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Introduction

Purpose of the *Australian code for the care and use of animals for scientific purposes* (the Code)

The purpose of the Code is to promote the ethical, humane and responsible care and use of animals for scientific purposes. The Code provides an ethical framework and governing principles to guide decisions and actions of all those involved in the care and use of animals for scientific purposes. The Code details the responsibilities of investigators, animal carers, institutions and animal ethics committees (AECs), and all people involved in the care and use of animals, and describes processes for accountability.

An obligation to respect animals underpins the Code. This obligation brings with it a responsibility to ensure that the care and use of animals for scientific purposes is ethically acceptable, balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits to humans, animals or the environment.

The use of animals for scientific purposes must have scientific or educational merit; must aim to benefit humans, animals or the environment; and must be conducted with integrity. When animals are used, the number of animals involved must be minimised, the wellbeing of the animals must be supported, and harm, including pain and distress, in those animals must be avoided or minimised.

Scope of the Code

The Code encompasses all aspects of the care and use of animals when the aim is to acquire, develop or demonstrate knowledge or techniques in any area of science—for example, medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes the use of animals in research, teaching associated with an educational outcome in science, field trials, product testing, diagnosis, the production of biological products and environmental studies.

The Code applies throughout the animal's involvement in activities and projects, including acquisition, transport, breeding, housing, husbandry, the use of the animal in a project, and the provisions for the animal at the completion of their use.

The Code applies to the care and use of all live non-human vertebrates and cephalopods.

Institutions are responsible for determining when the use of an animal species not covered by the Code requires approval from an AEC, taking into account emerging evidence of sentience and ability to experience pain and distress. 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. 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 them to experience pain and distress should be taken into account.

All those involved in the care and use of animals for scientific purposes must be aware of the relevant Commonwealth, state and territory legislation.

For research, institutions and investigators are reminded of their obligations under the *Australian code for the responsible conduct of research*.

Structure of the Code

SECTION 1

Section 1 describes the governing principles and ethical framework to guide decisions and actions of all those involved in the care and use of animals for scientific purposes. The application of these governing principles is further developed in subsequent sections of the Code.

SECTION 2

Section 2 describes the responsibilities of institutions, AECs, investigators and animal carers. It also outlines responsibilities in situations involving more than one institution and/or AEC, and application to an AEC.

SECTION 3

Section 3 outlines the principles for supporting and safeguarding the wellbeing of animals used for scientific purposes in terms of the animal's lifetime experience.

SECTION 4

Section 4 covers the care and use of animals in teaching activities, where the 'scientific purpose' is to impart or demonstrate knowledge or techniques to achieve an educational outcome in science.

SECTION 5

Section 5 describes responsibilities for addressing complaints and non-compliance related to the care and use of animals for scientific purposes.

SECTION 6

Section 6 describes responsibilities related to the independent external review of the operation of institutions.

SECTION 7

Section 7 describes responsibilities related to the use of animals for cosmetic testing.

Definitions

Activity: any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee. See also 'Project'.

Adverse event: any event that has a negative impact on the wellbeing of an animal. See also 'Unexpected adverse event'.

Alternative: encompasses replacement alternatives, reduction alternatives, and refinement alternatives as a whole. See 'Replacement alternatives', 'Reduction alternatives', 'Refinement alternatives'.

Animal: any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.

Animal carer: any person involved in the care of animals that are used for scientific purposes, including during their acquisition, transport, breeding, housing and husbandry.

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, which encompasses the diverse ways an animal may perceive and respond to their circumstances, ranging from a positive state of wellbeing to a negative state of distress.

Animal wellbeing: see 'Wellbeing'.

Application: a request for approval from an animal ethics committee to carry out a project or activity. An application may be for commencement of a project or activity, or an amendment to an approved project or activity.

Biological product: any product derived from animals, including blood products, vaccines, antisera, semen, antibodies and cell lines.

Clone: a genetic copy of another living or dead animal. A clone is not a twin derived by the fertilisation of an egg by a sperm.

Cloning to generate embryonic stem cells: the process of creating an embryo using cloning technology (usually somatic cell nuclear transfer) for the purpose of generating embryonic stem cells matched to the animal that donated the somatic cell.

Code: *Australian code for the care and use of animals for scientific purposes.*

Competent: the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

Compliance: acting in accordance with the Code.

Conflict of interest: a situation in which a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations, or where an institution's interests or responsibilities have the potential to influence the carrying out of its obligations.

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

Current best practice: a practice, procedure, method or process that has proven to be most effective in supporting and safeguarding animal wellbeing, and that:

- takes into consideration the relevant aspects of species-specific biology, physiology and behaviour
- is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals
- includes strategies to minimise adverse impacts.

Death as an endpoint: when the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects—that is, the investigator will not intervene to kill the animal humanely before death occurs in the course of a scientific activity. 'Death as an endpoint' does not include the death of an animal by natural causes or accidents, or the humane killing of an animal as planned in a project or because of the condition of the animal.

Distress: an animal is in a negative mental state and has been unable to adapt to stressors so as to sustain a state of wellbeing. Distress may manifest as abnormal physiological or behavioural responses, a deterioration in physical and psychological health, or a failure to achieve successful biological function. Distress can be acute or chronic and may result in pathological conditions or death.

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.

Facility: any place where animals are kept, held or housed, including yards, paddocks, tanks, ponds, buildings, cages, pens and containers.

Facility manager: person responsible for the overall management of a facility used for the breeding and holding of animals.

Genetic modification (of animals): the use of any technique for the modification of genes or other genetic material, but does not include sexual reproduction, homologous recombination or other techniques (as defined in the Gene Technology Act and Regulations, as amended from time to time).

Governing body: the body or person responsible for the administration and governance of the institution (e.g. university council or senate, board of an organisation, school board) or, where appropriate, its delegated officer.

Harm: a negative impact on the wellbeing of an animal.

Humane killing: the act of inducing death using a method appropriate to the species that results in a rapid loss of consciousness without recovery and minimum pain and/or distress to the animal.

Institution: any organisation or agency involved in the care and use of animals for scientific purposes, including universities, hospitals, research institutes, government departments, teaching organisations (including schools and colleges), vocational training organisations, agricultural organisations, commercial companies, and organisations involved in animal breeding and supply.

Investigator: any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

Livestock: animals used in agriculture and aquaculture.

Monitoring: measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Code. Monitoring occurs at different levels (including those of investigators, animal carers and animal ethics committees).

Must: used to indicate an obligatory component of the Code.

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 modify species-specific traits of behaviour, including social behaviour.

Person with ultimate responsibility: person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified.

Procedure: a technique employed when caring for or using animals for scientific purposes. One or more procedures may be used in an activity.

Program of veterinary care: system for the provision of veterinary care and advice. Elements of the program should include, where appropriate, animal clinical care; emergency care; preventive medicine; anaesthesia, analgesia and surgery; and animal quarantine. The extent of this program will depend on several factors, such as:

- the size of the establishment
- the number of animals involved
- the species used
- the nature and complexity of the activities conducted.

Examples of relevant guidelines include the *Guidelines for adequate veterinary care* (American College of Laboratory Animal Medicine), *Guidance for named veterinary surgeons* (Royal College of Veterinary Surgeons) and *Guidelines for the veterinary care of laboratory animals* (Federation of European Laboratory Animal Science Associations, European Society of Laboratory Animal Veterinarians, and European College of Laboratory Animal Medicine).

Project: an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.

Reduction alternatives: methods for obtaining comparable levels of information from the use of fewer animals in scientific procedures or for obtaining more information from the same number of animals.

Refinement alternatives: methods that alleviate or minimise potential pain and distress, and enhance animal wellbeing.

Replacement alternatives: methods that permit a given purpose of an activity or project to be achieved without the use of animals.

Research: as defined in the *Australian code for the responsible conduct of research*.

Reuse: the use of an individual animal more than once for a procedure, activity or project.

Routine husbandry: practices or procedures performed in relation to the care and management of animals with the primary purpose of maintaining their health and wellbeing.

Scientific purposes: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

Should: used to indicate a strongly recommended component of the Code. In some instances, a recommended component of the Code is an example of how it is anticipated that a person will meet the obligatory requirement of the Code.

Somatic cell nuclear transfer: moving the nucleus and its genetic material from a somatic cell to another cell (usually an egg cell from which the genetic material has been removed).

Standard operating procedure (SOP): detailed description of a standardised procedure or process.

Teacher: any person in charge of a teaching activity.

Teaching activity: any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.

Unexpected adverse event: an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were not expected
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Vertebrate pest animals: vertebrate animals, including native and introduced 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.

Wellbeing: an animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health and of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions.

Wildlife: free-living animals of native or introduced species, including those that are captive bred and those captured from free-living populations.

Xenosis: the potential spread of pathogens from a source animal of one species to a recipient animal of another species and, potentially, to the general population of the recipient species.

Xenotransplantation: any procedure that involves the transplantation, implantation or infusion of live cells, tissues or organs from another species, or body fluids, cells, tissues or organs that have ex vivo contact with live cells, tissues or organs from another species.

Section 1 ▶

Governing principles

Definitions that are particularly relevant to this section:

- activity
- animal
- current best practice
- investigator
- scientific purposes

This section describes the governing principles and ethical framework to guide decisions and actions of all people involved in the care and use of animals for scientific purposes.

The application of these governing principles is further developed in subsequent sections of the Code. Each person involved in the care and use of animals for scientific purposes must consider the governing principles when applying the Code to their specific circumstance.

Governing principles

1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:

(i) using animals only when it is justified

(ii) supporting the wellbeing of the animals involved

(iii) avoiding or minimising harm, including pain and distress, to those animals

(iv) applying high standards of scientific integrity

(v) applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:

(a) the *Replacement* of animals with other methods

(b) the *Reduction* in the number of animals used

(c) the *Refinement* of techniques used to minimise the adverse impact on animals

(vi) knowing and accepting one's responsibilities.

1.2 The care and use of animals for scientific purposes must be subject to ethical review.

1.3 A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

1.4 The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

Use animals only when justified

1.5 Evidence to support a case to use animals must demonstrate that:

(i) the project has scientific or educational merit, and has potential benefit for humans, animals or the environment

(ii) the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available

(iii) the project involves the minimum number of animals required to obtain valid data

(iv) the project involves the minimum adverse impact on the wellbeing of the animals involved.

1.6 Projects must only be undertaken:

(i) to obtain and establish significant information relevant to the understanding of humans and/or animals, or

(ii) to maintain and improve human and/or animal health and welfare, or

(iii) to improve animal management or production, or

(iv) to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or

(v) to achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements.

1.7 An animal ethics committee (AEC) must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified.

Support the wellbeing of animals

1.8 The wellbeing of animals used for scientific purposes must be considered in terms of the cumulative effects of an animal's lifetime experience. At all stages of the care and use of an animal, measures should be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal, and support the animal's wellbeing.

1.9 Practices and procedures used for the care and management of animals must be based on current best practice that:

(i) takes into consideration the relevant aspects of species-specific biology, physiology and behaviour

(ii) is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals

(iii) includes strategies to minimise adverse impacts.

Special ethical consideration and AEC approval are required where these conditions are precluded by the requirements of a project or activity.

Avoid or minimise harm, including pain and distress, to animals

1.10 Animals have a capacity to experience pain and distress, even though they may perceive and respond to circumstances differently from humans. Pain and distress may be difficult to evaluate in animals. Unless there is evidence to the contrary, it must be assumed that procedures and conditions that would cause pain and distress in humans cause pain and distress in animals. Decisions regarding the possible impact of procedures or conditions on an animal's wellbeing must be made in consideration of an animal's capacity to experience pain and distress.

1.11 Steps must be taken at all times to safeguard the wellbeing of animals by avoiding or minimising harm, including pain and distress to the animals.

1.12 Where the aim(s) of the project involves the animals experiencing pain and distress that will not be alleviated, the planned endpoint of the project must be as early as feasible to avoid or minimise pain and distress in the animals.

1.13 'Death as an endpoint' must be avoided unless it is essential for the aim(s) of the project. In these circumstances, the means to prevent or minimise harm, including pain and distress, must be considered, implemented and reviewed at all stages of the project.

1.14 Prompt action must be taken to alleviate pain and distress that were not anticipated in an approved project or activity, or occur as the result of an emergency. Such action must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity.

Apply high standards of scientific integrity

1.15 Regardless of the potential benefits of a project, the methods used must be scientifically valid, feasible, well designed and carefully conducted so that there is a reasonable expectation that the aims of the project will be achieved. Projects that are not scientifically valid must not be performed, no matter how mild the impact on the wellbeing of the animals.

1.16 Investigators must use methods that accord with current best practice that:

(i) take into consideration relevant aspects of species-specific biology, physiology and behaviour

(ii) are based on the best available scientific evidence, which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals

(iii) include strategies to minimise adverse impacts.

1.17 Animals used must be suited to the purpose of the project or activity, taking into account their biological characteristics, including morphology, physiology, behaviour, genetic makeup, temperament and behavioural conditioning, microbiological and nutritional status, and general state of health.

Apply Replacement, Reduction and Refinement (the 3Rs) at all stages

Replacement

1.18 Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented.

1.19 Before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined. Replacement techniques that must be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases.

1.20 Opportunities to replace the use of animals must be kept under review during the lifetime of a project. Where relevant and applicable, the outcome of this review must be implemented in current projects and taken into account in planning future projects.

Reduction

1.21 The number of animals used in a project must be the minimum necessary to achieve the proposed aim(s) and to satisfy good statistical design. The use of too few animals may invalidate the experimental result and result in wastage of animals.

1.22 The number of animals used may be reduced by the appropriate reuse of individual animals. The benefits of reusing animals must be balanced against any adverse effects on their wellbeing, taking into account the lifetime experience of the individual animal. Reuse of animals requires particular justification and specific AEC approval.

1.23 Activities involving the use of animals must not be repeated within a project or between projects unless such repetition is essential for the purpose or design of the project (e.g. sound experimental design, statistical analysis, corroboration by the same or another investigator).

1.24 Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals used.

1.25 All possible steps must be taken to reduce factors that are not part of the experimental design of the project and are known to contribute to variability of experimental results, including the use of animals of known genetic, biological and behavioural background. Reduction of experimental variables may result in reduced animal use.

1.26 Where practicable, tissue and other biological material from animals being killed must be shared among investigators or deposited in a tissue bank for subsequent distribution.

1.27 Breeding of animals must be managed to avoid or minimise the production of excess animals. A new line of animal should not be generated if a similar suitable animal line is available to the investigator. When a new animal line is generated, the colony should be made available as a source for other investigators, as appropriate.

Refinement

1.28 Steps must be taken at all times to support and safeguard animal wellbeing. The effectiveness of strategies for supporting and safeguarding animal wellbeing must be kept under review during the lifetime of activities, including projects. Where relevant and applicable, the outcome of this review must be implemented in current activities and taken into account in planning future activities, including projects.

1.29 People who care for and use animals must ensure that procedures are performed competently, and

(i) be competent for the procedure they perform, or

(ii) be under the direct supervision of a person who is competent to perform the procedure.

1.30 The duration of activities must be no longer than required to meet the aim(s) of the project, and must be compatible with supporting and safeguarding animal wellbeing. Animals must not be held for prolonged periods as part of an approved project before their use, without AEC approval.

Accept responsibilities

1.31 Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities (see Section 2), and act in accordance with the Code.

1.32 All activities, including projects, that involve the care and use of animals for scientific purposes must:

(i) be subject to ethical review, approval and monitoring by an AEC

(ii) commence only after approval has been granted by an AEC

(iii) be conducted in accordance with the AEC approval

(iv) cease if approval from the AEC is suspended or withdrawn.

Section 2 ▶

Responsibilities

Definitions that are particularly relevant to this section:

- activity
- animal
- investigator
- project
- scientific purposes

This section describes the responsibilities of:

- institutions (Chapter 2.1)
- institutions regarding the governance of an animal ethics committee (Chapter 2.2)
- animal ethics committees (Chapter 2.3)
- investigators (including teachers and people involved in wildlife studies) (Chapter 2.4)
- animal carers (Chapter 2.5)
- institutions, investigators and animal ethics committees in situations involving use of an external animal ethics committee, more than one institution and/or animal ethics committee, and projects conducted in other countries (Chapter 2.6)
- institutions with respect to developing an application form to an animal ethics committee (Chapter 2.7).

For research, institutions and investigators are reminded of their obligations under the *Australian code for the responsible conduct of research*.

2.1 Responsibilities of institutions

Definitions that are particularly relevant to this section

- institution
- governing body

This chapter describes the responsibilities of institutions regarding the care and use of animals for scientific purposes. The responsibilities of institutions regarding the governance of an animal ethics committee (AEC) are described in Chapter 2.2. The responsibilities of AECs regarding ethical review, approval and monitoring of animal care and use are described in Chapter 2.3.

Governing principle

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

Responsibilities

2.1.1 The governing body of an institution is responsible for ensuring that the care and use of animals for scientific purposes conducted on behalf of the institution complies with the Code.

2.1.2 Institutions must:

(i) ensure, through the operation of an AEC, that all activities involving the care and use of animals comply with the Code

(ii) promote compliance with the Code

(iii) ensure and support the effective operation of the AEC

(iv) identify clear lines of responsibility, communication and accountability

(v) ensure that all people involved in the care and use of animals understand their responsibilities and the requirements of the Code, have the necessary skills and knowledge, and have access to appropriate educational programs and resources

(vi) regularly monitor and review the institution's compliance with the Code.

Ensure compliance through an animal ethics committee

2.1.3 Institutions must ensure, through the operation of an AEC that is constituted and functioning in accordance with Chapters 2.2 and 2.3, and directly responsible to the governing body of the institution, that all activities involving the care and use of animals comply with the Code.

2.1.4 The institution may use an external AEC or share an AEC with another institution (see Clause 2.6.2).

Promote compliance

2.1.5 Institutions must promote compliance with the Code by:

(i) nominating a senior member of the institution to be responsible for overall institutional governance with respect to the care and use of animals

(ii) providing adequate resources to ensure that the AEC and people involved in the care and use of animals can meet their responsibilities, including monitoring animals and managing adverse impacts on their wellbeing

(iii) promoting and facilitating adoption of the governing principles of the Code in all aspects of animal care and use, including coordinating planning and operations, and sharing resources and information, to facilitate the application of Replacement, Reduction and Refinement (the 3Rs)

(iv) ensuring that policies and procedures are made available to all relevant people and AEC members, and are promoted within the institution. This includes institutional policies on the care and use of animals, work health and safety, confidentiality, freedom of information legislation, legal requirements, conscientious objection in the case of teaching activities, privacy and commercial-in-confidence considerations

(v) ensuring that guidelines for animal care and use are developed in consultation with the AEC, approved by the AEC, and implemented and promoted within the institution. Guidelines must include:

(a) how the competence of people involved in the care and use of animals will be assessed and ensured

(b) strategies to ensure the maintenance of a health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use

(c) monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed

(d) actions required for unexpected adverse events and emergencies, including those that require welfare interventions such as the emergency treatment or humane killing of any animal, to ensure that adverse impacts on animal wellbeing are addressed rapidly. Such guidance should include timeframes for actions, prompt reporting to the AEC, liaison between animal carers and investigators, and circumstances when consultation with a veterinarian, the performance of a necropsy by a competent person, and access to diagnostic investigations are required

(e) approval, in advance, for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people

(vi) ensuring availability and access to veterinary advice for the management and oversight of a program of veterinary care, quality management and project design to safeguard animal wellbeing

(vii) considering the appointment of an officer with veterinary or other appropriate qualifications, who is authorised by the institution to ensure that activities proceed in compliance with the Code and the decisions of the AEC.

Ensure and support the effective operation of the animal ethics committee

2.1.6 Institutions must ensure and support the effective operation of the AEC by:

(i) implementing policies and procedures so that the care and use of animals is ethically reviewed, approved and monitored by the AEC

(ii) ensuring that the terms of reference of the AEC are publicly available

(iii) providing mechanisms for prompt and effective response to recommendations from the AEC to ensure that the care and use of animals for scientific purposes within the institution complies with the Code

(iv) addressing concerns raised by the AEC regarding non-compliance with the Code that may include disciplinary action upon the advice of the AEC

(v) seeking advice 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 or areas adjacent to animal facilities.

Identify clear lines of responsibility, communication and accountability

2.1.7 Institutions must identify clear lines of responsibility, communication and accountability by:

(i) ensuring that a person is responsible for the wellbeing of animals at any given time and is clearly identified so that:

(a) animal wellbeing is monitored by competent people at all stages and sites of animal care and use. The scope of day-to-day monitoring must be clearly outlined and communicated to all parties

(b) appropriate actions are taken in cases of unexpected adverse events and emergencies that require welfare interventions, such as treatment or humane killing of an animal

(c) disease outbreaks and emergencies, such as fire, power failure and biosafety issues, are promptly detected and effectively managed

(ii) ensuring that procedures are developed for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes (see Section 5).

Ensure understanding of responsibilities

2.1.8 Institutions must ensure that all people involved in the care and use of animals understand their responsibilities and the requirements of the Code, are competent for the procedures they perform or are under the direct supervision of a person who is competent to perform the procedures, and have access to appropriate education programs and resources, by:

With respect to investigators

(i) ensuring that investigators are well informed of their responsibilities under the Code and their legal responsibilities

(ii) providing adequate resources for appropriate education, training, and assessment of competence of investigators, and certification of such competence to the satisfaction of the AEC.

With respect to animal care and management, animal carers and veterinary services

(iii) ensuring that practices and procedures for the care and management of animals are based on current best practice

(iv) employing adequate numbers of competent people to care for animals

(v) ensuring that the care and management of animals is under the direction of competent people with appropriate animal care or veterinary qualifications or experience

(vi) ensuring availability and access to appropriate veterinary and diagnostic services so that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use

With respect to work health and safety

(vii) advising relevant personnel and AEC members of the potential disease hazards and other occupational health and safety issues associated with the care and use of animals

With respect to projects involving more than one institution and/or animal ethics committee, and projects conducted in other countries

(viii) ensuring that procedures are developed in accordance with Chapter 2.6 and that relevant people are aware of their responsibilities in these situations.

Monitor and review compliance

2.1.9 Institutions must regularly monitor and review institutional compliance with the Code by:

(i) ensuring that an independent external review is conducted at least every four years to assess the institution's compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code (see Section 6)

(ii) conducting an annual review of the operation of the AEC (see Clauses 2.2.1 [v], 2.2.37 and 2.3.28–29)

(iii) conducting an annual review of the effectiveness of its processes regarding complaints and non-compliance (see Section 5).

2.1.10 Institutions should consider making publicly available:

(i) an annual report of compliance with the Code

(ii) a summary of the independent external review report (see Section 6).

2.2 Responsibilities of institutions regarding the governance of an animal ethics committee

Definitions that are particularly relevant to this section:

- animal
- animal ethics committee
- governing body of the institution
- institution
- investigator
- scientific purposes

This chapter describes the responsibilities of institutions that establish an animal ethics committee (AEC) regarding the governance of the AEC. Chapter 2.3 describes the responsibilities of AECs regarding ethical review, approval and monitoring of animal care and use. Chapter 2.1 describes the responsibilities of institutions regarding the care and use of animals for scientific purposes.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(ii) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

2.2.1 Institutions that establish an AEC must:

(i) ensure that the AEC membership will allow the committee to meet its responsibilities. Membership must comprise at least four people, one from each of four categories of membership (see Clause 2.2.4)

(ii) ensure that the AEC has terms of reference that are publicly available

(iii) provide the AEC with the resources required to carry out its responsibilities, and to maintain the AEC

(iv) establish procedures for the effective governance and operation of the AEC that will enable the AEC to meet its responsibilities under the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use

(v) conduct an annual review of the operation of the AEC.

Ensure appropriate animal ethics committee membership

Composition of the animal ethics committee

Chairperson

2.2.2 Institutions must appoint a chairperson of the AEC. Institutions should consider appointing a chairperson who holds a senior position in the institution. If the chairperson is an external appointee, institutions must provide the chairperson with the necessary support and authority to carry out the role. The chairperson may be appointed in addition to Category A to D members (see Clause 2.2.4).

2.2.3 Institutions should consider appointing a chairperson who is independent of the care and use of animals for scientific purposes.

Members

2.2.4 Institutions must ensure that membership of the AEC comprises at least one person from each of four categories of membership:

(i) Category A—a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.

(ii) Category B—a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.

(iii) 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 currently 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 endorsement by, such an organisation.

(iv) Category D—a person not employed by or otherwise associated with 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 undergraduate 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.

Additional members to assist the AEC to function effectively

2.2.5 Institutions should appoint to the AEC a person responsible for the routine care of animals within the institution.

2.2.6 Institutions may appoint additional members with skills and background of value to the AEC.

Access to expertise

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

Balance of membership

2.2.8 Categories C and D must together represent at least one-third of the AEC membership.

Appointment, reappointment and retirement of members

2.2.9 Institutions must develop procedures for the appointment, reappointment and retirement of AEC members.

2.2.10 Procedures must include the declaration of interests by prospective members and the management of conflicts of interest in making appointments.

2.2.11 Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the institution (see Clauses 2.1.2 [iv] and 2.2.22).

2.2.12 Institutions should ensure that AEC members undergo appropriate induction, and have access to appropriate education programs and resources.

Responsibilities of the chairperson

2.2.13 The chairperson is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with the institution's management.

Responsibilities of members

2.2.14 Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (see Clause 1.3) and meets the requirements of the Code.

2.2.15 To fulfil this responsibility, members should:

(i) be familiar with the Code and other policies and guidelines relevant to the business of the AEC

(ii) provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC.

2.2.16 During their appointment to the AEC, and before any deliberations of the AEC, members must declare any interest that could influence the objectivity of their decision making.

2.2.17 Members must maintain confidentiality regarding the content of applications and the deliberations of the AEC, in accordance with institutional requirements.

Ensure the animal ethics committee has terms of reference

2.2.18 The institution must ensure that the AEC has terms of reference that are publicly available and include the following provisions:

(i) the scope of its responsibilities for ethical review, approval and monitoring of animal care and use (see Chapter 2.3)

(ii) its institutional accountability

(iii) its mechanisms of reporting

(iv) the way in which it meets the requirements for categories of minimum membership.

Provide the animal ethics committee with adequate resources

2.2.19 The institution must provide the AEC with the resources required to carry out its responsibilities (see Chapter 2.3) and to maintain the AEC, and respond effectively to recommendations from the AEC regarding resources and workloads. Resources should include:

(i) staffing and administrative assistance, and financial resources

(ii) orientation and education of AEC members

(iii) where appropriate, the reimbursement of out-of-pocket expenses and/or payment of an allowance to AEC members.

Establish procedures for animal ethics committee governance and operation

2.2.20 Institutions must establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use. These procedures should include declaration of interests and management of conflicts of interest, confidentiality, appointment of and delegation of functions to an AEC Executive, administrative processes, meeting procedures, communication, complaints and non-compliance, records and documentation.

Declaration of interests and management of conflicts of interest

2.2.21 Procedures for declaration of interests and management of perceived or actual conflicts of interest involving AEC members, and experts whose advice is sought by the AEC, must require people with a conflict of interest to remove themselves from the AEC's decision making on matters that relate to the conflict of interest.

Confidentiality

2.2.22 Institutions should develop policies for maintaining confidentiality regarding the content of applications and the deliberations of the AEC, including how members may seek advice without breaching confidentiality.

Animal Ethics Committee Executive

2.2.23 If established, an AEC Executive:

(i) must include the chairperson and at least one member from Category C or D (see Clause 2.2.4)

(ii) may be delegated to approve minor amendments to approved projects or activities, for ratification at the next AEC meeting. The AEC should provide guidance on the type of activity that would be a minor amendment. A minor amendment may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress

(iii) must not approve new applications.

Administrative processes

2.2.24 Institutions should develop policies and procedures for the submission, receipt and processing of applications and reports to the AEC, and make these policies and procedures readily available.

Meeting procedures

2.2.25 At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for the conduct of a meeting, and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present.

2.2.26 Documented meeting procedures should include:

(i) timely distribution of papers to AEC members in advance of a meeting to enable members to be fully informed

(ii) the conduct of quorate AEC meetings, including circumstances where a face-to-face meeting is not possible—for example, through the use of videoconferencing and web-conferencing or, in special circumstances, teleconferencing

(iii) management of any perceived or actual conflicts of interest that may arise (see Clause 2.2.21)

(iv) frequency of meetings, which should be sufficient to allow for effective functioning of the AEC

(v) review and approval of new and ongoing activities (see Clauses 2.3.3–2.3.16).

Communication

2.2.27 The AEC must clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as promptly as possible.

2.2.28 The AEC should consider face-to-face meetings with applicants to resolve issues.

Complaints and non-compliance

2.2.29 Institutions must have procedures for dealing with complaints and non-compliance with the Code, complaints related to the AEC process, and irreconcilable differences between the AEC and an investigator (see Section 5).

Records

2.2.30 Institutions must ensure that records related to the AEC business are maintained, including:

(i) a register of all applications to the AEC, including the outcomes of deliberations

(ii) minutes that record decisions and other aspects of the AEC's operation

(iii) records of inspections conducted by the AEC (see Clause 2.3.22).

2.2.31 Where appropriate, the institution, in consultation with the AEC, should ensure that animal carers have access to records of approved projects and activities.

Documentation

2.2.32 Institutions, in consultation with the AEC, must develop documentation for:

(i) application for AEC approval to commence a project or activity that addresses the governing principles of the Code (see Chapter 2.7)

(ii) follow-up review of an approved project or activity at scheduled times and when circumstances trigger additional follow-up review, including:

(a) proposed amendment to an approved project or activity (see Clause 2.7.6)

(b) review of annual progress of an ongoing project or activity

(c) unexpected adverse events

(iii) reporting on an approved project or activity that has been completed or discontinued.

Standard operating procedures

2.2.33 Institutions, in consultation with the AEC, may allow the AEC to consider and approve standard operating procedures (SOPs) relating to the care and use of animals. Reference to SOPs can help people prepare applications to the AEC, but may make it more difficult for the AEC to apply rigour when evaluating procedures described in applications. An SOP must only be referenced in an application under the following conditions:

(i) the SOP must have current approval from the AEC

(ii) the SOP must include in its title the date of approval or last review by the AEC

(iii) investigators named in the application must be competent to implement the SOP

(iv) any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.

2.2.34 New SOPs must not be used until approved by the AEC, and may be included with an application for consideration by the AEC.

2.2.35 If an approved SOP is not reviewed by the AEC within three years of its approval, approval for the SOP lapses, and the SOP cannot be used.

2.2.36 Approved SOPs must be made available to all relevant people, including AEC members.

Conduct an annual review of the operation of the animal ethics committee

2.2.37 The institution must conduct an annual review of the operation of the AEC to ensure that it is effective and consistent with the Code and institutional policies. This must include an assessment of the AEC's annual report (see Clauses 2.1.9 and 2.3.28–29) and a meeting with the AEC chairperson.

2.3 Responsibilities of animal ethics committees

Definitions that are particularly relevant to this section:

- activity
- animal
- animal ethics committee
- institution
- investigator
- project
- scientific purposes

This chapter describes the responsibilities of animal ethics committees (AECs) regarding ethical review, approval and monitoring of animal care and use in accordance with the Code. Chapter 2.2 describes the responsibilities of institutions regarding the governance of an AEC. Chapter 2.1 describes the responsibilities of institutions regarding the care and use of animals for scientific purposes.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(ii) All activities, including projects, that involve the care and use of animals for scientific purposes must:

  (a) be subject to ethical review, approval and monitoring by an AEC

  (b) commence only after approval has been granted by an AEC

  (c) be conducted in accordance with AEC approval

  (d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

(iii) An AEC must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified (see Clause 1.7).

Responsibilities

2.3.1 The primary responsibility of an AEC is to ensure, on behalf of the institution for which it acts, that all activities relating to the care and use of animals are conducted in compliance with the Code.

2.3.2 The AEC must:

  (i) review applications for projects and approve only those projects that are ethically acceptable (see Clause 1.3) and conform to the requirements of the Code

  (ii) review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and conform to the requirements of the Code

  (iii) conduct follow-up review of approved projects and activities (see Clause 2.2.32 [ii]), and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code

  (iv) monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities

(v) take appropriate actions regarding unexpected adverse events

(vi) take appropriate actions regarding non-compliance

(vii) approve guidelines for the care and use of animals on behalf of the institution

(viii) provide advice and recommendations to the institution

(ix) report on its operations to the institution.

Review and approve new and ongoing activities

2.3.3 The AEC must provide competent, fair, consistent and timely review of applications and reports related to the care and use of animals.

2.3.4 The AEC must make a judgement on whether the proposed use, or continued use, of animals is ethically acceptable. This judgement must:

(i) be based on information provided by the applicant (see Chapter 2.7) that demonstrates the application of the principles outlined in Section 1

(ii) balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

2.3.5 The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of the Code.

2.3.6 The AEC must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings of the AEC (see Clauses 2.2.25 and 2.3.12).

2.3.7 Procedures should describe how applications and reports will be assessed 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.

2.3.8 The AEC must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant, and may use information in addition to that obtained from the applicant.

2.3.9 The AEC may decide that:

(i) an application to commence a project or activity, or amend an approved project or activity, is approved with or without conditions, deferred subject to modification, or not approved

(ii) following review of the annual report for an approved project or activity and possible consultation with the applicant, the approval for the project or activity is continued, suspended, modified or discontinued

(iii) an approval is suspended or withdrawn.

2.3.10 Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by AEC members, and should be made only by those present throughout the discussion.

2.3.11 Decisions 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 or activity that may lead to consensus. If consensus is still not achieved, 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.

2.3.12 For decision making, members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum as defined in Clause 2.2.25—that is, one member from each of the membership categories A, B, C and D, with Categories C and D together representing at least one-third of members present.

2.3.13 Decisions of the AEC must be made as promptly as possible.

2.3.14 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 must be assessed by the AEC according to the criteria applied to project approval.

2.3.15 When considering approval for the reuse of animals, the AEC must take into account:

(i) the pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions

(ii) the time allowed for recovery of the animals between activities

(iii) whether an animal has fully recovered from the previous activities

(iv) the pain and distress likely to be caused by the next and subsequent activities

(v) the total time over which an animal will be used.

2.3.16 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 formal agreements between the institution and funding bodies.

Monitor the care and use of animals

2.3.17 The AEC monitors the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records and reports.

2.3.18 The AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC. The AEC must ensure that identified problems and issues receive appropriate follow-up and, if necessary, refer suspected breaches of the Code to the institution.

2.3.19 The AEC should monitor activities that are likely to cause pain or distress at an early phase during the conduct of the activity. This requirement should be a condition of approval for the project or activity. These activities could include the study of pain, responses to stressors, models of human and animal diseases, or attempts to change behaviour by physical or chemical means.

2.3.20 A Category C or D member of the AEC should participate in animal facility inspections.

2.3.21 The AEC should determine the frequency and timing of inspections. Influencing factors include the number and accessibility of sites, the number and types of projects and activities, and whether inspections can be combined with scheduled AEC meetings. In addition, the AEC may decide that certain projects or activities require more frequent inspection than others. Inspections may be announced or unannounced.

2.3.22 The AEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (see Clause 2.2.30 [iii]).

2.3.23 AEC procedures should cover the delegation of authority to suitably qualified people to monitor animal care and use, including projects and activities conducted at remote sites (e.g. fieldwork). Procedures should include how reports of such monitoring are to be provided to the AEC (e.g. using still or video images).

Take action regarding unexpected adverse events

2.3.24 The AEC must take appropriate action in response to unexpected adverse events to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately (see Clause 2.1.5 [v] [d]). Actions may include consulting with relevant people and, where necessary, suspending or withdrawing approval for the project or activity.

Take action regarding non-compliance

2.3.25 When projects or activities that are in breach of the Code are detected, the AEC must ensure that:

(i) actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately (see Clauses5.2 [i] and 5.4 [i]). Actions may include suspending or withdrawing approval for the project or activity

(ii) actions are taken to address the issues in consultation with the person(s) involved

(iii) when considered necessary, such matters are referred to the institution for action

(iv) non-compliance receives appropriate follow-up.

Approve guidelines for the care and use of animals

2.3.26 The AEC must consider approval of guidelines for the care and use of animals that are referred to it by the institution (see Clause 2.1.5 [v]).

Provide advice and recommendations to the institution

2.3.27 The AEC must provide advice and recommendations to the institution regarding the care and use of animals for scientific purposes conducted on behalf of the institution, and strategies required to ensure that the requirements of the Code are maintained and that matters affecting animal wellbeing are addressed.

Report to the institution

2.3.28 The AEC must submit a written report on its operations at least annually to the governing body of the institution(s) for which it acts.

2.3.29 The report should advise on:

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

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

(iii) actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals

(iv) administrative or other difficulties experienced

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

2.4 Responsibilities of investigators

Definitions that are particularly relevant to this chapter:

- activity
- animal
- current best practice
- investigator
- person with ultimate responsibility
- procedure
- project
- scientific purposes
- unexpected adverse event

This chapter relates to the responsibilities of investigators—that is, researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes (see Clause 1.1).

(ii) The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use (see Clause 1.4).

(iii) Institutions, animal ethics committees (AECs) and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(iv) All activities, including projects, that involve the care and use of animals for scientific purposes must:

  (a) be subject to ethical review, approval and monitoring by an AEC

  (b) commence only after approval has been granted by an AEC

  (c) be conducted in accordance with the AEC approval

  (d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

2.4.1 Investigators have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use.

2.4.2 Investigators must only consider using animals when they are satisfied that a case can be made that the proposed use is ethically acceptable, based on whether such use demonstrates the principles in Clause 1.1, and balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (see Clause 1.3).

2.4.3 Investigators should seek advice and information from relevant experts, including other experienced scientists, veterinarians, animal care staff, or specialists in laboratory animals, livestock or wildlife, when necessary.

2.4.4 Investigators must:

(i) apply the principles of the Code (see Section 1) in all aspects of the care and use of animals, including planning, conducting and reviewing projects

(ii) follow relevant policies and procedures established by the institution and the AEC (see Clauses 2.1.5 [iv] and [v])

(iii) apply for and obtain written approval from an AEC before commencing a project that involves the use of animals, or an amendment to an approved project

(iv) conduct a project involving the use of animals in accordance with the conditions and requirements of the AEC approval, and cease the project if approval from the AEC is suspended or withdrawn

(v) undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures

(vi) ensure that procedures using animals are performed competently

(vii) maintain records of the care and use of animals

(viii) report to the AEC as required.

2.4.5 A person must be identified who has ultimate responsibility for the care and use of animals in a project. This person must:

(i) ensure that all people involved in the project understand and accept their roles and responsibilities

(ii) ensure that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities, including their education, training and supervision, as appropriate

(iii) be competent with respect to the wellbeing of animals used in the project.

This person does not relieve the individual responsibility of each investigator working with animals in the project.

Planning projects

2.4.6 When planning projects, investigators must only consider using animals when:

(i) the use of animals is justified (see Clauses 1.1 [i] and 1.5–1.7)

(ii) high standards of scientific integrity are applied (see Clauses 1.1 [iv] and 1.15–1.17)

(iii) Replacement, Reduction and Refinement (the 3Rs) are applied at all stages of the project (see Clauses 1.1 [v] and 1.18–1.30)

(iv) measures are taken to ensure that the animals' environment and management are appropriate for the species and support the animals' wellbeing (see Clauses 1.1 [ii] and 1.8–1.9)

(v) the project is designed to avoid or minimise harm, including pain and distress, to the animals (see Clauses 1.1 [iii] and 1.10–1.14)

(vi) all people involved in the care and use of animals in the project understand and accept their roles and responsibilities (see Clauses 1.1 [vi] and 1.31–1.32).

2.4.7 When planning projects, the person with ultimate responsibility for the conduct of the project must be identified (see Clause 2.4.5).

2.4.8 During planning, investigators must consider the following factors and be satisfied that:

Use animals only when justified (see Clauses 1.1 [i] and 1.5–1.7)

(i) the project has scientific or educational merit

(ii) the aims of the project cannot be achieved entirely or in part without the use of animals

(iii) the potential benefits justify the potential effects on the wellbeing of the animals involved

(iv) particular justification is provided for activities that involve severe compromise to animal wellbeing and for which the 3Rs cannot be fully applied for the activity to proceed, and for activities that involve the use of non-human primates (see Clause 2.7.4 [v])

Apply high standards of scientific integrity (see Clauses 1.1 [iv] and 1.15–1.17)

(v) the choice of species, source of the animals and biological status of the animals (e.g. genetic, nutritional, microbiological and general health status) are suited to the purpose of the project

(vi) factors that may contribute to variability of results are taken into account, including the biological status of the animals and their living conditions (e.g. physical, environmental and social conditions)

(vii) unintended adverse impacts on animal wellbeing that may confound experimental data are avoided or minimised

(viii) the methods and procedures to be used accord with current best practice and are appropriate for the purpose of the project

Apply Replacement, Reduction and Refinement (the 3Rs) (see Clauses 1.1 [v] and 1.18–1.30)

(ix) steps are taken to consider and apply the 3Rs at all stages of the project

(x) the project is designed to use the minimum number of animals to obtain valid data or achieve educational objectives, and to satisfy good statistical design

Support the wellbeing of animals (see Clauses 1.1 [ii] and 1.8–1.9)

(xi) living conditions and management that are appropriate for the species are available, including suitable housing facilities

(xii) any special requirements for the care and management of the animals are met (see Chapter 3.2)

(xiii) details and justification are provided for care and management of the animals that does not accord with current best practice (see Clause 1.9)

(xiv) procedures are in place for monitoring and managing animal health during the project (see Clause 3.2.1)

Avoid or minimise harm, including pain and distress (see Clauses 1.1 [iii] and 1.10–1.14)

(xv) known and potential causes of adverse impact on the wellbeing of animals are identified, and strategies to avoid or minimise harm, including pain and distress, are developed (see Chapter 3.1). Experimental and non-experimental factors must be considered

(xvi) a pilot study is incorporated into the design of the project if the potential impact on the animal cannot be predicted on the basis of available evidence, to allow staged assessment of the impact on animal wellbeing and the development of strategies to avoid or minimise any adverse impact

(xvii) the wellbeing of the animals is regularly monitored and assessed by competent people

Accept responsibilities (see Clauses 1.1 [vi] and 1.31–1.32)

(xviii) all people involved in the proposed project understand and accept their roles and responsibilities in the project and the relationship of their roles and responsibilities to those of other people involved in the project

(xix) procedures are performed competently, by people competent for the procedures or under the direct supervision of a person competent to perform the procedures, and provisions are made for the education, training and supervision of people nominated on the application, as appropriate

(xx) the conduct of the proposed project is feasible, after consultation with the facility manager if appropriate, and taking into consideration the available resources (e.g. funding, personnel, physical, equipment), the type and availability of animals required, and requirements to support the wellbeing of the animals

(xxi) appropriate approvals, and any administrative requirements of the institution and the AEC, are in place. These could include permits and licences, documentation to certify the biological status of animals, biosafety, work health and safety considerations, and arrangements for projects conducted at more than one institution.

2.4.9 Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution (see Clause 2.6.8).

Obtaining approval from an animal ethics committee

2.4.10 Before commencing a project, or an amendment to an approved project, investigators must:

(i) submit an application to the AEC

(ii) obtain written approval from the AEC.

2.4.11 Investigators must follow institutional and AEC policies and procedures when submitting an application to the AEC (see Clause 2.2.24 and Chapter 2.7), and provide information in the application as outlined in Clauses 2.7.4 and 2.7.6.

2.4.12 Investigators must use plain English in the application to the AEC to ensure that all AEC members are provided with sufficient information to participate effectively in the assessment of the application.

Conducting and reviewing projects

Clauses 2.4.13 – 2.4.29 are to be read in conjunction with Section 3 'Animal wellbeing'.

2.4.13 Investigators must conduct all aspects of a project in accordance with the conditions and requirements of the AEC approval and any subsequent amendments approved by the AEC.

2.4.14 Investigators must cease the conduct of a project or any part of a project if approval from the AEC is suspended or withdrawn.

Apply high standards of scientific integrity

2.4.15 Investigators must:

(i) confirm that animals are suitable for their proposed use at the time they are supplied or procured for that use

(ii) ensure that procedures involving animals accord with current best practice (see Section 3 for information regarding specific procedures).

Support animal wellbeing

2.4.16 Investigators must consider the wellbeing of animals used in the project in terms of the cumulative effects of the animal's lifetime experience. At all stages during the project, the investigator must ensure that the animal's environment and management are appropriate for the species and support the animal's wellbeing.

2.4.17 Investigators must ensure that animal care is provided by an adequate number of competent people (see Clause 2.5.1 [ii]).

Avoid or minimise harm, including pain and distress

2.4.18 Investigators must take steps at all times to safeguard the wellbeing of animals by avoiding or minimising known or potential causes of harm, including pain and distress, to the animals. Steps include:

(i) using methods that cause the least harm, including pain and distress

(ii) ensuring that procedures are performed competently, and that the investigators are:

(a) competent for the procedures they perform, or

(b) under the direct supervision of a person who is competent to perform the procedures

(iii) implementing and reviewing strategies to detect, avoid and minimise any pain and distress in the animals (see Chapter 3.1)

(iv) ensuring that animals used are identified either individually or in groups (see Clause 3.3.6)

(v) ensuring that people involved in the care and use of animals in the project are knowledgeable about the normal behaviour and signs of pain and distress for the species they will use

(vi) ensuring that animals are monitored and assessed at all stages of the project for signs of pain and distress, including deviations from normal behaviour (see Clauses 3.1.20–3.1.21). Such monitoring and assessment must be conducted at a frequency sufficient to detect such signs at an early stage, as determined by the procedure, and ensure that the planned endpoints are detected

(vii) maintaining records of monitoring and assessment of animal wellbeing (see Clauses 2.4.30–2.4.33 and 3.1.22)

(viii) taking prompt action based on the monitoring and assessment of animal wellbeing, in accordance with intervention points and humane endpoints approved by the AEC (see Clause 3.1.23)

(ix) taking prompt action, including alleviating pain and distress and promptly notifying the AEC, in response to unexpected adverse events and emergencies, in accordance with institutional and AEC policies and procedures (see Clauses 2.1.5 [v] [d] and 3.1.24–3.1.25). Alleviating unanticipated pain and distress must take precedence over an individual animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, animals must be humanely killed without delay

(x) ensuring the appropriate use of pharmacological and non-pharmacological means to minimise pain and distress (see Clauses 3.3.8–3.3.15). Use of pharmacological agents such as anaesthetics, analgesics and sedatives must be appropriate to the species, the individual animal (e.g. age, physiological status) and the scientific aims, and must be consistent with current veterinary or medical practice. Anaesthesia must be used for procedures that are likely to cause pain of a kind and degree for which anaesthesia would normally be used in veterinary or medical practice.

Apply Replacement, Reduction and Refinement (the 3Rs)

2.4.19 Investigators must continually consider how to apply the 3Rs during the conduct of the project (see Clauses 1.18–1.30). Any subsequent amendments to the approved project must only proceed following approval from the AEC.

Accept responsibilities

2.4.20 Investigators must:

(i) act in accordance with their role and responsibilities in the project

(ii) ensure that the scope of monitoring the wellbeing of the animals at all stages of their care and use in the project is clearly outlined and communicated to all parties. Depending on the type of project, this may include monitoring by animal carers.

Provisions for animals at the conclusion of their use and disposal of carcasses and waste material

2.4.21 Investigators must take prompt action regarding provisions for animals at the conclusion of their use, in accordance with procedures and protocols approved by the AEC (see Chapter 3.4).

2.4.22 Investigators must use humane procedures for killing an animal that are appropriate to the species and circumstances (see Clauses 3.3.45–3.3.46).

2.4.23 Unless otherwise required (e.g. as part of a project or for the investigation of a disease outbreak), investigators must ensure that all carcasses and tissues from animals that have died or been humanely killed are disposed of in a sanitary and appropriate manner.

2.4.24 Investigators should ensure that, if practicable, tissue samples from animals that have died or been humanely killed are provided or made available to other investigators for their work, or deposited in a tissue bank for subsequent distribution.

Projects involving hazards

2.4.25 For projects that involve hazards to other animals and humans, investigators must ensure that:

(i) all personnel are aware of these hazards, and any potential pathogenic effects from these hazards

(ii) appropriate procedures are implemented for quarantining and handling animals that pose a risk to other animals and to humans because of naturally acquired or experimentally induced infectious disease.

Creation and breeding of new animal lines where the impact on animal wellbeing is unknown or uncertain

2.4.26 The creation and breeding of a new animal line, including genetically modified and cloned animals, where the impact of the genotype on animal wellbeing is unknown or uncertain is regarded as a scientific purpose. Persons responsible for animals involved in such projects are regarded as investigators. Their responsibilities extend until the impact on animal wellbeing is known and the AEC has approved the final report on the generation of a new animal line. After this AEC approval, the new line can be treated as breeding stock, and responsibility for the animals and for obtaining AEC approval for procedures applicable to their breeding rests with the facility manager or animal carer (see Chapter 2.5).

2.4.27 Investigators must:

(i) not generate a new animal line using genetic modification if a similar, suitable animal model is available to the investigator or a relevant in vitro method can be used to achieve the aims of the project

(ii) ensure that AEC approval is in place from the start of the process until the impact of the genotype on wellbeing is known, and data on mortality, morbidity and population health of the new line are available. Procedures used for creating and breeding these animals must be regarded as part of a project and must be included in the project application to the AEC

(iii) use methods to support and safeguard the wellbeing of the animals involved (see Clause 3.3.24)

(iv) advise the AEC when the clinical status of the animals changes to a kind or degree that was not predicted

(v) maintain records of the number of animals used to create and maintain the new animal line, and the lineage and health status of the animals. Following approval from the AEC for the new animal line to be treated as breeding stock, the facility manager or animal carer is responsible for records of the maintenance of the animal line (see Clauses 2.5.11, 2.5.13 and 2.5.15 [x])

(vi) ensure that reports are provided to the AEC (see Clause 2.4.34), including:

(a) regular reports on the monitoring of a new animal line at a frequency determined by the AEC

(b) a final report on the generation of the new animal line

(vii) ensure that animals and their offspring are not sold, or transferred to another facility, unless the recipient of the animals accepts full responsibility for completion of the phenotype assessment.

Using privately owned animals

2.4.28 For projects involving the use of privately owned animals (e.g. livestock or companion animals), investigators must:

(i) ensure that all people involved in the care and use of such animals are aware of and accept their responsibilities relating to the animals

(ii) ensure that people responsible for the daily management of the animals during the project are familiar with and understand the Code, and are competent

(iii) provide the owner of the animal with a document, to be included in the application to the AEC, clearly stating the details and duration of the owner's responsibilities. The owner should acknowledge their acceptance of these responsibilities in writing.

Xenotransplantation

In the context of xenotransplantation:

- a 'recipient animal' is an animal that receives a transplant, implant or infusion of either live cells, tissues or organs from another species, or body fluids, cells, tissues or organs that have ex vivo contact with live cells, tissues or organs from another species
- a 'source animal' is an animal from which body fluids, cells, tissues or organs for use in xenotransplantation are obtained.

2.4.29 For projects involving xenotransplantation, investigators must ensure that measures are in place to minimise the potential for xenosis, including the appropriate screening of source animals, management of biohazardous waste and emergency plans for the management of adverse outcomes. Investigators should consider collecting and retaining tissue samples from source and recipient animals.

Maintaining records

2.4.30 Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers.

2.4.31 Investigators must ensure that records of monitoring and assessment of animals are in accordance with Clauses 3.1.21–3.1.22.

2.4.32 Investigators must ensure that records include:

(i) the origin/source of the animals and provisions for the animals at the conclusion of their use

(ii) the number of animals used

(iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes

(iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result

(v) any additional information requested by the AEC

(vi) names of people performing the procedures and entering the records

(vii) names and contact details of people responsible for monitoring and emergency incidents.

2.4.33 When activities involve genetically modified animals, records must include:

(i) the number of animals used for the creation and maintenance of genetically modified animals

(ii) the lineage and health status of the animals.

Reporting

2.4.34 Investigators must provide the following to the AEC in accordance with AEC and institutional policies and procedures (see Clauses 2.2.24 and 2.2.32):

(i) an annual report for an approved project, regardless of the duration of AEC approval for the project

(ii) prompt notification of any unexpected adverse events (see Clause 2.1.5 [v] [d])

(iii) a final report on outcomes as soon as practicable after completion or discontinuation of a project

(iv) reports on the creation and maintenance of genetically modified animals (see Clause 2.4.27 [vi])

(v) any other reports as required by the AEC.

2.5 Responsibilities of animal carers

Definitions that are particularly relevant to this chapter:

- activity
- animal carer
- animal
- care
- current best practice
- facility
- facility manager
- investigator
- routine husbandry
- scientific purposes
- unexpected adverse event

The number, training and competence of animal carers are important factors that contribute to high-quality animal care. This chapter relates to the responsibilities of people involved in the care of animals that are used for scientific purposes, including during their acquisition, transport, breeding, housing and husbandry.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes (see Clause 1.1).

(ii) The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal on completion of their use (see Clause 1.4).

(iii) Institutions, animal ethics committees (AECs) and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(iv) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with the AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

(v) Breeding of animals must be managed to avoid or minimise the production of excess animals (see Clause 1.27).

Responsibilities

2.5.1 The scope of responsibilities of people who provide care to animals is determined by their role and the stage of the animal use:

(i) Before an animal is supplied to an approved project for which an investigator is responsible, responsibility for the wellbeing of the animal rests with the person who is engaged by the institution to provide care for the animals (e.g. facility manager, animal technician, stock handler).

(ii) The investigator is responsible for the wellbeing of an animal throughout the period of use of the animal in the approved project, until provisions are made for the animal at the conclusion of their use (see Clause 2.4.1). The investigator must ensure that an adequate number of competent people can provide care for the animals (e.g. animal technicians, stock handlers, investigators). If an investigator acts as an animal carer during this period, their responsibilities include those of an animal carer.

2.5.2 Animal carers must, within the scope of their responsibilities:

(i) apply the principles of the Code in all aspects of the care of animals (see Section 1)

(ii) follow relevant policies and procedures established by the institution and the AEC (see Clauses 2.1.5 [iv] and [v])

(iii) undertake activities in accordance with the conditions and requirements of approval from an AEC

(iv) take measures to ensure that the animals' environment and management are appropriate for the species and the individual animal, and support the animals' wellbeing

(v) ensure that steps are taken to safeguard animal wellbeing by avoiding and minimising harm, including pain and distress, to the animals

(vi) consider the application of Replacement, Reduction and Refinement (the 3Rs) in all aspects of the care of animals for which they are responsible

(vii) ensure that their duties are performed competently

(viii) liaise with investigators and relevant project team members on all matters relevant to the wellbeing of the animals involved

(ix) maintain records of the care of animals

(x) report to the AEC as required.

2.5.3 If more than one person is responsible for the care of animals (e.g. animal technicians caring for animals in one or more animal breeding and holding facility, team of animal technicians and researchers caring for animals in a project, team of researchers and wildlife carers involved in the care of wildlife in a research project, several teachers and students caring for animals in a school), a person must be identified who has ultimate responsibility for the care of those animals. Depending on the situation, this person may be the facility manager, or the investigator with ultimate responsibility for a project. Identification of a person with ultimate responsibility for the care of animals does not relieve the individual responsibility of each person who provides care for animals.

Support animal wellbeing

2.5.4 Animal carers must:

(i) ensure that animals are cared for and managed so that species-specific or strain-specific physiological and behavioural needs are met

(ii) use procedures and practices that are based on current best practice (see Clause 1.9)

(iii) ensure that the health and biosecurity status of animals is maintained in a manner that safeguards animal wellbeing and meets the requirements of their proposed use, in accordance with institutional and AEC policies and procedures (see Clause 3.2.1).

Avoid or minimise harm, including pain and distress, to animals

2.5.5 Animal carers must:

(i) ensure that their duties are performed competently, and be

(a) competent for the duties they perform, or

(b) under the direct supervision of a person competent to perform those duties

(ii) monitor and assess the wellbeing of animals for which they are responsible (see Clause 2.5.1) with sufficient frequency to ensure that harm, including pain and distress, is promptly detected and managed (see Clauses 3.1.20–3.1.21). Where animal carers are involved in the monitoring and assessment of animals after they have been supplied to an approved project, the investigator must ensure that the scope and responsibilities for day-to-day monitoring are clearly outlined and communicated to all parties

(iii) maintain records of monitoring and assessment of animal wellbeing (see Clause 3.1.22)

(iv) take prompt actions based on the monitoring and assessment of animal wellbeing and in response to unexpected adverse events and emergencies, in accordance with institutional policies and procedures, and procedures approved by the AEC (see Clauses 2.1.5 [v] [d] and 3.1.23–3.1.25), including liaising with investigators and seeking veterinary advice.

2.5.6 If an emergency welfare intervention is considered necessary for an animal allocated to a project (e.g. treatment or humane killing of an animal), animal carers must take reasonable steps to first contact the responsible investigator. However, the welfare of the animal must be the priority at all times and may necessitate immediate intervention. Animal carers must promptly advise the responsible investigator of actions taken and the reasons for emergency interventions. Reporting of the event to the AEC, and responsibility for such reporting, must be in accordance with institutional and AEC policies and procedures (see Clause 2.1.5 [v] [d]).

Ensure provisions for animals at the conclusion of their use, and disposal of carcasses and waste material

2.5.7 Animal carers must take prompt action regarding provisions for animals at the conclusion of their use, in accordance with procedures and protocols approved by the AEC (see Chapter 3.4).

2.5.8 Animal carers must use humane procedures for killing an animal that are appropriate to the species and circumstances (see Clauses 3.3.45–3.3.46).

2.5.9 Unless otherwise required (e.g. as part of a project or for the investigation of a disease outbreak), animal carers must ensure that all carcasses and tissues from animals that have died or been humanely killed are disposed of in a sanitary and appropriate manner.

2.5.10 Animal carers should ensure that, if practicable, tissue samples from animals that have died or been humanely killed are provided or made available to investigators for their work, or deposited in a tissue bank for subsequent distribution.

Maintain records

2.5.11 Animal carers must maintain records of the care and monitoring of animals and, for breeding facilities, the health status and breeding performance of animals (see Clauses 3.1.22, 3.2.2 and 2.4.27 [v]). Animal carers must make these records available to the institution, the AEC, authorised external reviewers and, if relevant, investigators.

2.5.12 Records of animal monitoring must be sufficient to enable the AEC to verify that the wellbeing of animals has been monitored, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies.

2.5.13 Animal carers should ensure that records relating to health status and breeding performance include:

(i) the source, care, supply, movement between locations and use of the animals

(ii) details of all diseases in the facility

(iii) the fertility, fecundity, morbidity and mortality rates of breeding colonies

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

People managing and supervising breeding and holding facilities

2.5.14 The person responsible for the overall management of a facility used for breeding and holding animals (the facility manager) must be competent, with appropriate animal care or veterinary qualifications or experience. The person providing oversight of the program of veterinary care, including the care, husbandry and health of animals and biosecurity in a facility, must be competent and hold appropriate veterinary qualifications.

2.5.15 The facility manager, with support as required from the institution and other staff members, and advice from veterinarians, must:

(i) apply for and obtain written approval from the institution's AEC for all activities associated with the care and management of animals in the facility, including procedures applicable to breeding programs that are integral to the maintenance of an animal line (see also Clauses 2.4.26–2.4.27), and for any amendments to such activities (see Clause 2.2.24 and Chapter 2.7)

(ii) ensure that activities are implemented and conducted in accordance with the conditions and requirements of the AEC approval, and cease if approval from the AEC is suspended or withdrawn

(iii) ensure that all people involved in the care of animals at the facility understand and accept their role and responsibilities

(iv) ensure that procedures and resources are in place so that all people involved in the care of animals can meet their responsibilities, including education, training and supervision of staff, as appropriate

(v) ensure that quality management is promoted in the facility through the systems and procedures in place, and manage the day-to-day care of animals

(vi) arrange for experienced veterinary services in a timely manner, and ensure that staff follow veterinary advice regarding care, husbandry and health of animals, and biosecurity, in the facility

(vii) ensure the development and regular review of procedures for the care and management of animals that accord with current best practice (see Clause 1.9 and Chapters 3.2 and 3.3)

(viii) ensure that the wellbeing of animals for which they are responsible is monitored on a day-to-day basis by a competent person, and that appropriate actions are taken in accordance with both institutional and AEC policies and procedures, and actions documented in animal care procedures approved by the AEC (see Clauses 3.1.20–3.1.25)

(ix) ensure that the necessary permits, approvals and licences relating to the holding and supply of animals are in place. These may include permits, approvals or licences from Biosecurity, Australian Government Department of Agriculture, Fisheries and Forestry; the Office of the Gene Technology Regulator; and other Australian Government or state or territory government agencies; and may relate to the use of wildlife or genetically modified animals, or the importation of animals

(x) ensure regular assessment of the health status and breeding performance of all animals in accordance with current best practice, maintain appropriate records of this assessment, and make these records available to investigators, the AEC, the institution and authorised external people (see Clauses 2.5.11–2.5.13 and 3.2.2 [i])

(xi) liaise between investigators and facility staff, including informing investigators of any intended changes to the holding conditions for animals that may affect their studies

(xii) ensure that animals are suitable for their proposed use, and identify suitable animals for supply to a project (see Clauses 1.17, 3.1.9 and 3.2.9 [iii])

(xiii) communicate with the AEC regarding the management of the facility

(xiv) ensure that reports are provided to the AEC in accordance with AEC and institutional policies and procedures (see Clause 2.2.32), including:

(a) an annual report of activities

(b) prompt notification of unexpected adverse events relating to animals for which the facility manager is responsible (see Clause 2.1.5 [v] [d])

(xv) ensure that staff are advised of the work health and safety issues associated with the animals under their care and the precautions they must take, in accordance with institutional procedures (see Clauses 2.1.5 [iv] and 2.1.8 [vii]).

2.5.16 The facility manager should contribute to the development and maintenance of the institution's animal care policies and procedures, including those covering quality management.

2.5.17 When animals for which they are responsible are ill or injured, or show unexpected abnormalities, the facility manager must:

(i) ensure provision of prompt diagnosis and treatment under direct veterinary supervision and control (see Clause 2.1.5 [vi])

(ii) ensure appropriate actions in response to any subsequent report from the veterinarian on problems that may require changes to the management and/or care of the animals in the facility

(iii) for animals that die unexpectedly, ensure that institutional and AEC policies and procedures are followed regarding the conduct of a necropsy and access to diagnostic services when samples are collected for ancillary testing (see Clause 2.1.5 [v] [d]).

2.6 Other responsibilities of institutions, investigators and animal ethics committees

Definitions that are particularly relevant to this chapter:

- animal
- animal ethics committee
- governing body of the institution
- institution
- investigator
- scientific purposes

This chapter outlines the responsibilities of institutions, animal ethics committees (AECs) and investigators in situations involving:

- institutions that use an AEC established by another institution
- investigators who do not have direct access to an institutional AEC and use an AEC established by an institution
- projects involving more than one institution and/or AEC
- projects conducted by Australian investigators and institutions in other countries.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(ii) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Institutions and investigators that use an external animal ethics committee

2.6.1 An institution that has established an AEC ('the host institution') may be approached by another institution ('the second institution') seeking to access an external AEC or share an AEC. The host institution may also be approached by investigators who require AEC approval for the care and use of animals for scientific purposes but who lack direct access to an AEC. In such cases, the host institution should consult with their AEC before they accept oversight of the care and use of animals for scientific purposes conducted on behalf of the second institution or investigator.

Institutions that use an animal ethics committee that has been established by another institution

2.6.2 When an institution uses an AEC that has been established by another institution, such use must be based on a formal agreement that has been developed in consultation with the AEC. The agreement must include:

(i) procedures for ensuring that the second institution can meet its responsibilities regarding the AEC, as outlined in Chapter 2.2

(ii) procedures for communication between the AEC and the second institution, including governance and reporting

(iii) an undertaking by the second institution that their investigators and other relevant personnel will abide by the directions of the AEC

(iv) an undertaking by the second institution to abide by the AEC's policies and procedures regarding non-compliance

(v) the circumstances under which either institution may withdraw from the agreement.

Investigators who do not have direct access to an institutional animal ethics committee and use an animal ethics committee established by an institution

2.6.3 When an investigator who does not have direct access to an institutional AEC uses an AEC established by an institution, such use must be based on a formal agreement that has been developed in consultation with the AEC. The agreement must include:

(i) procedures for communication between the AEC and the investigator

(ii) an undertaking by the investigator that they will abide by the directions of the AEC

(iii) the circumstances under which either party may withdraw from the agreement.

Projects involving more than one institution and/or animal ethics committee

Responsibilities of institutions and animal ethics committees

2.6.4 Institutions must ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs. Procedures must be developed and implemented to ensure that:

(i) all parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Code

(ii) a project does not commence before each AEC approves, or the delegate AEC approves (see Clause 2.6.5), activities to be conducted by members of its institution. Each AEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts

(iii) the responsible AECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved

(iv) the responsible AECs can inspect the animals so that all phases of the project are monitored, including any animal transport between sites

(v) animals will receive appropriate care in all phases of the project, including any animal transport between sites

(vi) clear communication channels are established between all AECs and all investigators.

2.6.5 Institutions may agree to one AEC (the delegate AEC) approving the entire project, provided that all institutions involved agree to delegate the responsibility for decision making to, and support the necessary actions of, that AEC.

2.6.6 Arrangements between institutions should be as a formal agreement. Institutions should avoid unnecessary duplication of processes.

2.6.7 Arrangements should include mechanisms for reporting non-compliant activities between institutions and AECs.

Responsibilities of investigators

2.6.8 Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution (see Clause 2.4.9).

Projects conducted by Australian investigators and institutions in other countries

Responsibilities of institutions

2.6.9 Institutions should have procedures in place to ensure that, as a minimum, projects conducted on behalf of the institution in other countries:

(i) comply with the governing principles of the Code, provided that such compliance does not breach relevant local legislation

(ii) are not conducted in other countries as a mechanism of avoiding compliance with the Code.

2.6.10 Institutions that operate facilities that use animals for scientific purposes in other countries should ensure that projects conducted at those facilities comply with the principles of the Code as a minimum, provided that such compliance does not breach relevant local legislation.

Responsibilities of animal ethics committees

2.6.11 When considering approval for a project to be conducted in another country, the AEC may accept approval granted by a local AEC or its equivalent in that country if it is satisfied that outcomes would be equivalent to those expected through application of the Code.

2.6.12 The AEC must ensure that animal care and use in the other country is adequately monitored. The AEC may appoint an agent or delegate to conduct the monitoring and inspection on its behalf.

Responsibilities of investigators

2.6.13 Investigators responsible for a project conducted in another country should, as a minimum, ensure that:

(i) the project complies with the governing principles of the Code, provided that such compliance does not breach relevant local legislation

(ii) the project is not conducted in another country as a mechanism of avoiding compliance with the Code.

2.6.14 Investigators who plan to use animals in another country must obtain approval from their institutional AEC for such use. Investigators must provide the AEC with advice on how the proposed project can meet the principles of the Code, taking into account compliance with local requirements.

2.7 Responsibilities of institutions when developing an animal ethics committee application form

Definitions that are particularly relevant to this chapter:

- activity
- animal
- animal ethics committee
- investigator
- procedure
- project
- scientific purposes

This chapter outlines the responsibilities of institutions when developing documentation for application to an animal ethics committee (AEC) for approval for the care and use of animals for scientific purposes.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) The care and use of animals for scientific purposes must be subject to ethical review (see Clause 1.2).

(ii) A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits (see Clause 1.3).

(iii) An AEC must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified (see Clause 1.7).

(iv) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with the AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

2.7.1 Institutions that establish an AEC must, in consultation with the AEC, develop documentation (an application form) for applications for AEC approval to commence a project or activity and to amend an approved project or activity (see Clause 2.2.32). The institution will determine the style of the application form (e.g. electronic, web based, paper based).

2.7.2 Institutions must ensure that the design of the application form allows for the provision of information required by the AEC to assess the ethical acceptability of the proposed use of animals (see Clauses 1.3 and 2.3.4).

2.7.3 Institutions must ensure that procedures for applying to an AEC include a requirement for the use of plain English in the application, so that all AEC members are provided with sufficient information to participate effectively in the assessment of the application.

Information to be provided to an animal ethics committee for a project

2.7.4 The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances:

Using animals only when it is justified (see Clauses 1.1 [i] and 1.5–1.7)

(i) the scientific or educational aims of the project. This may include an outline of how the project relates to an overall program of work

(ii) the potential benefits of the outcomes, and the evidence that supports the use of animals. For teaching projects, justification must include an outline of how the attainment of educational outcomes will be assessed, including, as applicable, national educational outcomes, required Vocational Education and Training (VET) package competency achievements, endorsed program outcomes and other curriculum-related outcomes

(iii) details of why the use of animals is essential to achieve all the stated aims, potential alternatives that are available to replace the use of animals in all or part of the project, and why these alternatives are not suitable

(iv) information to support the case for ethical acceptability of the proposed use of animals, based on whether such use demonstrates the principles of the Code, and balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits

(v) particular justification for activities that involve:

  (a) severe compromise to animal wellbeing, and for which Replacement, Reduction and Refinement (the 3Rs) cannot be fully applied for the project to proceed, including:

    - unrelieved pain and distress, including where the planned endpoints will allow severe adverse effects to occur (see Clauses 1.12 and 3.1.18–3.1.19)
    - death as the endpoint (see Clause 1.13)
    - reuse and repeated use of animals (see Clauses 1.22–1.24 and 2.3.15)
    - prolonged restraint or confinement (see Clause 3.3.4)

  (b) use of non-human primates

Applying high standards of scientific integrity (see Clauses 1.1 [iv] and 1.15–1.17)

(vi) an overview of how the project is designed in relation to its aims

(vii) details of animals:

  (a) species, strain or breed chosen, and the reason for this choice

  (b) source of animals

Applying Replacement, Reduction and Refinement (the 3Rs) (see Clauses 1.1 [v] and 1.18–1.30)

(viii) a clear description of the steps taken to consider and apply the 3Rs

(ix) the number of animals required and the justification for this number. Where appropriate, information must be provided on:

  (a) experimental design and statistical considerations

  (b) for teaching projects, the ratio of students to animals, and the number of times that each animal will be used in each class, and/or handled per day and/or per week

(x) opportunities for sharing of tissues and other biological material from animals being killed

Supporting the wellbeing of animals (see Clauses 1.1 [ii] and 1.8–1.9)

(xi) details of housing, husbandry and care of the animals

(xii) details of the locations where animals will be housed and where procedures will be conducted

(xiii) details and justification for care and management of animals that does not accord with current best practice

Avoiding or minimising harm, including pain and distress, to animals (see Clauses 1.1 [iii] and 1.10–1.14)

(xiv) assessment of the potential adverse impact on animal wellbeing for the duration of the project, including:

  (a) a step-by-step description of what will happen to each animal, or group of animals, for the duration of the project, including provisions for the animal at the conclusion of their use

  (b) where applicable, procedures that apply to breeding programs that are integral to a project (such as the creation of a new line of animals, including genetically modified or cloned animals [see Clauses 2.4.26–2.4.27]), or that are integral to the maintenance of a line of animals in a facility (see Clause 2.5.15 [i])

  (c) identification of known and potential causes of adverse impacts on the wellbeing of an animal and how such impacts will be avoided or minimised. Experimental and non-experimental factors must be addressed (see Clauses 3.1.2–3.1.19)

(xv) details of how the wellbeing of animals will be monitored and assessed throughout the project, the frequency of monitoring and assessment, the actions to be taken if problems are identified, and the criteria for intervention points and humane endpoints (see Clauses 3.1.20–3.1.28)

Knowing and accepting responsibilities (see Clauses 1.1 [vi] and 1.31–1.32)

(xvi) identification of the person with ultimate responsibility for the conduct of the project and/or the care of the animals (see Clauses 2.4.5 and 2.5.3)

(xvii) the name of the project, the people involved and their responsibilities

(xviii) the competence of people for all procedures they will undertake using animals, or details of their supervision by a person who is competent to perform the procedures

(xix) assurance that adequate resources will be available for the conduct of the project

(xx) details of any participation of staff from other institutions, and if and how the facilities of another institution will be used (see Clause 2.4.9)

(xxi) any actual or potential interest, including any financial interest or other relationship or affiliation, that may affect judgements and decisions regarding the wellbeing of the animals involved

(xxii) any additional administrative details as required by the institution and the AEC—for example, details of collaborations, permits and licences, certification of the biological status of the animals, and work health and safety considerations

(xxiii) a declaration by the responsible investigator(s) stating that they and all others involved in the project are familiar, and will comply, with the requirements of the Code, and providing assurance that adequate resources will be available to undertake the project.

Information to be provided to an animal ethics committee for activities associated with the care and management of animals in facilities

2.7.5 The application to commence activities associated with the care and management of animals in facilities should include the information outlined in Clause 2.7.4, as appropriate for the circumstance.

Information to be provided to an animal ethics committee for an amendment to an approved project or activity

2.7.6 The application for an amendment to an approved project or activity should include the information outlined in Clause 2.7.4, where relevant.

Section 3 ▶

Animal wellbeing

Definitions that are particularly relevant to this section:

- animal
- animal wellbeing
- current best practice
- distress
- facility
- investigator
- pain
- program of veterinary care
- scientific purposes
- wildlife

This section applies to all species of animals used for scientific purposes, and to all activities and situations involving their care and use. It outlines the principles for supporting and safeguarding the wellbeing of animals used in terms of the animal's lifetime experience. These principles underpin the National Health and Medical Research Council (NHMRC) *Guidelines to promote the wellbeing of animals used for scientific purposes: the assessment and alleviation of pain and distress in research animals*.

Information in this section is presented in four chapters:

- Chapter 3.1 outlines how to approach supporting and safeguarding the wellbeing of animals.
- Chapter 3.2 provides information on supporting the wellbeing of animals during their care and management.
- Chapter 3.3 provides information on safeguarding the wellbeing of animals during the conduct of specific procedures.
- Chapter 3.4 provides information on provisions for animals at the conclusion of their use.

Information provided in this section is based on the assumption that approval has been obtained from an animal ethics committee (AEC) before any activity, including projects, commences (see Clause 1.32). The necessity and requirements for AEC approval are addressed in other sections of this document.

Sources of additional information include:

- NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: the assessment and alleviation of pain and distress in research animals*
- NHMRC *Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes*

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) The wellbeing of animals used for scientific purposes must be considered in terms of the cumulative effects of the animal's lifetime experience. At all stages of the care and use of an animal, measures should be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal, and support the animal's wellbeing (see Clause 1.8).

(ii) Animals have a capacity to experience pain and distress, even though they may perceive and respond to circumstances differently from humans. Pain and distress may be difficult to evaluate in animals. Unless there is evidence to the contrary, it must be assumed that procedures and conditions that would cause pain and distress in humans cause pain and distress in animals. Decisions regarding the possible impact of procedures or conditions on an animal's wellbeing must be made in consideration of an animal's capacity to experience pain and distress (see Clause 1.10).

(iii) Steps must be taken at all times to safeguard the wellbeing of animals by avoiding or minimising harm, including pain and distress, to the animals (see Clause 1.11).

(iv) The development of strategies to support and safeguard animal wellbeing must include the application of high standards of scientific integrity (see Clauses 1.15–1.17), and the application of Replacement, Reduction and Refinement (the 3Rs) (see Clauses 1.18–1.30).

3.1 Strategies to support and safeguard animal wellbeing

3.1.1 The planning and conduct of activities involving the care and use of animals must support and safeguard animal wellbeing. Steps include:

(i) identifying known and potential causes of adverse impact on animal wellbeing, taking into consideration both intended and unforeseen consequences

(ii) taking steps to avoid or minimise adverse impacts, including setting intervention points and humane endpoints, and monitoring animals

(iii) reviewing the effectiveness of strategies to support and safeguard animal wellbeing

(iv) implementing changes to strategies to ensure the ongoing support and safeguarding of animal wellbeing

(v) ensuring that all relevant people are aware of and accept their responsibilities regarding the wellbeing of the animals.

Identify known and potential causes of adverse impacts on animal wellbeing

3.1.2 Circumstances with the potential to have an adverse impact on the wellbeing of an animal must be identified. Experimental and non-experimental causes must be considered, including acquisition and breeding, capture, transport, housing and care, social and physical environment, handling, restraint, sample collection, non-surgical procedures, anaesthesia, surgical procedures, genetic modification, humane killing and provisions for the animal at the conclusion of their use.

3.1.3 In each instance, factors that might contribute to the level and duration of harm, including pain and distress, and the risk of such occurrences, must be considered and assessed, taking into account the predicted likelihood and consequences.

3.1.4 If the potential impact on the animal, or the validity and efficacy of criteria for intervention to minimise harm, including pain and distress, cannot be predicted on the basis of available evidence, the incorporation of a pilot study into the design of the project must be considered.

Take steps to avoid or minimise adverse impacts on animal wellbeing

Support the animals' wellbeing

3.1.5 Animals must be cared for and managed so that species-specific or strain-specific physiological and behavioural needs are met.

3.1.6 Practices and procedures used for the care and management of animals must be appropriate for the situation, the species and strain of animal, and the activities to be undertaken, and must be based on current best practice. Where the requirements of a project or activity preclude or modify these conditions, special ethical consideration and specific AEC approval is required.

3.1.7 The living conditions in indoor facilities in which animals are bred, held and used must be checked daily (see Clause 3.2.17 [i]).

3.1.8 Procedures must be in place at all stages of animal supply, housing and care to ensure that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use (see Clause 3.2.1).

3.1.9 Animals that are sourced, bred or held for scientific purposes must be suitable for their proposed use, taking into account their biological characteristics, temperament, behavioural conditioning, microbiological and nutritional status, and general state of health (see Clause 1.17). Where appropriate, the suitability of animals should be assessed before they are selected.

3.1.10 Assessment of animals (e.g. wellbeing, suitability for purpose, health) must be undertaken by a competent person, or under the direct supervision of a competent person.

3.1.11 Animals should be acclimatised to the housing/holding conditions, experimental conditions and personnel, and any changes to such conditions, before they are used (see Clauses 3.2.10–3.2.11). Animals that do not adapt satisfactorily should not be used. Prompt provisions should be made for such animals, as appropriate.

3.1.12 For animals that normally live in social groups, social isolation or separation from a group must be avoided unless specific justification is provided to, and approval is obtained from, an AEC (see Clause 3.2.23).

3.1.13 Animals must be identified either individually or in groups.

Avoid or minimise harm, including pain and distress

3.1.14 Animals used must be suited to the purpose of the project or activity (see Clause 1.17), and their suitability must be assessed before they are used.

3.1.15 Scientific and educational methods used must accord with current best practice.

3.1.16 Procedures, husbandry and care must be performed competently, by people who are competent or by people under the direct supervision of a competent person.

3.1.17 Potential causes of pain and distress that are not part of the design of a project or activity should be eliminated or controlled to minimise the adverse impact on animal wellbeing and the risks to quality of data.

3.1.18 If pain and distress are predicted or unavoidable consequences of a project, methods for minimising such pain and distress must be incorporated into the design of the project, including:

(i) establishing and implementing early intervention points and endpoints (see Clauses 3.1.26–3.1.28)

(ii) monitoring animals to ensure that the planned endpoints are detected, and taking appropriate action (see Clauses 3.1.20–3.1.25)

(iii) using pharmacological agents and non-pharmacological measures for avoiding and minimising pain and distress (see Clauses 3.3.8–3.3.15.and 3.3.17 [iii]).

3.1.19 Where it is established that the aim(s) of the project involves animals experiencing pain and distress that will not be alleviated:

(i) the planned endpoint of the project must be as early as feasible to avoid or minimise pain and distress to the animals

(ii) the animals must be monitored and assessed so that the planned endpoints are detected, and actions must be taken in accordance with the AEC approval for the project.

Monitor animals and take appropriate action

3.1.20 Animals must be monitored and assessed:

(i) by a competent person who is knowledgeable about the normal behaviour and signs of pain and distress for the species, or a person under the direct supervision of a competent person

(ii) with sufficient frequency to ensure that any harm, including pain and distress, is promptly detected and managed

(iii) in accordance with the AEC approval for the project or activity.

3.1.21 Methods for monitoring and assessment of animal wellbeing should include:

(i) the criteria that will be used to assess wellbeing

(ii) the level and frequency of monitoring to ensure that any changes in an animal's condition are detected early

(iii) the criteria that will be used to determine when action is required

(iv) actions that will be taken so that adverse impacts on animal wellbeing, including predicted effects and unforeseen complications, are addressed rapidly and effectively

(v) the methods for recording observations, treatments and actions

(vi) flexibility to ensure a rapid and effective response to changes during the course of the project or activity.

3.1.22 Records of the monitoring and assessment of animal wellbeing must be:

(i) sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies

(ii) accessible to all people involved in the care of the animal

(iii) available for audit by the institution, the AEC and authorised external reviewers.

3.1.23 Prompt action must be taken based on the monitoring and assessment of animals, in accordance with:

(i) institutional and AEC policies and procedures (see Clause 2.1.5 [v] [c])

(ii) the intervention points and humane endpoints approved by the AEC for a project, or actions documented in procedures for animal care approved by the AEC.

3.1.24 Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress, in accordance with institutional and AEC policies and procedures (see Clause 2.1.5 [v] [d]). Alleviation of pain and distress of a severity that was not anticipated in an approved project or activity must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity. If necessary, animals must be killed humanely without delay.

3.1.25 When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person (see Clause 2.1.5 [v] [d]).

Set intervention points and experimental humane endpoints

3.1.26 If pain and distress are predicted or unavoidable consequences of a project, validated criteria that are appropriate for the species and the nature and time course of the predicted effects must be established to identify:

(i) the earliest time point at which data can be obtained and the study completed (experimental endpoint[s])

(ii) when intervention is necessary to minimise pain and distress (intervention point[s])

(iii) when the animal should be humanely killed, regardless of whether the aims of the study have been achieved (humane endpoint[s]).

3.1.27 Intervention points and endpoints must be applied as early as feasible and ensure that:

(i) the duration and extent of pain and distress are minimised

(ii) valid data are obtained at the earliest time point before or following the onset of pain and distress.

3.1.28 'Death as an endpoint' must be replaced with early experimental and humane endpoints whenever possible. Where death as an endpoint is essential for the aim(s) of the project and cannot be avoided:

(i) the project must be designed to minimise the number of animals that will die

(ii) steps to avoid or minimise pain and distress, including early experimental and humane endpoints, must be considered, implemented and reviewed at all stages of the project.

Review the effectiveness of strategies to support and safeguard animal wellbeing

3.1.29 The effectiveness of strategies to support and safeguard animal wellbeing must be kept under review during the lifetime of a project or activity. Formal review must be conducted at least annually, but preferably more regularly, during the course of a project or activity, and in response to adverse outcomes.

Implement changes to the strategy to ensure its ongoing effectiveness

3.1.30 Where relevant and applicable, the outcomes from review of the effectiveness of strategies to avoid or minimise adverse impacts on animal wellbeing must be implemented in current projects or activities and taken into account in planning future activities. Any subsequent amendments to an approved project or activity must not proceed without prior approval from the AEC.

Accept responsibilities

3.1.31 The person responsible for the wellbeing of animals at any given time must be clearly identified (see Clauses 2.1.7 [i], 2.4.20 [ii] and 2.5.1).

3.1.32 When developing strategies for supporting and safeguarding animal wellbeing, investigators and animal carers should:

(i) consult with all relevant people and/or groups responsible for the wellbeing of the animals

(ii) clearly identify the person responsible for monitoring the animals

(iii) ensure good communication and cooperation between all parties involved.

3.2 Animal care and management

This chapter outlines how to support and safeguard the wellbeing of animals during their care and management.

Animal health

3.2.1 Procedures for ensuring that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use (see Clause 3.1.8) must include:

(i) monitoring and assessment of animals by a competent person with sufficient frequency to ensure that sick or injured animals are promptly detected and identified, and that appropriate action is taken

(ii) provision of veterinary clinical care and advice

(iii) prompt detection and effective management of disease outbreaks and emergencies such as fire, power failure and biosafety issues

(iv) preventive protocols under veterinary direction or supervision, as appropriate, including animal biosecurity; quarantine; and the surveillance, diagnosis, treatment and control of diseases.

Acquisition and breeding

3.2.2 When animals are specifically bred for scientific purposes, the breeding program must be managed in accordance with current best practice to ensure the wellbeing of the colony, herd or flock, and all animals involved, including:

(i) maintaining, monitoring and reviewing adequate records. To allow an assessment of reproductive performance, records should include data relevant to fertility, fecundity, morbidity and mortality

(ii) ensuring that specified requirements for genetic constitution and health status are met and certified

(iii) ensuring that breeding of excess animals is avoided or minimised (see Clause 1.27), including assessment of the details and reason for culling of animals and, when relevant, accurate and timely genotyping.

Further information about breeding animals, including genetically modified animals, is provided in Clauses 2.4.26–2.4.27, 2.5.15 [i] and 3.3.24.

3.2.3 When animals are obtained from a breeding and holding facility outside the institution, the health status of the colony from which the animals are acquired must be assessed before animals are transported, to ensure that the animals will be suitable for the intended scientific purpose and compatible with the biosecurity status and requirements of the receiving facility.

3.2.4 Wildlife must not be taken from their natural habitats or otherwise disturbed unless it is essential for the work proposed and no alternative source of animals or data is available. Practices to minimise transmission of pathogens between animals and between sites must be implemented.

Transport of animals

3.2.5 Methods and arrangements for the transport of animals must support and safeguard the wellbeing of the animals before, during and after their transport, and take into account the health, temperament, age, sex and previous experiences of the animals; the number of animals travelling together and their social relationships; the period without food or water; the duration and mode of transport; environmental conditions (particularly extremes of temperature); and the care given during the journey.

3.2.6 Transport methods and arrangements must:

(i) be appropriate for the species and the circumstances

(ii) minimise harm, including pain and distress, arising from factors such as containment, movement, noise, disruption of social groups, and changes in the environment and personnel

(iii) ensure that animals are:

(a) provided with appropriate food and water when necessary

(b) provided with the physical and social environment appropriate for the species

(c) protected from, and treated for, injury and disease.

3.2.7 Both suppliers and recipients of animals must ensure that satisfactory delivery procedures are in place, including receipt of the animals by a responsible person, accountability for animal numbers, and adherence to other regulatory codes, such as quarantine.

3.2.8 People responsible for monitoring animals during transport must be able to recognise and respond to animal needs during transport.

Admission of new animals to breeding and holding facilities

3.2.9 When new animals are admitted to breeding and holding facilities, their wellbeing must be supported and safeguarded by:

(i) ensuring that the health and wellbeing of the animals is assessed by a competent person before their admission, and quarantine and preventive or other health treatment is provided, if appropriate (see Clauses 3.1.10 and 3.2.1)

(ii) ensuring that appropriate accommodation is available and that animals are transferred to this accommodation without unnecessary delay

(iii) assessing the suitability of the animals for their intended scientific purpose (see Clauses 1.17, 2.4.15 [i], 2.5.15 [xii] and 3.1.9).

Acclimatisation and conditioning

3.2.10 If there is any change in the housing/holding conditions at the time an animal is supplied or selected for use in a project, sufficient time should be allowed for the animal to acclimatise before the project commences.

3.2.11 Before a project commences, the animals should be conditioned to the handling, experimental conditions and people who will conduct the procedures.

3.2.12 Animals that do not adapt satisfactorily after acclimatisation and/or conditioning should not be used, and prompt provisions should be made for such animals, as appropriate.

Housing and care

3.2.13 Animals must be provided with accommodation, physical and social environmental conditions, food, water and care to meet species-specific or strain-specific physical and behavioural needs. If the requirements of a project or activity preclude or modify these conditions, special ethical consideration and specific AEC approval are required (see Clauses 1.9 and 3.1.5).

3.2.14 Facilities must be appropriately staffed, designed, constructed, equipped, maintained and managed to achieve a high standard of animal care. Facilities must be suitable for the type of animals kept and the aims of the activities undertaken.

3.2.15 Animals held outdoors must be protected from adverse environmental conditions and predation, and provided with access to adequate shelter, food and water.

3.2.16 The housing and care of animals that are administered infectious organisms must take into account risks to other animals and to humans, and appropriate procedures to minimise such risks must be implemented.

Indoor facilities

3.2.17 Indoor facilities should be designed and operated to:

(i) control environmental factors such as air quality, temperature, humidity, light and noise within limits compatible with the health and wellbeing of the species held. Capacity for control of the microclimate by the caging systems or by the individual animals should be taken into account

(ii) enable appropriate segregation of species or activities that might affect other animals held in the same facility

(iii) exclude vermin

(iv) limit contamination associated with the keeping of animals, and the delivery of food, water and bedding

(v) prevent the entry of unauthorised people and other animals.

3.2.18 Indoor facilities must be clean, tidy and in good repair. Walls and floors should be constructed of safe, durable materials that can be cleaned and disinfected readily. There must be adequate storage areas for food and equipment, a reticulated water supply and proper facilities for drainage, if appropriate.

3.2.19 Noxious odours, particularly ammonia, must not exceed a level compatible with the health and comfort of the animals and personnel.

3.2.20 Chemicals used in a facility, including detergents, disinfectants, deodorisers and pesticides must be appropriate for the purpose, and contamination of the animals' environment must be avoided during their use. Chemicals should be used in consultation with the relevant investigators who use the facility.

Pens, cages and containers

3.2.21 Pens, cages and containers must be:

(i) constructed of safe, durable materials

(ii) kept clean

(iii) maintained in good repair

(iv) secure and escape-proof

(v) protective of animals against climatic extremes

(vi) designed to minimise injury to animals

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

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

3.2.22 The number of animals in, and placement of, cages, pens or containers should enable the social and environmental conditions for the species to be maintained.

3.2.23 If an animal of a species that normally lives in social groups must be housed in isolation or separated from a group, the duration of such housing conditions must be minimised (see Clause 3.1.12). The animal should be able to see, hear and smell animals of the same species unless such contact is precluded by the requirements of the activity.

Food and water

3.2.24 Animals must receive, and be able to access, appropriate, uncontaminated, nutritionally adequate food of a quantity and composition that maintain normal growth of immature animals and normal weight of adult animals, and meet the requirements of pregnancy, lactation or other conditions.

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

3.3 Specific procedures

This chapter outlines how the wellbeing of animals may be supported and safeguarded during the conduct of specific procedures. This includes procedures used during the care and management of animals and procedures used during the conduct of approved projects.

General requirements that apply to all procedures

3.3.1 Procedures must:

(i) be appropriate for the species and the circumstances

(ii) accord with current best practice

(iii) be compatible with the purpose and aims of the project or activity

(iv) cause the least harm, including pain and distress, to the animals

(v) be performed competently, and by a person who is competent for the procedures, or under the direct supervision of a person who is competent to perform the procedures.

Handling and restraining animals

3.3.2 If handling or restraint is likely to cause harm, including pain and distress, to the animal, the use of chemical restraint (e.g. sedatives) should be considered.

3.3.3 When handling or restraint is required, the animal should be conditioned to the method used, whenever possible.

3.3.4 If prolonged restraint or confinement of an animal is required as part of a project:

(i) methods used must take into consideration the animal's physiological and behavioural needs, and ability to exercise

(ii) the animals must be assessed regularly by a person with veterinary, or other appropriate, qualifications who is independent of the project

(iii) if any adverse impact is detected, the animal must be released, or the method of restraint must be modified to minimise that impact.

Routine husbandry procedures

3.3.5 Routine husbandry procedures must be performed competently, and by a person who is competent for the procedures, or by a person under the direct supervision of a person who is competent to perform the procedures. Routine husbandry procedures are not part of a project and include, for example, clipping coats and nails, and vaccinations.

Identification of animals

3.3.6 Methods used to identify animals must:

(i) be appropriate for the species and the circumstances

(ii) be compatible with the purpose and aims of the project or activity

(iii) involve non-invasive methods whenever possible. The use of invasive methods must conform with Clause 3.3.1

(iv) cause the least harm, including pain and distress, to the animals.

Injections, blood sampling and non-surgical procedures

3.3.7 When performing injections, blood sampling and non-surgical procedures, procedures used must:

(i) minimise the risk of an animal developing complications (e.g. tissue damage, infection, haematoma, bleeding)

(ii) be performed under aseptic conditions if there is a potential risk of infection

(iii) if the procedure involves the transplantation of cells or tissues, include management of the effects of tissue rejection and immunosuppression.

Anaesthesia, analgesia and sedation, and management of pain and distress

3.3.8 The use of local and general anaesthetics, analgesics and sedatives must be considered as part of a plan to manage pain and distress, and such use should at least parallel their use in current veterinary or medical practice.

3.3.9 When anaesthetics, analgesics and sedatives are used, the choice of agent and its administration must:

(i) be appropriate for the species, age, developmental stage and physiological status of the animal

(ii) be compatible with the purpose and aims of the project or activity, and appropriate for the type of procedure.

3.3.10 Unless there is evidence to the contrary, it must be assumed that fetuses have comparable requirements for anaesthesia and analgesia as adult animals of the species. Approaches to avoid or minimise pain and distress in the fetus must be designed accordingly.

3.3.11 Regardless of their mechanism of action, the effectiveness of all anaesthetics must be monitored throughout anaesthesia.

3.3.12 When general anaesthesia is used, procedures must conform with current veterinary or medical practice and ensure that:

(i) induction is smooth, with minimum distress to the animal

(ii) the animal and the effectiveness of the anaesthetic are monitored to maintain an adequate plane of anaesthesia, minimise physiological disturbances, and monitor and manage potential complications (e.g. hypothermia, and cardiovascular and respiratory depression)

(iii) when an animal is to recover from an anaesthetic, the animal is monitored and cared for to avoid and manage complications during the post-anaesthetic period (e.g. airway obstruction, hypothermia, cardiovascular and respiratory compromise, injury from uncoordinated movements or other animals)

(iv) records are maintained of the use of anaesthetics and other drugs, monitoring of the animal, and the management of complications.

3.3.13 Animals that develop signs of pain and distress must be treated promptly, in accordance with the intervention points and humane endpoints approved by the animal ethics committee (AEC), and institutional and AEC policies and procedures (see Clauses 2.1.5 [v] [d] and 3.1.23–3.1.24).

3.3.14 Neuromuscular blocking agents must only be used in conjunction with adequate general anaesthesia or an appropriate surgical procedure that eliminates sensory awareness. The animal must be monitored to ensure that an adequate plane of anaesthesia is maintained or sensory awareness has been eliminated. Because the paralysis abolishes many criteria for assessing anaesthetic depth and pain perception (e.g. character of respiration, and corneal and flexor withdrawal reflexes), continuous or frequent monitoring of physiological variables (e.g. heart rate, blood pressure, pupil size, electroencephalogram), together with the effects on these of mild sensory stimuli, must be used.

3.3.15 Electroimmobilisation must not be used as an alternative to analgesia or anaesthesia.

Surgical procedures

3.3.16 The wellbeing of animals that have undergone surgical procedures must be supported and safeguarded by:

(i) conducting surgical procedures under appropriate local and/or general anaesthesia. The requirement for anaesthesia of the fetus or embryo must be taken into account before conducting surgery on a pregnant female

(ii) using aseptic procedures if the animal is expected to recover from surgery

(iii) ensuring that all procedures conform to accepted standards in veterinary or medical practice, as appropriate for the procedure and circumstances

(iv) ensuring that potential complications during and after the procedure are avoided or minimised, that animals are monitored for complications, and that any complications that do occur are effectively managed. Potential complications include hypothermia, dehydration, blood loss, tissue trauma, metabolic disturbances, poor tissue perfusion and cardiovascular and/or respiratory failure, infection, delayed wound healing and impaired function

(v) ensuring that pain management that is appropriate for the species and the procedure is effective, and includes effective anaesthesia as well as avoiding and minimising postoperative pain and distress

(vi) ensuring that, for non-recovery surgery, the animal remains unconscious throughout the procedure and death is confirmed at the end of the procedure

(vii) ensuring that animals that undergo more than one surgical procedure have recovered to good general health before any subsequent procedure is performed, unless otherwise approved by an AEC.

Postprocedure care

3.3.17 After any procedure:

(i) animals must be monitored and assessed with sufficient frequency to ensure that both predicted and unforeseen consequences are detected early (see Clauses 3.1.1 and 3.1.20–21). If an animal has undergone a surgical procedure, surgical wounds must be inspected regularly for evidence of infection and progress of healing

(ii) prompt action must be taken so that predicted and unforeseen consequences, including pain and distress, are addressed rapidly and effectively (see Clauses 3.1.23–3.1.24)

(iii) appropriate care and supportive treatment that will support and safeguard animal wellbeing must be provided, including nursing of the animal, pharmacological management of pain and distress, provision of fluid and nutritional support, and prevention or control of infection

(iv) appropriate records must be maintained and made accessible to all people involved in the postprocedural care of the animal (see Clauses 2.4.30–2.4.33, 2.5.11 and 3.1.22).

3.3.18 If an animal must be housed in isolation or separated from a group after a procedure, the duration of such housing conditions should be minimised. The animal should be able to see, hear and smell animals of the same species unless such contact will interfere with data collection and interpretation (see Clause 3.1.12).

3.3.19 If an animal is to be isolated or restrained for a prolonged period after a procedure, the animal should be conditioned to the housing or restraint conditions before the procedure is undertaken (see Clauses 3.1.11 and 3.3.3).

3.3.20 Animals that have undergone surgery for transplantation of organs or tissues must be managed to avoid or minimise adverse impacts from potential rejection of the transplant and the effects of immunosuppression.

Projects involving the fetus or embryo

3.3.21 Where a project involves the fetus or embryo, the requirements for anaesthesia and analgesia of the fetus or embryo must be taken into account (see Clauses 3.3.8–3.3.15).

3.3.22 If a procedure conducted on a fetus or embryo would compromise the ability of the animal to survive after birth or causes untreatable pain and distress, the animal (neonate/fetus/embryo) must be killed humanely before or immediately after birth.

Induction of tumours

3.3.23 For animals in studies that involve the induction of tumours, methods used and endpoints chosen must ensure that valid results are obtained with minimal harm, including pain and distress, to the animal. Animal wellbeing must be supported and safeguarded by:

(i) considering potential adverse impacts associated with the development and biology of the tumour (including growth rate, invasiveness, potential for ulceration, development of metastases and cachectic effects), effects of therapeutic agents, side effects of immunotherapy including irradiation, and consequences of surgery involved in transplantation of tumours

(ii) choosing an appropriate implantation site or method of induction of the tumour that causes the least harm, including pain and distress, to the animal. The footpad, tail, brain or eye must not be used unless there is no valid alternative

(iii) monitoring the growth or impact of the tumour and efficacy of therapy, and using early experimental endpoints, to obtain valid results as early as possible. Death from the tumour must not be an endpoint

(iv) establishing and implementing early intervention points and humane endpoints (see Clauses 3.1.26–3.1.28)

(v) wherever possible, using techniques that facilitate measurement of tumour growth and determination of early endpoints

(vi) monitoring and assessing animals for signs of pain and distress, including changes in body condition and body weight; ulceration; adverse effects of procedures used for induction of the tumour; signs of growth, invasion and metastases of the tumour; and toxic effects of therapeutic agents.

Creation and breeding of new animal lines where the impact on animal wellbeing is unknown or uncertain

This clause should be read in conjunction with Clauses 2.4.26–2.4.27 and the NHMRC *Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes*.

3.3.24 When creating and breeding new animal lines where the impact on animal wellbeing is unknown or uncertain, the wellbeing of the animals must be supported and safeguarded by:

(i) considering the nature and extent of potential impact on animal wellbeing due to:

(a) genetic modification and the difficulty in predicting the potential impact

(b) the procedures used to create a new animal line

(ii) using methods for the generation, monitoring and phenotypic description of a new animal line that accord with current best practice

(iii) using the least invasive method for genotyping, and identifying the animal appropriately to allow the genotype result to be matched to the animal

(iv) assessing the impact of genetic modification on the wellbeing and genetic stability of newly created genetically modified animals and their offspring across a number of generations.

Modification of behaviour and neurological function

3.3.25 Positive reinforcement should be used to motivate an animal to modify their behaviour or perform specific tasks.

3.3.26 Prolonged deprivation of water, food, social interaction or sensory stimuli must not be used to induce an animal to modify their behaviour.

3.3.27 If some form of biological stress is essential for the aims and purpose of the project, the duration and severity of the impact on the wellbeing of the animal must be as mild as possible.

3.3.28 Painful or noxious stimuli should be avoided. If their use is justified, the level and duration of the stimulus must be minimised, and provision must be made for the animal to be able to escape the stimulus.

3.3.29 Projects involving the withholding or restriction of food or water must be designed so that the animal experiences no continuing detrimental effect. Changes in fluid balance or body weight must be monitored, recorded and maintained within the limits approved by the AEC.

3.3.30 When a study involves neurological impairment that produces loss of function in the animal (e.g. impaired movement of the limbs or trunk; loss of sensibility to touch, sound, temperature or pain, or awareness of surroundings; or impairment of appetite or thirst), the special needs of the animal because of that loss of function must be met. Such animals should be provided with special care, caging and other facilities, as required.

Immunomodulation and production of antibodies

3.3.31 When agents or treatments are used to suppress the immune system (e.g. irradiation):

(i) procedures to minimise the risk of infection must be followed

(ii) animals must be appropriately monitored so that potential side effects are promptly identified and effectively managed.

3.3.32 When adjuvants are used to produce antibodies, the adverse impacts on animal wellbeing should be minimised by:

(i) using an adjuvant that provides an adequate antibody titre while causing the least adverse impact on the wellbeing of the animal

(ii) using a ratio of adjuvant to antigen that reduces the probability of adverse reactions

(iii) choosing the volume, site and frequency of injection of adjuvant that together optimise the antibody response and minimise the risk of complications

(iv) choosing a method and frequency of blood sampling that minimise the potential for harm, including pain and distress.

Wildlife and field techniques

See also clauses on acquisition (Clause 3.2.4), housing and care (Clauses 3.2.13–3.2.25), transport (Clauses 3.2.5–3.2.8) and identification (Clause 3.3.6).

General considerations

3.3.33 The wellbeing of wildlife must be supported and safeguarded by:

(i) using methods, techniques and equipment that:

(a) are appropriate for the species and the situation, and the purpose and aims of the project or activity

(b) minimise the risk of transmission of disease, and direct and indirect disturbance to the habitat

(ii) avoiding or minimising harm, including pain and distress:

(a) to target and non-target species

(b) to dependent young

(c) from indirect effects arising from impact on the habitat and environment.

Capture and handling

3.3.34 To minimise the risk of injury or stress-induced disease, procedures for the capture and handling of wildlife must include:

(i) the involvement of a sufficient number of competent people to restrain animals in a quiet environment and prevent injury to animals and handlers

(ii) chemical restraint (e.g. sedatives) where appropriate, if the period of handling is likely to cause harm, including pain and distress, to animals

(iii) restraint and handling of animals for the minimum time needed to achieve the purpose and aims of the project or activity

(iv) making provisions for captured animals that are ill or injured, including treatment of pain and distress.

Use of traps

3.3.35 If trapping is used to capture wildlife, the wellbeing of both target and non-target animals must be considered by:

(i) selecting a trap that is suited to the species and the circumstances, and designed to ensure protection of trapped animals from injury, predators, parasites and environmental extremes

(ii) monitoring traps to minimise the time animals will spend in traps, and to avoid or minimise adverse impacts on trapped animals

(iii) minimising the number of days of continuous trapping within an area, and removing or deactivating traps that are not in use or are no longer required

(iv) minimising the potential adverse impact caused by disrupting social structure, and adverse impacts on dependent young (e.g. by avoiding trapping in the breeding season)

(v) minimising the numbers of non-target species that are trapped, and implementing a management plan for captured non-target species to ensure their wellbeing or ensure that they are humanely killed.

3.3.36 Wet pitfall traps must not be used to capture vertebrate animals. If wet pitfall traps are used to capture invertebrates, they must be managed and monitored to minimise the inadvertent capture of vertebrates, including by locating the trap where vertebrate entry is unlikely and using the smallest possible trap diameter.

Transport, holding and release

3.3.37 Transport of wildlife must be in accordance with Clauses 3.2.5–3.2.8.

3.3.38 If animals are to be held in captivity, the duration must be minimised and consistent with the purpose and aims of the project or activity. If animals are to be released, all possible steps must be taken to avoid their becoming habituated to human activity.

3.3.39 Procedures for any release of wildlife must ensure that:

(i) release occurs at the site of capture, unless otherwise approved by the AEC (see also Clauses 3.4.4–5)

(ii) the timing of release coincides with the period of usual activity for the species, unless safety of the animals is assured by other means, such as release into appropriate cover

(iii) animals are protected from injury and predation at the time of their release

(iv) animals that have been sedated or anaesthetised have recovered to full consciousness before their release. During their recovery, animals should be held in an appropriate area where they can maintain normal body temperature and are protected from injury and predation (see Clause 3.3.12 [iii]).

Tracking the movement of wildlife

3.3.40 When devices are used to track the movement of wildlife, the weight, design and positioning of attached devices must minimise interference with the normal survival requirements of the animal.

Interference activities

3.3.41 Interference activities such as call playback, spotlighting, tiling, rock turning, investigating a nest box and disturbing nest sites must be conducted in a manner that minimises any risk to the wellbeing of the wildlife.

Voucher specimens

3.3.42 Alternatives to collecting animals as voucher specimens (e.g. tissue samples, digital photography) must be considered, where appropriate. When animals are collected as voucher specimens:

(i) the number taken must be the minimum required for identification or to establish distribution

(ii) the specimens must be appropriately documented and lodged with an institution that manages a publicly accessible reference collection.

Studies involving vertebrate pest animals

3.3.43 The principles of the Code must be applied equally to animals that are considered to be pests.

3.3.44 Captive feral and pest species must be killed humanely unless the aims of a project require their release, or the study involves death as an endpoint.

Humane killing

3.3.45 The method and procedures used for killing an animal must be humane and:

(i) avoid pain or distress and produce rapid loss of consciousness until death occurs

(ii) be compatible with the purpose and aims of the project or activity

(iii) be appropriate to the species, age, developmental stage and health of the animal

(iv) require minimum restraint of the animal

(v) be reliable, reproducible and irreversible

(vi) ensure that animals are killed in a quiet, clean environment away from other animals

(vii) ensure that death is established before disposal of the carcass, fetuses, embryos and fertilised eggs.

3.3.46 Dependent offspring of animals to be killed must be cared for or humanely killed.

3.4 Provisions for animals at the conclusion of their use

3.4.1 Provisions for animals at the conclusion of their use must be made promptly and in accordance with the animal ethics committee (AEC) approval. Provisions may include:

(i) rehousing (rehoming) (see Clauses 3.4.2–3.4.3)

(ii) return to normal husbandry conditions or natural habitat (see Clauses 3.4.4–3.4.5)

(iii) humane killing (see Clauses 3.3.45–3.3.46)

(iv) reuse (see Clauses 1.22, 1.24 and 2.3.15)

(v) tissue sharing (see Clauses 1.26, 2.4.24 and 2.5.10).

Rehousing (rehoming)

3.4.2 Opportunities to rehome animals should be considered wherever possible, especially when the impact of the project or activity on the wellbeing of the animal has been minimal and their physiological condition and behavioural attributes indicate that they can be introduced to a new environment with minimal, transient impact on their wellbeing.

3.4.3 An animal must not be released to a person at the conclusion of their use unless:

(i) the AEC has approved such release

(ii) safeguards are in place and approved by the AEC to ensure the ongoing wellbeing of the animal. In the case of primary and secondary level students, safeguards must include a written commitment from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal, and demonstrating an awareness of relevant legislative requirements regarding the animal being rehomed

(iii) transport of animals between sites is in accordance with Clauses 3.2.5–3.2.8.

Return to normal husbandry conditions or natural habitat

3.4.4 The return of animals to normal husbandry conditions and the release of wildlife to their natural habitat must be in accordance with current best practice.

3.4.5 If release of wildlife animals is permitted, such release must comply with Clause 3.3.39.

Section 4 ▶

The care and use of animals for the achievement of educational outcomes in science

Definitions that are particularly relevant to this section:

- activity
- animal
- animal ethics committee
- institution
- investigator
- project
- scientific purposes
- teacher
- teacher activity

This section covers the care and use of animals in teaching activities where the 'scientific purpose' is to impart or demonstrate knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirement.

All parts of the Code apply to teaching activities. This section provides additional guidance on the responsibilities outlined in other sections when animals are used for teaching activities. It must be applied in addition to other parts of the Code, particularly Section 2 'Responsibilities' and Section 3 'Animal wellbeing'.

It is expected that animals used in teaching activities will receive a high standard of care, that their wellbeing will be supported and safeguarded in accordance with the governing principles outlined in Section 1, and that their use will occur only in accordance with approval from an animal ethics committee (AEC).

If you are involved in the care and use of animals in teaching activities in a school, you need to:

- be aware of the governing principles that apply to the care and use of animals (see Section 1), and
- know your responsibilities, and
- be aware of your duty of care to the animals, and
- follow the policies and procedures established by your school and your state or territory education department about how to implement the Code.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes (see Clause 1.1).

(ii) The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal on completion of their use (see Clause 1.4).

(iii) People involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(iv) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with the AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

Institutions

4.1 The responsibilities of institutions involved in the care and use of animals for teaching activities are as outlined in Chapter 2.1.

4.2 The responsibilities of institutions regarding the governance of an AEC overseeing the care and use of animals in teaching activities are as outlined in Chapter 2.2.

4.3 Institutions must ensure that animals are used for teaching only when their use is essential to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements, and suitable alternatives to replace the use of animals to achieve the educational outcome are not available (see Clause 1.5).

4.4 Institutions must identify the person with ultimate responsibility for the care and use of animals in teaching activities. This person must:

(i) ensure that all people involved in the care of animals understand and accept their role and responsibilities

(ii) ensure that procedures and resources are in place so that all people involved in the care and use of animals can meet their responsibilities

(iii) be competent with respect to the wellbeing of animals under their care.

This person does not relieve the individual responsibility of the teacher who is involved in the care and use of animals in teaching activities.

Primary and secondary sectors (including secondary agricultural colleges)

4.5 Institutions involved in the care and use of animals in teaching activities in the primary and secondary sectors must ensure that they have access to an AEC. This may be a regional or central state AEC.

4.6 Institutions must ensure that the following activities using animals are not demonstrated to, or carried out by, primary or secondary level students:

(i) animal breeding that does not achieve an educational outcome in science and fails to provide for the lifetime welfare of animals (and their offspring, if relevant)

(ii) surgical, invasive and other harmful procedures, other than routine husbandry procedures

(iii) induction of an infectious disease or illness

(iv) production of nutritional deficiency

(v) exposure to conditions that would cause an animal to experience pain and distress

(vi) administration of drugs or chemicals unless for therapeutic or diagnostic purposes

(vii) administration of toxins, ionising radiation or biohazards.

4.7 Institutions must ensure that humane killing of animals is not demonstrated to, or carried out by, primary or secondary level students unless it is required:

(i) to achieve an educational outcome in science as specified in the relevant curriculum or competency requirement, or

(ii) as part of veterinary clinical management of an animal, under the direction of a veterinarian.

Animal ethics committees

4.8 The responsibilities of an AEC overseeing the care and use of animals in teaching activities are as outlined in Chapter 2.3.

Teachers as investigators and animal carers

4.9 When teachers use animals for teaching activities, the teacher has the responsibilities of an investigator under Chapter 2.4.

4.10 When teachers are responsible for the care of animals that are used for teaching activities, including during their acquisition, transport, breeding, housing and husbandry, the teacher has the responsibilities of an animal carer under Chapter 2.5.

4.11 Teachers have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use (consistent with Clause 2.4.1).

4.12 Teachers must ensure that students have the opportunity to discuss the ethical and social issues, and legal responsibilities, involved in the care and use of animals for scientific purposes, at a level appropriate to their learning ability and comprehension, and before the use of animals commences.

4.13 Teachers must ensure that the students are supervised by a person who is competent for the procedure being performed, and that the level of supervision of students takes into account the competency and responsibilities of each student.

4.14 Teachers must ensure that animals are not released to students, or any other person, for temporary care, or at the completion of the use of the animal (see Clauses 3.4.2–3.4.3), unless:

(i) the AEC has approved such release

(ii) safeguards are in place and approved by the AEC to ensure the ongoing wellbeing of the animal. In the case of primary and secondary level students, safeguards must include a written commitment from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal, and demonstrating awareness of relevant legislative requirements regarding the animal being rehomed or under their care

(iii) transport of animals between sites is in accordance with Clauses 3.2.5–3.2.8.

Obtaining approval from an animal ethics committee

4.15 Teachers, and the person with ultimate responsibility for a teaching activity, must follow institutional and AEC procedures when submitting an application to an AEC (see Chapter 2.7) and provide information in the application form as outlined in Clause 2.7.4. The AEC may be a regional or central state AEC (see Clause 4.5).

4.16 AEC approval may be sought to repeat a particular teaching activity that may involve different students, times, locations or animals.

4.17 AEC approval is not required for the training and application of agricultural extension work practices, or the training of students in veterinary science, veterinary nursing or animal technology to achieve competency-based outcomes in routine procedures if all of the following apply:

(i) the animals are at their home property or a premises licensed by a state or territory Veterinary Surgeons Board

(ii) the procedures would normally occur as part of routine management or veterinary clinical management of the animal

(iii) the animals are not subjected to anything additional to routine management or veterinary clinical management of the animal

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

Section 5 ▶

Complaints and non-compliance

Definitions that are particularly relevant to this section:

- animal
- animal ethics committee
- institution
- investigator
- scientific purposes

Institutions may receive complaints about the care and use of animals for scientific purposes. Complaints may be raised by any person or group, including investigators, animal carers, animal ethics committees (AECs), AEC members, students, employees of the institution and members of the public. Complaints may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers, the AEC and governance officials. Institutions may also become aware of activities relating to the care and use of animals for scientific purposes that are not being conducted in accordance with the Code.

This section outlines the responsibilities of institutions and AECs for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities (see Section 2), and act in accordance with the Code (see Clause 1.31).

(ii) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

5.1 Institutions must have procedures for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes, including:

(i) complaints concerning the care and use of animals by the institution, including conscientious objection in the case of teaching activities

(ii) complaints concerning the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution

(iii) complaints concerning the process for independent external review

(iv) non-compliance with the Code by any party or person involved in the care and use of animals including investigators, animal carers, the AEC, governance officials, and external parties subject to agreements described in Clauses 2.6.3 and 2.6.6. Non-compliance may also involve breaches of relevant state or territory legislation, and institutions should have procedures for advising regulatory authorities (see Clause 5.12).

5.2 Institutional procedures must:

(i) give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately

(ii) clearly define the mechanisms for receiving, investigating and addressing complaints

(iii) clearly define the mechanisms for addressing non-compliance with the Code

(iv) clearly define the responsibilities of all parties

(v) ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers

(vi) identify and ensure appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies

(vii) be made available to all relevant people.

5.3 For projects involving more than one institution and/or AEC (see Clauses 2.6.4–2.6.7), procedures should include mechanisms for reporting between the relevant institutions and AECs on complaints and non-compliance.

Receiving, investigating and addressing complaints

Complaints concerning the care and use of animals

5.4 Institutions must ensure that:

(i) where complaints relate to activities that have the potential to adversely affect animal wellbeing, the activities cease immediately

(ii) where complaints relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval

(iii) where complaints raise the possibility of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with procedures specified in that document

(iv) where complaints allege misconduct that falls outside the range of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with institutional processes for dealing with other forms of misconduct.

5.5 Following the AEC's investigation of complaints referred to it by the institution, the AEC:

(i) must ensure that, where activities are conducted in accordance with an AEC approval, the activities are reviewed in consultation with all relevant people to ensure that the reason for the complaint is addressed. The AEC may decide that modification to a project or activity is required, or an approval for a project or activity is suspended or withdrawn

(ii) should ensure that, where activities are not conducted in accordance with AEC approval, the matter is referred back to the institution for action.

Complaints concerning the animal ethics committee process

5.6 Where complaints concerning the AEC process of review of an application or report cannot be resolved by communication between the complainant and the AEC that is the subject of the complaint, the institution should ensure that the complainant has access to a person or agency external to the AEC for review of the process followed by the AEC. This person or agency may be within the institution. Following this review, the AEC may need to review its process in reaching its decision regarding the application or report, and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden.

Complaints concerning the process for independent external review

5.7 Institutions must ensure that the process for conducting an independent external review, developed in consultation with the review panel, includes an appeals process that relates to the process for the review (see Clause 6.5).

Referral to a person or agency external to the institution

5.8 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the processes referred to in Clauses 5.1–5.7.

Addressing non-compliance

5.9 Institutions must have procedures for addressing non-compliance with the Code, so that behaviours that create and support compliance are encouraged, and behaviours that compromise compliance are not tolerated.

5.10 The institution must maintain records of breaches of the Code.

Advising regulatory authorities

5.11 Any person can report alleged breaches of legislation to relevant state or territory government authorities.

5.12 The institution should advise relevant state or territory government authorities of alleged breaches of legislation that had a significant impact on animal wellbeing.

Section 6 ▶

Independent external review of the operation of institutions

Definitions that are particularly relevant to this section:

- animal
- animal ethics committee
- institution
- investigator
- scientific purposes

Independent external review assists institutions to assess whether the procedures they have established meet the goals set out in the Code, and provides assurance that the institution, through its animal ethics committee (AEC), is delivering effective oversight of the care and use of the animals in its charge. The 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.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities (see Section 2), and act in accordance with the Code (see Clause 1.31).

(ii) All activities, including projects, that involve the care and use of animals for scientific purposes must:

(a) be subject to ethical review, approval and monitoring by an AEC

(b) commence only after approval has been granted by an AEC

(c) be conducted in accordance with AEC approval

(d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

Institutions

6.1 Institutions must ensure that an independent external review is conducted at least every four years to assess the institution's compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code (see Clause 1.9 [i]).

6.2 Institutions must:

(i) make arrangements for the review to be conducted by external people who are independent of the institution and the activities conducted on behalf of the institution, and who have appropriate qualifications and/or experience relevant to the activities of the institution

(ii) establish procedures so that members of the review panel declare their interests, and any conflicts of interest are managed

(iii) ensure that members of the review panel are advised of requirements for confidentiality

(iv) provide the review panel with the necessary authority and resources to conduct the independent review of the activities of the institution. This will include access to people, information, records and premises, and provision of reasonable assistance

(v) ensure that the findings and recommendations of the review are made widely known within the institution

(vi) ensure that timely actions are taken to address the recommendations of the review

(vii) consider publishing a summary of the external review report (e.g. as part of an institutional annual report or website) and making the summary report available to the relevant regulatory authority and funding bodies of the institution (see Clause 2.1.10).

6.3 Reviews carried out under the administration of state or territory legislation may satisfy the requirement for an independent external review.

Review panel

6.4 Members of the review panel must:

(i) declare their interests before their appointment to the review panel

(ii) adhere to confidentiality requirements regarding the review.

6.5 The review panel must:

(i) develop a process for the manner in which the review is to be conducted, in consultation with the institution. This process should accord with the principles of natural justice and include an avenue for the process and the outcomes to be appealed

(ii) document the findings and recommendations from the review and provide a report to the governing body of the institution.

Scope and outcomes of the independent external review

6.6 Areas covered by the independent external review should include:

(i) the conduct of all people involved in the care and use of animals for scientific purposes on behalf of the institution, including the AEC, institutional officers and administrators, investigators and animal carers

(ii) the adequacy of the institutional program to ensure that the care and use of animals for scientific purposes is conducted in compliance with the Code; is subject to ethical review, approval and monitoring by an AEC; and is conducted in accordance with the AEC approval

(iii) the adequacy of institutional support, resources and educational programs for the AEC and its members, and for people involved in any aspect of the care and use of animals for scientific purposes, to ensure that they can meet their responsibilities under the Code

(iv) whether the AEC is operating effectively in accordance with the Code

(v) the effectiveness of institutional strategies to promote and monitor the implementation of the governing principles

(vi) whether there is effective monitoring of the wellbeing of animals

(vii) whether facilities used to house animals are managed to support and safeguard animal wellbeing

(viii) if applicable, an assessment of the report from the previous external review and actions taken in response to recommendations in that report.

6.7 The review panel should provide recommendations that:

(i) identify areas of non-compliance

(ii) support strategies for short-term and long-term continual improvement

(iii) give recognition to behaviours and actions by individuals and teams that support compliance.

Section 7 ▶

Cosmetic Testing

Definitions that are particularly relevant to this section:

- activity
- animal
- animal ethics committee
- institution
- investigator
- project
- replacement alternatives
- scientific purposes

The use of animals for cosmetic testing is banned in Australia. This section provides additional guidance about the responsibilities of institutions, animal ethics committees (AECs) and investigators with respect to this ban. This section must be read in conjunction with other sections of the Code.

All those considering the use of animals for cosmetic testing must be aware of the requirements under the *Industrial Chemicals Act 2019* and the *Industrial Chemicals (General) Rules 2019* (as amended from time to time) as they apply to their specific circumstances.

Additional definitions relevant to this section

In addition to those outlined in the 'Definitions' section of the Code, the following definitions apply to this section.

Act: the *Industrial Chemicals Act 2019*, as amended from time to time.

Animal test data: data or information obtained from tests involving the use of animals. (For full definition, see the Act and General Rules.)

Chemical ingredient: an industrial chemical used as an ingredient or component of a cosmetic (see also 'industrial chemical').

Cosmetic: substance or preparation:

- intended for placement in contact with any external part of the human body with a view to altering the odours of the body, changing its appearance, cleansing it, protecting it, perfuming it or maintaining it in good condition
- not intended for therapeutic use.

(For full definition, see the Act and General Rules.)

Finished cosmetic product: cosmetic in its final formulation. (For further information and examples, see the *Australian Industrial Chemical Introduction Scheme* and the *Therapeutic Goods Administration* websites.)

General Rules: the *Industrial Chemicals (General) Rules 2019*, as amended from time to time.

Industrial chemical: a chemical that is used for purposes other than for agricultural, veterinary or therapeutic purposes, or in food or animal feed. An ingredient or component of a cosmetic can be an industrial chemical. (For full definition, see the Act and General Rules.)

Background

The use of animals for cosmetic testing is banned in Australia. The ban recognises the existence of viable alternatives to the use of animals for cosmetic testing. It also recognises the need to maintain protection of human health and the environment. Implementation of the ban includes:

- reforms to the Commonwealth industrial chemicals legislation to ban the use of new animal test data from 1 July 2020 to support the import or manufacture in Australia of industrial chemicals used solely in cosmetic products
- incorporation of a testing ban (for chemical ingredients in cosmetics and finished cosmetic products) in state and territory legislation, triggered by changes to the Code.

Industrial Chemicals Act 2019

The import or manufacture in Australia of industrial chemicals is regulated by the *Industrial Chemicals Act 2019* (the Act). Chemicals that are used for agricultural, veterinary or therapeutic purposes, or in food or animal feed are not industrial chemicals and are regulated by other legislation (e.g. *Therapeutic Goods Act 1989*).

The Act establishes the Australian Industrial Chemicals Introduction Scheme (AICIS) and bans the use of animal test data obtained from tests involving the use of animals conducted on or after 1 July 2020 (new animal test data) to support the import or manufacture in Australia of industrial chemicals for use solely in cosmetic products.

The Act incorporates the *Industrial Chemicals (General) Rules 2019* (the General Rules) that set out details about how this ban will operate. The General Rules restrict the use of new animal test data for the import or manufacture in Australia of industrial chemicals that have multiple end uses, including an end use in cosmetics, unless certain exceptions apply to protect human health or the environment.

The approach outlined in the Act and the General Rules allows for the use of animal test data in limited circumstances for industrial chemicals that have multiple end uses including an end use in cosmetics. One of these circumstances is where there is:

- a potential for humans or the environment to be exposed to the chemical
- no available alternative means of determining the risk of this exposure.

This approach is consistent with the regulation in the European Union. It is necessary to continue to protect human health and the environment during non-cosmetic uses.

The Code

The Code applies to the use of animals for testing of any chemical or product.

The Act and the General Rules apply to the use of new animal test data only and do not ban the use of animals for testing of chemical ingredients to be used in cosmetics or testing of finished cosmetic products.

The ban on the use of animals for testing of chemical ingredients to be used in cosmetics, or testing of finished cosmetic products, is covered by the Code.

Governing principles

Each person involved in the care and use of animals for scientific purposes must consider the governing principles in Section 1 when applying the Code to their specific circumstance; in particular:

(i) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes (see Clause 1.1).

(ii) Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented (see Clause 1.18).

(iii) Before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined. Replacement techniques that must be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases (see Clause 1.19).

(iv) Institutions, AECs, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code (see Clause 1.31).

(v) All activities, including projects, that involve the care and use of animals for scientific purposes must:

  (a) be subject to ethical review, approval and monitoring by an AEC

  (b) commence only after approval has been granted by an AEC

  (c) be conducted in accordance with AEC approval

  (d) cease if approval from the AEC is suspended or withdrawn (see Clause 1.32).

Responsibilities

Institutions

7.1 Institutions must ensure, through the operation of an AEC, that all activities involving the care and use of animals comply with the Code (Clause 2.1.3).

7.2 Institutions must have policies and procedures in place to ensure that animals are not used for the testing of:

(i) finished cosmetic products

(ii) a chemical ingredient unless the proposed use of animals is justified by a purpose other than use in a cosmetic.

Animal ethics committees

7.3 The AEC must not approve a project or activity involving the use of animals for testing of finished cosmetic products.

7.4 The AEC may approve a project or activity involving the use of animals for testing of a chemical ingredient only if the proposed use of animals is ethically acceptable and conforms to the requirements in the Code (Clauses 2.3.4 and 2.3.5), and the proposed use of animals is justified by a purpose other than use in a cosmetic.

Investigators

7.5 Investigators must not use animals for testing of finished cosmetic products.

7.6 Investigators must only consider using animals for testing of a chemical ingredient if such use is justified by a purpose other than use in a cosmetic (Clause 2.4.6).

7.7 Investigators must ensure that the evidence provided in the application to the AEC (Clause 2.7.4) includes the information outlined in Clause 7.6, as appropriate for the circumstances.

Projects involving more than one institution and/or animal ethics committee

7.8 When a project or activity involving the use of animals for testing of a chemical ingredient or finished cosmetic product involves more than one institution and/or AEC, institutions, AECs and investigators must meet the relevant requirements outlined in Clauses 2.6.4–2.6.8.

Projects conducted by Australian investigators and institutions in other countries

7.9 When a project or activity involving the use of animals for testing of a chemical ingredient or finished cosmetic product is conducted by Australian investigators and/or institutions in another country, institutions, AECs and investigators must meet the relevant requirements outlined in Clauses 2.6.9–2.6.14.

Appendix: Process Report

Background

The *Australian code of practice for the care and use of animals for scientific purposes* (the Code) was first produced by National Health and Medical Research Council (NHMRC) in 1969 with revisions undertaken in 1979, 1983, 1985, 1990, 1997, 2004 and 2013. Revisions take into account changing community views and scientific developments.

In developing and issuing the 8th edition of this Code, the NHMRC and its principal committees are required under the *National Health and Medical Research Council Act 1992* (Section 13) to undertake public consultation on the draft Code.

The review of the 7th edition of the Code was overseen by NHMRC's Animal Welfare Committee and Code Reference Group, expert working committees established under section 39 of the *National Health and Medical Research Council Act 1992*. During the review process, NHMRC sought to ensure the full involvement of stakeholders and the community including institutions, researchers, teachers, members of animal ethics committees, veterinarians, animal welfare organisations, state and territory regulators, relevant commonwealth departments, the Australian Research Council, Universities Australia and the Commonwealth Scientific Industrial Research Organisation.

Key steps in the process

- Targeted consultation (20 July – 22 September 2009) to identify key issues, with 70 submissions received
- Establishment of the Code Editorial Advisory Group, consisting of eight Code Writing Groups, to consider the submissions received during targeted consultation and provide advice to the Code Reference Group on the eight major sections of the 7th edition in preparation for public consultation
- Preparation of the draft document for public consultation on the advice of the Code Editorial Advisory Group, Code Reference Group, Animal Welfare Committee, Research Committee and NHMRC Council
- Public consultation (4 October to 2 December 2011) with 246 submissions received
- Consideration of the submissions received during public consultation and development of the 8th edition
- Consideration of the revised Code by the Animal Welfare Committee
- Consideration of the revised Code by the Research Committee
- Consideration of the revised Code by NHMRC Council

At its 196th session on 21 June 2013, NHMRC Council advised NHMRC's CEO that the final document should be issued. The CEO issued the 8th edition of the Code under Section 7(1a) of the *National Health and Medical Research Council Act 1992* on 26 June 2013.

2021 update (Section 7: Cosmetic testing)

- Establishment of the Code Advisory Group consisting of representatives from the state and territory governments, animal advocacy groups and the co-endorsers of the Code
- Development of the draft amendments to the Code for public consultation as a new section in the Code (Section 7) on the advice of the Code Advisory Group, Animal Welfare Committee, and NHMRC principal committees (Research Committee and Council)
- Public consultation (8 October to 20 November 2020) with 23 submissions received
- Consideration of submissions received during the public consultation and development of the revised Section 7
- Consideration of the revised Section 7 by the Animal Welfare Committee, Research Committee and NHMRC Council.

At its 222nd session on 11 March 2021, NHMRC Council advised NHMRC's CEO to issue the final Section 7. The CEO issued the 8th edition of the Code (updated 2021), which incorporates Section 7, under Section 7(1a) of the *National Health and Medical Research Council Act 1992* on 1 June 2021.

Working Committees

Information on the NHMRC working committees involved with the development of the Code can be found on the NHMRC website:

- 2010–13: Development of the 8th edition of the Code
- 2019–21: Development of the 2021 update to the 8th edition of the Code, which incorporated *Section 7: Cosmetic testing*.
- Disclosures of interest were managed in accordance with the requirements of the *National Health and Medical Research Council Act 1992*.

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