appointees who will care for animals must be appropriately instructed in their duties and in institutional policy.

4.5.15 Personnel should be informed of the important zoonotic diseases of animals under their care and of precautions that should be taken. Regular health checks of personnel who handle animals are recommended in the interests of both personnel and animals.

4.6 ROUTINE HUSBANDRY PROCEDURES

4.6.1 Routine husbandry procedures that are not part of a project (for example, clipping coats and nails, and vaccinations) must be performed by competent personnel.

4.6.2 Routine husbandry procedures on livestock must at least comply with the relevant codes of practice and legislation.

4.6.3 In general, procedures applied to the maintenance of breeding stock and supply of animals are viewed as routine husbandry.

4.6.4 When special breeding requirements are integral to a research or teaching project such as in the creation of a new strain of genetically modified animal, then procedures applicable to breeding must be regarded as part of the project and should be included in the proposal to the AEC (see 3.3.60 and 3.3.61).

4.7 IDENTIFICATION OF ANIMALS

4.7.1 Animals must be identifiable, whether individually or in groups. Where possible, animals should be identified by the attachment of a label to the cage, container, pen, yard or paddock in which they are kept. Otherwise, identification of individual animals may require a physical mark such as a tattoo, neckband, individual tag, or electronic numbering device such as a microchip. It is essential that the more invasive identification procedures be performed, or closely supervised, by an experienced practitioner. The method chosen should be the most appropriate for the species and the project and result in the least pain and distress to the animal.

4.7.2 The person-in-charge of the facility is responsible for ensuring that animals are identified before allocation to a project, after which time the investigator or teacher is responsible.

4.8 DISPOSAL OF CARCASSES AND WASTE MATERIAL

4.8.1 Prompt, sanitary disposal of carcasses and waste material must be in accordance with any Commonwealth, State or Territory legislation, local council by-laws and community standards.

SECTION 5 WILDLIFE STUDIES

Section 5 makes particular reference to free-living vertebrates and those captured from free-living populations, including native, non-indigenous and vertebrate pest species. It should be read in conjunction with the rest of the Code.

All scientific and teaching activities involving wildlife require AEC approval.

5.1 WILDLIFE FROM NATURAL HABITATS

5.1.1 Many species of wildlife are protected by State or Territory laws. Officers of the relevant State or Territory conservation authorities must be consulted when these species are required. Permits incorporating conditions are usually necessary to collect, keep, release and kill protected fauna, and to transport such species between States and Territories.

5.1.2 Observational studies of free-living animals have the potential to cause adverse effects because of interference with normal behaviour, particularly if there is an effect on the rearing of young. Such studies must be designed to minimise any impact on animal wellbeing.

5.1.3 Animals should not be taken from natural habitats unless animals bred in captivity are unavailable or unsuitable for the scientific purpose.

5.1.4 Investigators and teachers must recognise that field studies may cause disturbance to the habitat and adversely affect the resources available to both target and non-target species. Efforts must be made to minimise such potential disturbance.

5.1.5 Studies must not be repeated unnecessarily. Where repeated studies are proposed, AECs must decide whether repetition is necessary for enhancing the understanding and management of the species or ecosystem.

5.1.6 Reuse of individual animals requires AEC approval (see 3.3.11). However, the nature of wildlife field studies may require, or result in, recapture of individual animals. Measures should be put in place to minimise the effects of this.

5.1.7 The capture, holding, transportation, handling and release of animals from their natural habitat must be in accordance with the following:

(i) investigators and teachers must be aware that the effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling can be cumulative;

(ii) an assessment of the potential sources of stress and how they will be eliminated or minimised must form part of the proposal; and

(iii) all materials and equipment used in the capture, holding, transportation and manipulation of animals must be cleaned and maintained in a way that minimises the assessed risk of disease transmission.

5.2 CAPTURE OF WILDLIFE

General

5.2.1 Capture is stressful to animals and alternatives should be considered. Steps must be taken to minimise any distress caused to the captured animals and to the populations from which they are taken. The following conditions apply to capture:

(i) there must be careful choice of suitable capture techniques;

(ii) personnel must be skilled in the capture techniques;

(iii) if animals are to be retained after capture, they must be provided with safe enclosures or caging suitable for the species; and

(iv) animal wellbeing must be protected by regular assessment of signs of distress and remedial action taken as necessary.

5.2.2 For catching and killing fish, practices that ensure a rapid loss of consciousness should be used wherever possible.

Use of traps

5.2.3 If capture is to be by trapping, the proposal must include details of the suitability of the trapping technique for the species and how the traps will be managed to minimise the impact on both target and non-target species. The proposal should take into account issues such as:

(i) the time animals will spend in traps;

(ii) protection of animals from predators or parasites;

(iii) protection from environmental effects such as dehydration, hyperthermia, hypothermia and drowning;

(iv) deprivation of food and water;

(v) potential for impact via disruption of social structure;

(vi) potential for impact on dependent young;

(vii) deactivation of traps when not in use or no longer required;

(viii) size of trap;

(ix) construction of trap (for example, conformation of the walls, lids, covers or grids);

(x) minimisation of the numbers of non-target species trapped; and

(xi) a management plan, in compliance with relevant legislation, for non-target species captured.

5.2.4 Traps and nets used to capture animals in water must be set and monitored to prevent drowning.

5.2.5 Wet pitfall traps must not be used for the capture of vertebrate animals. If they are used for the capture of invertebrates, they must be managed to minimise the inadvertent capture of vertebrates.

Non-trap capture

5.2.6 Principles applicable to non-trap capture techniques are similar to those detailed above for traps. The skill of the operator is essential to ensure minimal impact on target and non-target species.

5.2.7 Electro-fishing may be used as a capture technique only by people with training that covers both animal welfare and human safety aspects. Any impact on non-target species must be minimised.

5.3 HANDLING AND RESTRAINT OF WILDLIFE

5.3.1 Captured free-living animals are to be handled using techniques and timing appropriate to the species. Procedures should incorporate the following to minimise the risk of injury or stress-induced disease:

(i) skilled handling in a quiet environment;

(ii) limiting the time of handling and restraint to the minimum needed to achieve the scientific or educational objectives;

(iii) using sufficient competent persons to restrain animals and prevent injury to either animals or handlers; and

(iv) using chemical restraint such as tranquillisation, where appropriate, if the period of handling is likely to cause undue stress to animals.

5.3.2 Wherever possible, the long-term and short-term consequences of capture, handling and restraint should be recorded.

5.4 HOLDING AND RELEASE OF WILDLIFE

5.4.1 The time for which an animal is held should be minimal and consistent with the achievement of scientific or educational objectives.

5.4.2 Animals must be held in a way that minimises stress and injury. Investigators and teachers must base management practices for captured animals on available information about the normal behaviour of the species and the likely response to captivity.

5.4.3 Holding areas and containers must be safe, quiet and hygienic.

5.4.4 Close confinement devices such as bags and crates must:

(i) allow animals to rest comfortably;

(ii) minimise the risk of escape and injury;

(iii) be adequately ventilated;

(iv) maintain animals within appropriate levels of ambient light, temperature and humidity; and

(v) minimise the risk of disease transmission.

5.4.5 Animals should be released at the site of capture unless the AEC approves a proposal outlining reasons why an alternative site is preferred.

5.4.6 Time of release must be consistent with the usual active time of the species.

5.4.7 All reasonable steps must be taken at the time of release to protect animals from injury and predation.

5.5 TRANSPORTATION OF WILDLIFE

5.5.1 Animals captured in the wild are particularly susceptible to the stress of transportation and all reasonable steps must be taken to minimise this. The general principles for transportation detailed in Section 4.2 of the Code apply, and particular reference should be made to the International Air Transport Association (IATA) Live Animals Regulations.

5.5.2 Stress during transportation should be minimised by:

(i) the use of appropriately-sized, designed and constructed transportation containers;

(ii) limiting exposure of animals to extremes of temperature, noise, visual disturbance and vibration;

(iii) providing, if appropriate for the species, an inner shelter within the transportation container;

(iv) ensuring that animals are separated where there is incompatibility of species, age, size, sex or reproductive status;

(v) preventing unnecessary handling; and

(vi) the administration of tranquillising agents by skilled personnel, where appropriate.

5.6 IDENTIFICATION OF WILDLIFE

5.6.1 The method chosen to identify individual animals must be that which causes the least distress and interference with the normal functioning of the animal within the context of the scientific purpose. Identification of individual animals by wildlife carers requires AEC approval if performed for scientific purposes, but not if performed for routine husbandry.

5.7 FIELD TECHNIQUES

5.7.1 Minor procedures in the field often involve only capture and release of animals, possibly facilitated by tranquillising or short-acting anaesthetic agents. Such procedures include identification (for example, leg banding, ear tagging, microchipping, and radio-tracking devices placement), examination, measurement and sampling (for example, hair, feathers, scales, blood, and stomach contents of birds). Such procedures may be carried out, subject to AEC approval, only if the following requirements are met:

(i) the procedures must be performed in a clean area by competent persons, using clean equipment;

(ii) equipment and agents necessary to provide for the health and welfare of the animals and relief of pain or distress must be readily available;

(iii) sedated or anaesthetised animals should experience uneventful recovery to full consciousness in an observation area where they are able to maintain normal body temperature and are protected from injury and predation;

(iv) the potential impact of the procedures on dependent young is minimised; and

(v) the methods and equipment used are appropriate to the species and cause the least distress and interference with normal behaviour.

5.8 VOUCHER SPECIMENS

5.8.1 Optimal use of voucher specimens requires that they become part of a publicly accessible reference collection. Therefore:

(i) if it is anticipated that voucher specimens may be taken, the need to do so must be justified to the AEC;

(ii) numbers of voucher specimens taken must be the minimum required for identification or to establish distribution;

(iii) consultation with a museum or similar institution must take place before collection to ensure the use of proper preservation and holding techniques, the availability of necessary equipment and the collection of essential data;

(iv) voucher specimens should be lodged with a museum or similar institution where they are made available for further study; and

(v) proper documentation of the specimens, including reasons for collection, is essential. Data should be maintained with the specimens.

5.9 STUDIES OF WILDLIFE INTERACTION

5.9.1 Studies of wildlife interaction may involve work in the field or the laboratory and can include interaction between species (for example, predator-prey), within species (for example, competition) and between species and habitat.

5.9.2 The primary ethical considerations with studies of wildlife interaction are the degree of manipulation required to set up the interaction and the effect of the observer(s) on the interaction.

5.9.3 Efforts should be made to reduce animal usage (for example, by employing modelling theory).

5.9.4 Field studies should include an assessment of the wellbeing of animals not included in the project, including other species, that may be influenced by the manipulation.

5.9.5 In studies of predatory encounters, unstaged natural encounters in the field should be used wherever possible.

5.9.6 Models should be used wherever possible instead of live animals if staging is required in studies of predatory encounters.

5.10 STUDIES OF VERTEBRATE PEST ANIMALS

5.10.1 All principles set out in the Code apply equally to animals considered to be pests.

5.10.2 The primary purpose of studies involving vertebrate pest animals is often to measure the efficacy of methods of killing or control. Proposals to an AEC to perform such studies must include sufficient information for the AEC to assess the potential benefits in relation to the adverse impact on both the target and non-target animals.

SECTION 6 THE USE OF ANIMALS IN TEACHING

Teachers should note that all parts of the Code, including the principles of the 3Rs, are applicable to teaching activities in schools, colleges and tertiary institutions.

This section refers to the special ethical considerations and issues of responsibility that must be addressed when animals are used for teaching activities. It should be read in conjunction with the rest of the Code.

6.1 GENERAL PRINCIPLES

6.1.1 Animals are not to be used for teaching activities unless there are no suitable alternatives for achieving all of the educational objectives (see Appendices 4 and 5).

6.1.2 All teaching activities involving the use of animals must first be approved by an AEC. The AEC must be satisfied that there is no suitable alternative, and that the number of animals involved and the impact on them, is minimised.

6.1.3 Students should be given the opportunity to discuss the ethical, social and scientific issues involved in the use of animals for scientific purposes, including teaching. Students should be made aware of the Code and relevant Commonwealth and State or Territory legislation. Where students use animals as part of their training, they should be advised of this prior to the commencement of these classes.

6.1.4 The use of non-animal models to achieve educational outcomes is still evolving and therefore should be kept under constant review. The institution will therefore need to establish mechanisms to respond to enquiries or complaints concerning the use of animals within the institution and ensure that personnel and students may voice their concerns without jeopardising their employment, careers, or coursework.

6.1.5 In the case of vocational training involving procedures that may cause adverse impacts on the animals used, the need for students to carry out such procedures should be justified to the AEC on a case-by-case basis.

6.1.6 AEC approval is not required for formal work experience or agricultural extension work involving routine procedures if all of the following apply:

(i) the animals are on their home property;

(ii) the procedures would occur normally as part of routine management;

(iii) the animals are not subjected to anything additional to what would occur in routine management; and

(iv) the teacher is competent to carry out the procedure.

6.2 RESPONSIBILITIES OF TEACHERS

6.2.1 The person-in-charge of students has responsibility for the care and use of animals from the time of acquisition until completion of the project. That person must:

(i) ensure that all care and use of animals is in accordance with the Code and all relevant provisions of Commonwealth and State or Territory legislation;

(ii) have relevant training and qualifications;

(iii) incorporate into the proposed activities any methods for the Replacement, Reduction or Refinement in the use of animals, provided such methods are compatible with the educational objectives;

(iv) obtain AEC approval before the activities commence and ensure that activities are conducted as directed and approved by the AEC;

(v) where available, use alternative methods to prepare students for teaching activities involving animals;

(vi) ensure that there is close, competent supervision of all students; and

(vii) ensure that in the event of injury to animals, treatments ranging from a minor procedure to euthanasia are available.

6.2.2 The teacher responsible must ensure that before commencing work with animals, students:

(i) are instructed in the appropriate methods of handling and caring for animals; and

(ii) have demonstrated that they are capable of performing the necessary tasks with care and competence.

6.2.3 People who are supervising students undertaking research must ensure that, prior to using animals, the students receive instruction in the ethical and legal responsibilities involved in the use of animals for scientific purposes, as well as in the appropriate methods for animal care and use. The proposal must specify whether the student or the supervisor is responsible for the welfare of the animals at each stage of the project.

6.2.4 Teachers must keep a record of the number of students involved and the number of animals used in each activity and the welfare outcomes (see 3.1.9).

6.3 PROPOSALS FOR TEACHING ACTIVITIES TO AN AEC

6.3.1 In addition to information outlined in 2.2.15 and 2.2.16, all proposals for animal use in teaching in which students are to interact with, or handle, animals or carry out a procedure on an animal must include details of:

(i) the maximum number of students to be supervised by each teacher;

(ii) the minimum and maximum number of animals to be used by each student;

(iii) the maximum number of times each animal will be used; and

(iv) how the attainment of the educational objectives will be assessed.

6.4 ANIMALS IN SCHOOLS AND COLLEGES

This section applies to all schools and colleges, including TAFE and agricultural colleges.

6.4.1 All schools and colleges using animals for scientific purposes (see definition) must access an AEC. Access may best be achieved by the establishment of regional or central State AECs for schools and colleges.

6.4.2 The Head of the school or college is responsible for ensuring that school activities involving animals comply with the Code.

6.4.3 The following activities using animals must not be carried out in schools or colleges:

(i) surgical, invasive and other harmful procedures other than normal animal husbandry operations;

(ii) induction of any infectious diseases or illness;

(iii) production of nutritional deficiency giving rise to distress;

(iv) exposure to stimuli that cause distress; and

(v) administration of toxins, ionising radiation and other bio-hazardous materials.

6.4.4 When the purpose of the activity is for students to interact with animals, consideration should be given to alternatives to the temporary introduction of animals to the school or college, such as observing animals in purpose-built facilities, in their natural environment or under field conditions.

6.4.5 Mechanisms must be put in place to ensure that all use of animals in schools and colleges complies with the principles of the Code. Mechanisms may include:

(i) the establishment of a policy committee;

(ii) the designation of a person who is responsible for promoting awareness of these principles;

(iii) the acquisition or development of detailed guidelines; and

(iv) appropriate teacher training.

6.4.6 A college, school, or group of schools may request AEC approval to repeat a particular activity that may involve different students, times, locations, or animals. In these circumstances:

(i) teachers must not vary any aspect of the project without AEC approval; and

(ii) such approval may be granted for a maximum of three years conditional on an annual report to the AEC.

6.4.7 If the same project is the subject of subsequent proposals, the applicant must continue to implement the 3Rs or justify why this cannot be done.

6.4.8 Animals must be well cared for at all times, including on weekends and holidays.

6.4.9 Detailed animal care guidelines and complete animal care records must be available in schools and colleges for inspection by AEC members and regulatory authorities.

6.4.10 Students must not be allowed to take animals home unless there is a clear, written undertaking from a parent or guardian that the animals will be cared for adequately and responsibly.

6.4.11 Animals should not be held for longer than necessary.

6.4.12 Holding facilities must be secure at all times against human and animal interference.

6.4.13 The unexpected death of an animal, or adverse outcome, should be reported promptly to the AEC.

APPENDIX I EXTERNAL REVIEW OF THE OPERATION OF INSTITUTIONS AND THEIR ANIMAL ETHICS COMMITTEES

1. INTRODUCTION

The Code embodies a system of self-regulation by which each institution must put in place processes to ensure that the care and use of animals for scientific purposes is undertaken in an ethical and humane manner. In keeping with the notion of self-regulation, the Code defines areas of responsibility and sets out the principles that guide these activities to ensure the expected goals are met. A key component of any institutional process is the AEC which determines whether a proposed use of animals is justified according to the principles of the Code, and then monitors the ongoing scientific activities. Importantly, through the membership of the AEC, the Code requires input from the wider community in the oversight of these activities. Thus, the effective operation of the AEC in all aspects of its responsibilities is central to ensuring that an institution meets its responsibilities under the Code.

To assist institutions to assess whether the processes they have established meet the goals set out in the Code, a formal external review of the operation of their AEC, at least every three years, is recommended (see 2.1.2). This Appendix is intended as a guide to assist institutions in structuring this external review to best meet their specific needs and to achieve the desired outcomes.

Existing government compliance processes carried out under the administration of State and Territory animal welfare legislation may achieve the outcomes set out in this document. Information on inspection, review and other compliance processes conducted under these legislations is available from the relevant government departments.

2. SCOPE AND OUTCOMES OF THE EXTERNAL REVIEW

The aim of the external review is to validate that the welfare of animals used for scientific purposes, including research and teaching, by an institution is safeguarded in accordance with the Code.

The primary focus of the external review should be to establish evidence that all scientific and teaching activities involving the use of animals are adequately justified, that the welfare of those animals used is given due consideration and that the AEC is effective, taking into account its terms of reference as set out in the Code.

As a result of these enquiries, the external review should enable the institution to evaluate and, if necessary, modify processes to ensure it meets its responsibilities under the Code. The external review may also assist scientific and animal care personnel to identify opportunities to promote animal welfare.

The external review process should be educational and provide an opportunity for self-assessment so that members of the AEC and those at the institution who have responsibilities for animal care and use, are involved in achieving the desired outcomes.

As a result of the external review, the institution should know that:

- the AEC is operating effectively according to the requirements of the Code;

- AEC processes are fair and transparent to all involved;
- there is effective communication between the AEC and researchers and the AEC and senior management;
- the AEC is a committee of standing within the institution;
- the AEC is receiving necessary support to meet its responsibilities;
- the involvement of external members in AECs is actively supported and facilitated;
- there are effective strategies to promote and monitor the implementation of the 3Rs by the institution;
- there is effective monitoring of the welfare of animals; and
- any facilities used to house animals are managed to achieve high standards of animal welfare.

3. CONDUCT OF THE EXTERNAL REVIEW

It is recognised that there are many acceptable models for the conduct of an external review, some of which are already in place, and the approach taken will vary with particular institutional needs.

To maximise the benefits to the institution, 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. For example, elements of the external review may include:

- review of paperwork (for example, the AEC terms of reference, proposals for scientific and teaching activities, procedures, minutes and reports, previous review reports, approved standard operating procedures and records of monitoring animal welfare);
- attendance at an AEC meeting to view the normal running of the meeting;
- inspection of animal teaching and research areas and animal holding facilities; and
- discussions with the Chairperson and members of the AEC and scientific and animal care personnel.

The review team may find it helpful to track a particular proposal as a way of understanding how the processes work in a given institution.

The institution and the review team should establish an agreed timetable and approach for the conduct of the external review, access to information and confidentiality. The institution should consider ways in which it can facilitate involvement of personnel in the external review process.

The review team should report to the Head of the institution, making recommendations to address any problems identified with the operation of the AEC or with the application of the principles of the Code.

The institution may consider publishing a summary of the external review report, possibly in an institutional annual report or web site. The summary report could also be made available to the relevant regulatory authority and funding bodies of the institution.

APPENDIX 2 LEGISLATION AND CODES OF PRACTICE

ANIMAL WELFARE

In Australia, legislation to protect animal welfare is the responsibility of State and Territory governments. Although there are some differences in specific legislative requirements, in each case the Code is the basis for describing practices and procedures to protect the welfare of animals used for scientific purposes.

Australian Capital Territory

Animal Welfare Act 1992 (ACT) Part 4
Administered by the Department of Urban Services PO Box 144
Lyneham ACT 2602
PH: 02 6207 2249
www.act.gov.au/environ

New South Wales

Animal Research Act 1985
Administered by the Animal Welfare Unit, NSW Agriculture, Locked Bag 21,
Orange NSW 2800
PH: 02 6391 3670
www.agric.nsw.gov.au/Aw/index.html

Northern Territory

Animal Welfare Act 1999
Administered by the Department of Business, Industry, and Resource Development,
GPO Box 3000, Darwin, NT 0801
PH: 08 8999 8474
http://notes.nt.gov.au/dcm/legislat/legislat.nsf

Queensland

Animal Care and Protection Act 2001
Administered by the Animal Welfare Unit, Department of Primary Industries, GPO Box 46, Brisbane QLD 4001
PH: 07 3235 4315
www.dpi.qld.gov.au/animalwelfare

South Australia

Prevention of Cruelty to Animals Act 1985
Administered by the Department of Environment and Heritage, National Parks and Wildlife Division, GPO Box 1047,
Adelaide SA 5001
PH: 08 8204 8894
www.environment.sa.gov.au/parks/about/html

Tasmania

Animal Welfare Act 1993
Administered by the Department of Primary Industry, Water and Environment
St John's Avenue, New Town TAS 7008
PH: 03 6233 6883
www.dpiwe.tas.gov.au

Victoria

Prevention of Cruelty to Animals Act 1986. Part 3
Administered by the Bureau of Animal Welfare, Department of Primary Industry, Attwood VIC 3049
PH: 03 9217 4107
www.dpi.vic.gov.au/dpi/index.htm

Western Australia

Animal Welfare Act 2002
Administered by the Department of Local Government and Regional Development, PO Box R1250, Perth WA 6844.
PH: 9217 1500
www.dlgrd.wa.gov.au

Copies of all the above legislation can be downloaded from the AustLII Data base: **www.austlii.edu.au/database.html#act**

Protection of native wildlife

Wildlife Protection (Regulation of Export and Import) Act 1982
http://scaleplus.law.gov.au/html/comact/4/2320/top.htm

Environment Protection and Biodiversity Conservation Act 1999
www.ea.gov.au/epbc/index.html

Environment Protection and Biodiversity Conservation Amendment (Wildlife Protection) Act, 2001
http://scaleplus.law.gov.au/html/comact/11/6370/top.htm

The above is Commonwealth legislation administered by the Department of Environment and Heritage
GPO Box 787, Canberra ACT 2601.
PH: 02 6274 1111
www.ea.gov.au

Information about State and Territory legislation that affects the use of wildlife for scientific purposes should be obtained from the relevant government departments.

Use of genetically modified organisms

Gene Technology Act 2000.
Administered by the Office of the Gene Technology Regulator
MDP 54, PO Box 100,
Woden ACT 2606.
PH: 1800 181 030.
OGTR issues guidelines for the certification of PC2 animal facilities.
www.ogtr.gov.au

Import and export of animals and biological materials

Australian Quarantine Act 1908.
Administered by the Australian Quarantine and Inspection Service (AQIS),
Department of Agriculture, Fisheries and Forestry,
GPO Box 858, Canberra ACT 2601.
PH: 02 6272 4282.
www.daff.gov.au

Air transportation of animals

The *International Air Transport Association (IATA) Live Animal Regulations* are the worldwide standards for transporting animals by commercial airlines.
IATA, 2000 Peel Street
Montreal, Quebec, H3A, 2R4, Canada.
www.iata.org/whatwedo/live_animals

Cloning

The Prohibition of Human Cloning Act 2002 (the Act) strictly prohibits the placing of a human embryo (see Section 21) and the placing of a human embryo clone (see Section 10) in an animal. The Act also prohibits the placing of an animal embryo in the body of a human for any period of gestation (see Section 21).
http://scaleplus/law/gov/au/html/comact/browse TOCN.htm

Other relevant Australian codes of practice Livestock

Model codes of practice for the welfare of livestock are sponsored by the Standing Committee of Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) and cover livestock, transportation, handling and husbandry.

Copies of these codes are available from CSIRO Publishing,
PO Box 1139, Collingwood, Victoria 3066.
www.publish.CSIRO.au

Model codes of practice for the welfare of animals

Current versions of the following Model codes of practice are available at www.publish.csiro.au/index

Animals at Saleyards
Cattle
Domestic Poultry
Farmed Buffalo
Farming of Ostriches

Feral Livestock Animals
Husbandry of Captive Bred Emus
Intensive Husbandry of Rabbits
Land Transport of Cattle
Land Transport of Horses
Land Transport of Pigs
Land Transport of Poultry
Land transport of Sheep
Livestock at Slaughtering Establishments
Pigs
The Camel
The Farming of Deer
The Goat
The Sheep
Transport of livestock

Wildlife

National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas 1998

A report by the Australian Science, Technology and Engineering Council.
www.dest.gov.au/archives/Science/astec/etrhics/ethics.html

APPENDIX 3 POLICIES & GUIDELINES

The Code sets out the principles that guide the decisions on how animals are used for scientific purposes. The policies and guidelines listed below, which come from a number of sources, should 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. Guidelines do not have the same standing as the Code and are intended to be used flexibly, allowing scope for interpretation and adaptation to various circumstances.

# Indicates those guidelines that have been specifically drafted with reference to the Code.

Administration of substances

Refining Procedures for the Administration of Substances
Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory Animals 2001; 35(1): 1-41.
www.lal.org.uk/pdffiles/refinement.pdf

Antibody production

G*uidelines on the Production of Monoclonal Antibodies* 2001
Published by the National Health and Medical Research Council, MDP 100, GPO Box 9848, Canberra ACT 2601.
http://www.nhmrc.gov.au/research/awc/monosyn.htm

Guidelines on the Production of Monoclonal Antibodies 2003
Published by the NSW Animal Research Review Panel
www.animalethics.org.au

CCAC Guidelines on Antibody Production 2002
Published by the Canadian Council on Animal Care
www.ccac.ca/english/gdlines/antibody/antibody.pdf

The Production of Polyclonal Antibodies in Laboratory Animals
Report and recommendations of ECVAM Workshop
ATLA 1999; 27(1): 79-102.

Assessment of pain and distress

Assessment and Control of Severity of Scientific Procedures on Laboratory Animals
Report of the Laboratory Animal Science Association Working Party
Laboratory Animals 1990; 24: 97-130.

Ethical guidelines for investigations of experimental pain in conscious animals
International Association for the Study of Pain. *Pain* 1983; 16(2): 109-10.

Morton DB, Griffiths PHM. *Guidelines on the Recognition of Pain, Distress, and Discomfort in Experimental Animals and a Hypothesis for Assessment.*
Veterinary Record 1985; 116: 431-436.

Behavioural studies

Guidelines for the Ethical Use of Animals in Applied Ethology Studies.
Applied Animal Behaviour Science 2003; 81: 291-305.

Methods and Welfare Considerations in Behavioural Research with Animals 2002.
Report published by the National Institutes of Health (USA).
www.nimh.nih.gov/researchfunding/animals.cfm

Guidelines for the Care and Use of Mammals in Neuroscience and Behavioural Research 2003.
National Research Council, The National Academies Press, Washington DC.

Blood collection

 # Guidelines on Blood Collection 2003.
Published by the NSW Animal Research Review Panel.
www.animalethics.org.au

Removal of Blood from Laboratory Animals and Birds.
Report of the BVA/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory animals 1993; 27: 1-22, 1994; 28: 178-179.
www.lal.org.uk/pdffiles/BLOOD.PDF

Dogs

 # Policy on the Care of Dogs used for Scientific Purposes. 1997.
Published by the National Health and Medical Research Council, MDP 100, GPO Box 9848, Canberra ACT, 2601.
http://www.nhmrc.gov.au/research/acw/dogsyn.htm

*# Care and Housing for Dogs in Scientific Institutions*1999.
Guidelines published by the NSW Animal Research Review Panel.
www.animalethics.org.au

Genetically modified animals

CCAC Guidelines for Transgenic Research 1997.
Published by the Canadian Council on Animal Care.
www.ccac.ca/english/gui_pol/gdlines/transgen/transge1.htm

#Guidelines for the creation, breeding, care and use of genetically modified animals for scientific purposes (pending).
Published by the National Health and Medical Research Council, MDP100, GPO Box 9848 Canberra ACT 2601

Refinement and Reduction in Production of Genetically Modified Mice
Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory Animals 2003; 37, Supplement 1.

Housing and husbandry

 # Housing Rabbits in Scientific Institutions 2003.
Guidelines published by the NSW Animal Research Review Panel.
www.animalethics.org.au

Refining Rodent Husbandry: The Mouse 1998.
Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory Animals, 32: 233-259, 1998
www.lal.org/uk/pdfiles/lab1566.pdf

Refinements in Rabbit Husbandry 1993.
Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory Animals 1993; 27: 301-329
http://www.lal.org.uk/pdffiles/RABbit.PDF

Laboratory Birds: Refinements in Husbandry and Procedures 2001
Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement
Laboratory Animals 2001; 35, Supplement 1.

Humane end-points

CCAC Guidelines for Choosing Appropriate End-points in Experiments Using Animals for Research, Teaching and Testing 1998.
Published by the Canadian Council on Animal Care
www.ccac.ca/english/gui_pol/gdlines/endpts/app9to10.htm

Humane killing

Euthanasia of Animals Used for Scientific Purposes 2001.
Published by the Australian and New Zealand Council for the Care of Animals in Research and Teaching.
www.adelaide.edu.au/ANZCCART

Recommendations for Euthanasia of Experimental Animals
Report of a United Kingdom Working Party.
Laboratory Animals 1996; 30: 293-316, 1997; 31: 1-32.
www.lal.org.uk/workp.html

Report of the AVMA Panel on Euthanasia 2000.
Published by the American Veterinary Medical Association
www.avma.org/resources/euthanasia.pdf

Euthanasia of Amphibians and Reptiles 1989
Published by UFAW, Wheathampstead, Hertsfordshire, UK
www.ufaw.org.uk

Induction of tumours

UKCCCR Guidelines for the Welfare of Animals in Experimental Neoplasia 1997
Published by the United Kingdom Coordinating Committee on Cancer Research
www.ncrn.org.uk/Csg/publications.htm

Non-human primates

 # Policy on the care and use of non-human primates for scientific purposes 2003
Published by the National Health and Medical Research Council, MDP 100, GPO Box 9848, Canberra ACT 2601.
http://www.nhmrc.gov.au/research/awc/nonhsyn.htm

Training of personnel

 # Training of Personnel 2003.
Guidelines published by the NSW Animal Research Review Panel
www.animalethics.org.au

CCAC- National Institutional Animal User Training. Recommended Syllabus for an Institutional Training Program 1999.
Published by the Canadian Council on Animal Care
http://www.ccac.ca/english/gui_pol/gdlines/niaut/NIAUTCOV.HTM

Education and Training in the Care and Use of Laboratory Animals: A Guide for developing Institutional Programs 1991.
Report of the ILAR Committee on Educational Programs in Laboratory Animal Science.
http://www.nap.edu/catalog/1592.html

FELASA recommendations for the education and training of persons carrying out animal experiments.
Published by the Federation of European Laboratory Animal Science Associations.
Laboratory Animals 1990; 24:121-131
http://www.lal.org.uk/pdffiles/lafel6.pdf

Use of animals in teaching

 # Use of Animals in Post-Graduate Surgical Training 2003.
Guideline published by the NSW Animal Research Review Panel
www.animalethics.org.au

 # Animal Welfare in Schools 2003.
Joint Guideline published by NSW Department of Education and Training, Catholic Education Commission and the Association of Independent Schools of NSW
http://www.cecnsw.catholic.edu.au/AWGallPartsAC5.pdf

 # Teaching Artificial Insemination and Pregnancy Testing in Cattle 2003.
Guideline published by the NSW Animal Research Review Panel
www.animalethics.org.au

 # Teaching Cervical or Vaginal Artificial Insemination of Sheep 2003.
Guideline published by the NSW Animal Research Review Panel
www.animalethics.org.au

Wildlife research

 # Guideline on Captive Wildlife 2003.
Published by the NSW Animal Research Review Panel.
www.animalethics.org.au

 # Guideline on the Collection of Voucher Specimens 2003.
Published by the NSW Animal Research Review Panel.
www.animalethics.org.au

 # Guideline on the Use of Pitfall Traps 2003.
Published by the NSW Animal Research Review Panel.
www.animalethics.org.au

 # Guideline on Wildlife Surveys 2003.
Published by the NSW Animal Research Review Panel.
www.animalethics.org.au

CCAC Guidelines on the Care and Use of Wildlife **2003.**
Published by the Canadian Council on Animal Care.
www.ccac.ca

CCAC Guidelines on the Care and Uses of Fish 2003.
Published by the Canadian Council on Animal Care.
www.ccac.ca

Fish Welfare 2002.
Report published by the Fisheries Society of the British Isles.
www.le.ac.uk/biology/fsbi

Guidelines for the Use of Fishes in Research 2004.
Published by American Fisheries Society.
http://www.fisheries.org/html/Public_Affairs/Sound_Science/Guidelines2004.shtml

Guidelines for the Use of Live Amphibians and Reptiles in Field Research 1987.
Published by the American Society of Ichthyologists and Herpetologists, The Herpetologists League and the Society for the Study of Amphibians and Reptiles.
www.asih.org/pubs/herpcoll.html

Guidelines for the Capture, Handling and Care of Mammals 1998.
Published by the American Society of Mammalogists.
www.mammalsociety/org/committees/index.asp

Guidelines to the Use of Wild Birds in Research 1999.
Published by the Ornithological Council.
www.nmnh.si.edu/BIRDNET/GuideToUse/index.htm;

APPENDIX 4 INFORMATION SOURCES

FURTHER READING

The following texts have been selected on the basis that they contain information that will be most helpful in the implementation of the principles of the 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.

Ethics & AECs

Armstrong, SJ & Botzler, RG (eds) 2003, *The Animal Ethics Reader,* Routledge, London.

Baker RM, Burrell, JH & Rose, MA (eds.) 1994, *Effective Animal Experimentation Ethics Committees*. Conference proceedings, ANZCCART, Adelaide, Australia.

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Animal welfare

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Baker RM, Jenkin, G & Mellor, DJ (eds) 1994, *Improving the Wellbeing of Animals in the Research Environment. Conference proceedings*. ANZCCART, Adelaide, Australia.

Broom, DM & Johnson, KG 1993, *Stress and Animal Welfare*. Chapman and Hall Animal Behaviour Series. Chapman and Hall, London UK.

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Fraser, AF (ed.) 1985, *Ethology of Farm Animals: A Comprehensive Study of the Behavioural Features of the Common Farm Animals*. World Animal Science Series A5. Elsevier, Amsterdam, The Netherlands.

Griffin, DR 1992, *Animal Minds*. The University of Chicago Press, Chicago USA.

Lawrence, AB & Rushen, J 1993, Stereotypic *Animal Behavior. Fundamentals and Applications to Welfare*. CAB International, Oxford, UK.

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Rogers, LJ 1997, *Minds of their Own. Thinking and Awareness in Animals*. Allen and Unwin, Sydney.

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Alternatives to the use of animals

Balcombe, J 2000, *The Use of Animals in Higher Education: Problems,* Alternatives and Recommendations. Humane Society US, Washington DC.

Curren RD, Southee JA, Spielman H, Liebsch M, Fentem, J.H & Balls, M 1995, *The Role of Prevalidation in the Development, Validation and Acceptance of Alternative Methods*. ECVAM Prevalidation Task Force Report 1. ATLA, 23:211-217.

Davidson, I & Hennessen, W (eds.) 1986, *Developments in Biological Standardisation, Reduction in Animal Usage in the Development and Control of Biological Products*. S.Karger, Basel, Switzerland.

Hendriksen, CFM et al. 1994, *Alternatives to Animal Testing in the Quality Control of Immunobiologicals: Current Status and Future Prospects*. ECVAM Workshop Report 4. ATLA, 22: pp 420-434.

Jukes, N & Chiuia, M 2003, *From guinea pig to computer mouse: alternative methods for a progressive humane education,* 2nd edn, InterNICHE, Leicester, UK.

Reinhardt, CA (ed.) 1994, *Alternatives to Animal Testing*. New Ways in the Biomedical Sciences, Trends and Progress. VCH, Weinheim.

Seibert, H. et al. 1996, *Acute Toxicity Testing In Vitro and the Classification and Labelling of Chemicals*. ECVAM Workshop Report 16. ATLA, 24: pp 499-510.

Langley G, Harding G, Hawkins P, Newman C, Swithenby S, Thompson D, Tofts, P & Walsh V 2000, *Volunteer studies replacing animal experiments in brain research: Report and recommendations of volunteers in research and testing workshop. Alternatives to Laboratory Animals* (ATLA) 28: pp 315-331.

Reduction of animal use – experimental design

Festing MFW, Overend P, As RG, Borja, MC & Berdoy, M 2002, *The Design of Animal Experiments. Laboratory Animals Handbook No 14.* Royal Society of Medicine Press, London.

Holzhütter H-G, Archer G, Dami N, Lovell DP, Saltelli, A & Sjöström, M 1996, *Recommendations for the Application of Biostatistical Methods During the Development and Validation of Alternative Toxicological Methods.* ECVAM Biostatistics Task Force Report 1. ATLA, 24: pp 511-530.

Management of pain and distress

AVMA Coloquium 1987, *Recognition and alleviation of animal pain and distress*. Journal of the American Veterinary Medical Association, 191(10): pp 1184-1298.

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WEB-BASED INFORMATION

The following websites access a range of information that may be helpful in the application of the Code.

# Indicates those that have been specifically developed with reference to the Code.

General

Animal Ethics Infolink
www.animalethics.org.au

Animal Welfare Information Centre (AWIC)
www.nal.usda.gov/awic

Animal Welfare Research Group, University of Edinburgh
www.vet.ed.ac.uk/animalwelfare index.htm

Caring for Animals in Research and Education (CARE)
www.med.unsw.edu.au/physiology/CARE/intro_frame.htm

Centre for Alternatives to Animal Testing (CAAT)
http://caat.jhsph.edu

Centre for Best Practice for Animals in Research
http://www.mrc.ac.uk/index/public-interest/public-ethics_and_best_practice.htm

Fund for the Replacement of Animals in Medical Research (FRAME)
http://www.frame.org.uk/

Institutional Animal Care and Use Committee (IACUC) information resource, American Association for Laboratory Animal Science (AALAS)
www.iacuc.org/

Institute for Laboratory Animal Research (ILAR)
http://dels.nas.edu/ilar/

Laboratory Animals
www.lal.org.uk/

Environmental enrichment

Refinement of Housing, Conditions and Environmental Enrichment for Laboratory Animals.
www.awionline.org/lab_animals/biblio/laball.htm

Environmental Enrichment Information: Resources for Laboratory Animals.
www.nal.usda.gov/awic/pubs/enrich/intro.htm

Animal models for biomedical research

European Mouse Mutant Archive (EMMA)
www.emma.rm.cnr.it/

Model Animals for Biomedical Research
www.nih.gov/science/models

Transgenic Animal Web
www.med.umich.edu/tamc

Gene Knockout Database
www.bioscience.org/knockout/knochome.htm

Mouse Genome Informatics, Jackson Laboratories
www.informatics.jax.org

MRC Mammalian Genetics Unit
www.mgu.har.mrc.ac.uk

The Mouse Transgenic List
www.med.ic.ac.uk/db/dbbm/tglist.htm

The Mouse Catalog
http://www.rodentia.com/wmc/index.html

NetVet Information Resources
netvet.wustl.edu/

Zebrafish International Resource Center
www.zfin.org/zf_info/stckctr/stckctr.html

Pain management

Pain and Distress: recommended resources
http://www.hsus.org/ace/18787

Pain Management Database
http://www.altwebsearch.org/aadb/aadb_search.cfm

ORGANISATIONS

Australian

Australian and New Zealand Council for the Care and Use of Animals in Research and Teaching (ANZCCART)
Mitchell Building, Room B-03
University of Adelaide, SA 5005
www.adelaide.edu.au/ANZCCART/

Other countries

Association for Assessment and Accreditation of Laboratory Animal Care International
11300 Rockville Pike Suite 1211, Rockville Maryland 20852 USA.
Email: accredit@aaalac.org.
www.aaalac.org

Animal Procedures Committee, Home Office (UK)
Allington Towers, 19 Allington Street, London, SW1E 5EB, UK.
Email: apc.secretariat@homeoffice.gsi.gov.uk
www.apc.gov.uk

Animal Welfare Information Centre (AWIC)
US Department of Agriculture, National Agriculture Library, 10301 Baltimore Avenue, Beltsville MD 20705-2551.
Email: awic@nalusda.gov
www.nal.usda.gov/awic

Canadian Council on Animal Care (CCAC)
315-350 Albert Street, Ottawa ON Canada K1R 181
www.ccac.ca/

Council of Europe
Avenue de l'Europe
67075 Strasbourg Cedex
www.coe.int/animalwelfare

Institute for Laboratory Animal Research (ILAR)
The Keck Center of the National Academies, 500 Fifth Street NW Keck 687, Washington DC 20001.
Email: ILAR@nas.edu
http://dels.nas.edu/ilar/

Laboratory Animal Welfare Teaching Exchange (LAWTE)
www.lawte.org

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health, Department of Health and Human Services, 9000 Rockville Pike, Bethesda Maryland, 20892.
www.nih.gov/grants/olaw/olaw.htm

Universities Federation for Animal Welfare (UFAW)
The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire, AL48AN, UK
Email: ufaw@ufaw.org.uk
www.ufaw.org.uk

APPENDIX 5 ALTERNATIVES TO THE USE OF ANIMALS

ORGANISATIONS

A number of organisations around the world are working towards the development and validation of Replacement methods. Many have informative web sites. See also Appendix 4, Information Sources, Further reading, 'Alternatives to the use of animals'.

Animals Australia, PO Box 1023
Collingwood, Vic 3066.
http://www.animalsaustralia.org

Centre for Alternatives to Animal Testing (CAAT)
The Johns Hopkins University, Bloomberg School of Public Health, 615 N Wolfe Street, Baltimore MD 21205. Email: caat@jhsph.edu
Internet: http://caat.jhsph.edu

European Centre for the Validation of Alternative Methods (ECVAM)
EC-Joint Research Centre, Ispra site, Via E, Fermi 1, I-21020 Ispra (VA) Italy.
http://ecvam.jrc.cec.eu.int/index.htm

European Resource Centre for Alternatives in Higher Education (EURCA)
Learning Technology Section, Faculty Group of Medicine and Veterinary Science, The University of Edinburgh, Hugh Robson Link Bld., 15 George Square, Edinburgh EH8 9XD Scotland.
www.eurca.org

Focus on Alternatives
http://www.focusonalternatives.org.uk/

Fund for Replacement of Animals in Medical Experiments (FRAME)
Russell & Burch House, 96-98 North Sherwood Street, Nottingham NG 14EE, UK.
http://www.frame.org.uk

Human Society of the United States (HSUS)
2100 L Street NW, Washington DC 20037 USA.
http://www.hsus.org/ace/352

Interagency Co-ordinating Committee on the Validation of Animal Models (ICCVAM)
NICEATM/NIEHS, 79 Alexander Drive, Mail Drop EC-17, Research Triangle Park, NC 27709, USA.
http://iccvam.niehs.nih.gov/

Psychologists for the Ethical Treatment of Animals (PsETA)
http://www.psyeta.org/

The Medical Advances Without Animals (MAWA) Trust
http://www.mawa.asn.au

UC Davis Center for Animal Alternatives
School of Veterinary Medicine, University of California, Davis CA 95616 USA.
http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm

Alternative databases

Alternatives to Animal Testing on the Web (ALTWEB)
http://altweb.jhsph.edu

Animal Welfare Information Center (AWIC) - National Agriculture Library (USA)
http://www.nal.usda.gov/awic

Association of Veterinarians for Animal Rights (AVAR) Alternatives in Education Database
http://www.avar.org

Consortium of North American Veterinary Interactive New Concept:Education (CONVINCE) Data base
http://www.convince.org

Inter-NICHE
19 Brookhouse Avenue, Leicester LE2 OJE, UK
www.interniche.org

National Library of Medicine (USA) - publishes a regular annotated bibliography on alternatives to animal testing
http://toxnet.nlm.nih.gov/altbib.html

NORINA
http://oslovet.veths.no/NORINA/

FRAME and the AWIC sites give guidance on how to search other databases, such as Medline, for information on Replacement Alternatives.

Loan Programs

The following organisations will lend resource material as alternatives to the use of animals in education.

Humane Society International - Australia.
PO Box 439, Avalon, NSW Australia
Email: alternative@his.org.au
www.hsi.org.au

InterNICHE (International Network for Humane Education) Loan Program
19 Brookhouse Avenue, Leicester LE2 OJE, UK.
Email: lolioli@hotmail.com
www.interniche.org

APPENDIX 6 ORGANISATIONS ENDORSING THE CODE

National Health and Medical Research
Council (NHMRC)
Department of Health and Ageing
MDP 100
GPO Box 9848
CANBERRA ACT 2601
Phone: Toll Free 1800 020 103
(inside Australia only)
Email: research@nhmrc.gov.au
Internet: www.nhmrc.gov.au

Commonwealth Scientific and Industrial
Research Organisation (CSIRO)
CSIRO Enquiries
Bag 10
CLAYTON SOUTH VIC 3169
Phone: 1300 363 400 (inside Australia only)
+61 3 9545 2176
Email: enquiries@csiro.au
Internet: www.csiro.gov.au

Australian Vice-Chancellor's Committee
(AV-CC)
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Email: enquiries@avcc.edu.au
Internet: www.avcc.edu.au

Australian Research Council (ARC)
GPO Box 2702
CANBERRA ACT 2601
Phone: + 61 2 6284 6600
Email: info@arc.gov.au
Internet: www.arc.gov.au/arc_home/
default.htm

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