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

Draft

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Definitions

Activity: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transport, production, housing, care, use and fate of animals. Activities are described in an application to the Animal Ethics Committee (AEC), and conducted as part of an approved project.

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

Alternative to replace the use of animals: see ‘Replacement alternatives’.

Alternative: encompasses replacement alternatives, reduction alternatives, and refinement alternatives as a whole (see ‘Replacement’, ‘Reduction’, ‘Refinement’).

Animal carer: any person involved with the care of animals that are bred, supplied or held for scientific purposes.

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

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

Animal wellbeing: see ‘Wellbeing’.

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

Animals at early stages in their development, that is in their embryonic, fetal and larval forms, can experience pain and distress but this occurs at different stages of development in different species and thus decisions as to their welfare should, where possible, be based on evidence of their neurobiological development. As a guide, when embryos, fetuses and larval forms have progressed beyond half the gestation or incubation period of the relevant species, or they become capable of independent feeding, the potential for the experience of pain or distress should be taken into account.

Application: an application to carry out an activity for consideration by an AEC. An application may be for commencement of an activity, or an amendment to an approved activity.

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

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 person who donated the somatic cell.

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

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 AEC are addressed, and as a result, all members accept the final decision, even though it may not be an individual's preferred option.

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

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

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

**Facility manager:** person responsible for the overall management of animal acquisition, breeding and holding facilities.

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

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

**Governing body:** the body responsible for the administration and governance of the institution (for example, University Council or Senate, Board of an organisation) and where appropriate its delegated officer.

**Harm:** any event or circumstance that has 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 with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural organisations, commercial companies, wildlife groups, farms.

**Investigator:** any person who uses animals for 'scientific purposes' as defined. Includes researchers; teachers, undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys (see also 'Teacher').

**Livestock:** animals used in agriculture and aquaculture.

**Minor amendment:** any change to an approved project that does not involve an impact on the wellbeing of animals.

**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, AECs).

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

Project: an ‘activity’ or ‘activities’ that form a discrete piece of work outlined in an application to an Animal Ethics Committee (AEC). An approved application is an approved project (see also ‘Activity’).

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 to be achieved without the conduct of experiments or other scientific procedures on animals. Examples may include, but are not be limited to, inanimate synthetic models, simulators, computer simulations and other audio-visual material, live demonstrations, field trips, road kill, cadaver dissections, cadaver clinical procedures, animal ‘volunteers’ as in body donation programs, and clinical patients as in strategic partnerships and alliances.

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

Scientific activity: an activity required to achieve the scientific purposes (see also ‘Teaching activity’).

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, 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 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: confines the meaning of ‘investigator’ to a person in charge of a teaching activity involving the use of animals in primary, secondary and tertiary institutions, including vocational, veterinary, postgraduate and researcher training.

Teaching activity: an undertaking intended to impart or demonstrate knowledge or techniques in any area of science.

Unexpected adverse event: an event that may have a negative impact on the wellbeing of animals that was not foreshadowed in the approved application, or approved procedures for an animal facility.

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 (for example, during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were not expected. Examples of clinical signs that may develop include, but are not restricted to, abnormal posture, decreased mobility, diarrhoea, vomiting, respiratory difficulty, collapse, abdominal swelling, rapid weight loss
- adverse effects in a larger number of animals than predicted during the planning of the project, based on the number of animals actually used, not the number approved for the study
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- a greater level of pain or distress than was predicted during the planning of the project
- power failures, inclement weather, emergency situations or other factors external to the project 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’s present state with regard to its relationship with all aspects of its environment, both internal and external. It implies a positive mental state, successful biological function, positive experiences and freedom from adverse conditions.

**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 \textit{vivo} contact with live cells, tissues or organs from another species.

**Zoonosis:** any disease communicable to man from another animal species.
Section 1: Principles for the care and use of animals for scientific purposes

This Code applies to all aspects of the care and use of animals for scientific purposes where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.
- **Animal**: means any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife), and octopus and squid.
- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

The foundations of this Code are that the use of animals for scientific purposes must have scientific and/or educational merit, must be beneficial to humans, animals or the environment and must be conducted with integrity. The Code recognises the inherent imperative to respect animals, which carries an obligation to promote their wellbeing and to minimise harm to animals, including pain and/or distress. The use of animals for scientific purposes must be adequately justified and subject to ethical review. The Code provides a framework that facilitates the application of ethical principles to guide decisions as to if and how animals are used for scientific purposes, details the responsibilities of those involved and describes processes for accountability.

**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) promoting 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) persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities.

1.2 The consequences of all decisions and actions should validate respect for animals that are used for scientific purposes.

1.3 Animals may be used only when it is established that the proposed activity has demonstrable scientific or educational merit and that the use of animals is essential to achieve the proposed aims.

1.4 A judgement as to whether a proposed use of animals is ethically acceptable is informed by evidence that such use is justified and takes into consideration predicted benefits and potential effects on the wellbeing of the animals involved.
1.5 The obligation to respect animals and the associated responsibilities apply throughout the animal’s lifetime and include breeding, care and husbandry, the animal’s role in a scientific or educational activity and the animal’s future on completion of the activity.

Using animals only when justified

1.6 Evidence to support the case to use animals must demonstrate that:

(i) the activity has scientific or educational merit and the predicted outcomes will be beneficial
(ii) the use of animals is essential to achieve all the stated aims, and suitable alternatives to replace the use of animals to achieve all the stated aims are not available (Replacement)
(iii) the activity involves the minimum number of animals required to obtain valid data (Reduction)
(iv) the activity involves the minimal negative impact on the wellbeing of animals involved (Refinement).

1.7 Scientific or educational activities must only be undertaken:

(i) to obtain and establish significant information relevant to the understanding of humans and/or animals
(ii) for the maintenance and improvement of human and/or animal health and welfare
(iii) for the improvement of animal management or production
(iv) to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or
(v) for the achievement of educational objectives.

1.8 An institutional Animal Ethics Committee (AEC) must be satisfied that there is sufficient evidence to support a case that the use of animals for a scientific purpose is justified.

Promoting the wellbeing of animals and avoiding or minimising harm

1.9 Although animals may perceive and respond to circumstances via different neurological and sensory mechanisms, they have a capacity to experience pain and distress. 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.

1.10 The wellbeing of animals used for scientific purposes must be considered in terms of the animal’s lifetime experience. At all stages of the care and use of an animal, the methods used and the conditions to which an animal is exposed should promote the animal’s wellbeing. Known or potential causes of pain, distress, or lasting harm to the animals must be prevented, alleviated or minimised, including through the application of the principles of Replacement, Reduction and Refinement (the 3Rs):

(i) the Replacement of animals with other methods
(ii) the Reduction in the number of animals used
(iii) the Refinement of techniques used to minimise the adverse impact on animals.
Applying high standards of scientific integrity

1.11 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 potential benefits will be achieved in practice. Work that is of doubtful scientific validity should not be performed, no matter how mild the impact on the wellbeing of the animals.

1.12 Investigators must use scientific and educational methods that accord with current best practice.

Accepting responsibilities

1.13 Institutions, Animal Ethics Committees, investigators and animal carers must be aware of and accept clearly defined responsibilities (see Section 2) and act in accordance with the Code.

1.14 Persons involved with any aspect of the care and use of animals for scientific purposes must consider the application of Replacement, Reduction and Refinement (the 3Rs in all aspects of that care and use, over the whole of an animal’s life:

(i) the Replacement of animals with other methods
(ii) the Reduction in the number of animals used
(iii) the Refinement of techniques used to reduce the adverse impact on animals.

Institutions

1.15 Institutions must implement policies and procedures to:

(i) promote compliance with the Code, reflecting in particular the principles in Clause 1.1 and the application of the 3Rs
(ii) ensure and support the effective operation of the Animal Ethics Committee
(iii) identify clear lines of responsibility, communication and accountability and ensure that the person responsible for the wellbeing of animals at any given time is clearly identifiable
(iv) ensure all persons 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.

Animal Ethics Committees (AECs)

1.16 On behalf of the institution, through ethical review, approval and monitoring, AECs must ensure that all care and use of animals is conducted in compliance with the Code.

1.17 An AEC must approve and monitor housing conditions, practices and procedures involved in the care of animals in the facilities of institutions.

Investigators

1.18 Investigators are responsible for all matters that relate to the wellbeing of animals that they use in an activity. Investigators must:

(i) treat those animals with respect, demonstrated by following the principles outlined in Clause 1.1
(ii) obtain AEC approval before commencing the activity. The application to undertake an activity must demonstrate the scientific or educational merit of the activity, the expected benefits, and the balance of evidence that supports the use of animals. It must provide details of the ways in which all ethical and welfare aspects of the proposed activity will be managed, including consideration and application of the principles of the 3Rs.

(iii) conduct the activity in accordance with AEC approval and report to the AEC as required.

Animal carers
1.19 Persons responsible for the day-to-day care of animals that are bred, supplied or held for scientific purposes must:

(i) treat those animals with respect, demonstrated by following the principles outlined in Clause 1.1

(ii) ensure that, within the scope of their responsibilities, the wellbeing of the animals is an essential consideration.

Replacement
Application of “Replacement” includes the following:

1.20 Methods that replace or partially replace the use of animals must be considered and, where possible, implemented.

1.21 Before the use of animals is considered, all existing information relevant to the scientific or educational aim(s) including extant databases must be examined and methods that replace or partially replace such use of animals must be investigated, considered, and, where possible, applied. Replacement techniques that should be considered include the use of epidemiological data, physical and chemical analysis, computer and mathematical models, in vitro systems or non-sentient organisms.

1.22 Persons involved with the care and use of animals should ensure they are aware of emerging alternatives to replace animals in their field of expertise.

1.23 Opportunities to replace the use of animals should be kept under review during the lifetime of a project and, where relevant, the outcome of these deliberations be taken into account in planning future activities.

Reduction
Application of “Reduction” includes the following:

1.24 Each project must use no more than the minimum number of animals necessary to achieve the scientific or educational aims and to satisfy good statistical design. The use of too few animals may invalidate the experimental result and result in wastage of animals.

1.25 The number of animals should not be reduced to the detriment of an individual animal.

1.26 Activities involving the use of animals must not be repeated within a project or between projects unless such repetition is appropriate and essential for the purpose or design of the project.
1.27 All possible steps must be taken to reduce factors that may contribute to variability of experimental results, including as appropriate the use of animals of known genetic, biological and behavioural background. This may result in reduced animal use.

1.28 Where practicable, tissue from animals being killed should be shared among investigators or deposited in a tissue bank for subsequent distribution.

1.29 Breeding of animals must be managed to minimise the production of excess animals.

Refinement

Application of “Refinement” includes the following:

1.30 Persons involved with any aspect of the care and use of animals for scientific purposes must take steps at all times to promote the wellbeing of the animals involved and to prevent, alleviate or minimise known or potential causes of pain, distress, or lasting harm to the animals.

1.31 In making decisions about the impact of circumstances on the wellbeing of animals, it must be recognised that animals have the capacity to experience pain and distress. Evidence must be gathered that has been used to predict whether animals may experience pain and/or distress and to inform procedures to monitor and manage such circumstances.

1.32 Practices and procedures used must be based on recognised standards of good practice, that take into consideration relevant aspects of species-specific biology, physiology and behaviour, are based on evidence of the potential negative impact of conditions and procedures on the wellbeing of the animals and include strategies to minimise such impacts. Special consideration is required where these conditions are precluded by the requirements of a project and must be approved by the AEC.

1.33 Persons who conduct procedures involving animals must be competent to perform the procedure, or be under the direct supervision of a person competent to perform the procedure.

1.34 Investigators and animal carers must:

(i) ensure that the person responsible for the wellbeing of the animals at all stages of the activity is clearly identified

(ii) ensure arrangements are in place so that nominated personnel can be contacted at all times in the event of emergencies

(iii) be knowledgeable about the normal behaviour and the signs of pain and distress in the species they will use or under their care. They should have access to diagnostic and therapeutic expertise in the event that known signs or unfamiliar signs appear in animals.

(iv) regularly observe and assess animals to detect deviations from normal behaviour and signs of pain and/or distress

(v) take prompt action to treat animals with signs of pain and/or distress not anticipated in applications to the AEC. Alleviation of such pain or distress must take precedence over an individual animal’s reaching the planned end-point of the activity, or the continuation or completion of the project. If necessary, animals must be humanely killed without delay.

(vi) ensure that appropriate actions are taken in cases of emergency that require welfare interventions, such as treatment or humane killing of an animal
(vii) provide prompt notification to the AEC of any unexpected adverse events (see definition) that may have a negative impact on the wellbeing of an animal in their care.

1.35 In addition to above clauses (1.30-1.34):

(i) projects must be designed to ensure animal wellbeing, and avoid, alleviate or minimise pain and/or distress in animals.

(ii) animals used must be suited to the scientific or educational purpose taking into account their biological characteristics including morphology, physiology, behaviour and genetic makeup, temperament and behavioural conditioning, microbiological and nutritional status and general state of health.

(iii) animals must not be taken from natural habitats unless animals bred in captivity are not available or are not suitable for the specific scientific purpose.

(iv) scientific and educational methods used must accord with current best practice.

(v) where it is established that the purpose of the project involves the animals experiencing pain and/or distress that will not be alleviated, the planned end-point of the project must be as early as feasible to avoid or minimise pain and/or distress in the animals.

(vi) using ‘Death as an end-point’ (see definition) must be avoided, where possible. Where death as an end-point is accepted as essential for the purpose of the project, investigators must consider, and implement where possible, the means to prevent or minimise pain and/or distress.

(vii) the duration of activities should be no longer than required to meet the objectives of the project, and must be compatible with maintaining animal wellbeing. Animals should not be held for prolonged periods as part of an approved project prior to their use, without AEC approval.
Section 2: Responsibilities

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers, teachers, undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this section:

- **Activity**: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transport, production, housing, care, use and fate of animals.

- **Project**: an ‘activity’ or ‘activities’ that form a discrete piece of work outlined in an application to an Animal Ethics Committee. An approved application is an approved project (see ‘Activity’).

This section describes the responsibilities of:

- Institutions (Section 2.1)
- Institutions – Governance of an AEC (Section 2.2)
- Animal Ethics Committees (Section 2.3)
- Investigators (including teachers and persons involved with wildlife studies) (Section 2.4)
- Animal carers (Section 2.5)

Key principles related to responsibilities

As outlined in Section 1:

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

   (a) using animals only when it is justified
   (b) promoting the wellbeing of the animals involved
   (c) avoiding or minimising harm, including pain and distress, to those animals
   (d) applying high standards of scientific integrity
   (e) persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities.

(ii) Persons involved with any aspect of the care and use of animals for scientific purposes must consider the application of Replacement, Reduction and Refinement (the 3Rs) in all aspects of that care and use:
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(a) the Replacement of animals with other methods
(b) the Reduction in the number of animals used, and
(c) the Refinement of techniques used to reduce the adverse impact on animals.

(iii) Institutions, AECs, investigators and animal carers must be aware of and accept clearly defined responsibilities and act in accordance with the Code.

2.1 Responsibilities of institutions

Additional definitions specifically relevant to this part:

• Institution: any organisation or agency involved with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural institutions, commercial companies, wildlife groups, farms.

• Governing body of the institution: the body responsible for the administration and governance of the institution (for example, University Council or Senate, Board of an organisation) and where appropriate its delegated officer.

This section describes the responsibilities of institutions regarding the care and use of animals for scientific purposes. Section 2.2 describes the responsibilities of institutions regarding the governance of an Animal Ethics Committee (AEC). Section 2.3 describes the responsibilities of AECs regarding ethical review, approval and monitoring of animal care and use.

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 is compliant with the Code.

2.1.2 Institutions must ensure through an Animal Ethics Committee (AEC) constituted and functioning in accordance with Section 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.

2.1.3 Institutions must implement policies and procedures to ensure that the care and use of animals is:

(i) designed and conducted, and

(ii) ethically reviewed, approved and monitored by an AEC

in accordance with the Code and the Australian code for the responsible conduct of research.

2.1.4 Institutions must ensure that policies and procedures relevant to the care and use of animals are made available to all personnel.

2.1.5 Institutional policies and procedures must reflect the principles outlined in Clause 1.1 (see 2.1.6 to 2.1.9)

2.1.6 Institutions must promote compliance with this Code by

(i) providing adequate resources to ensure that persons involved with the care and use of animals can meet their responsibilities to comply with the Code. Such responsibilities include the monitoring of animals and management of adverse impacts on their wellbeing

(ii) nominating a senior individual from the institution to oversee compliance with the Code
(iii) promoting and facilitating adoption of the principles of the 3Rs in all aspects of animal care and use, including the co-ordination of activities and sharing of resources and information.

2.1.7 Institutions must ensure and support the effective operation of the AEC by

(i) ensuring the development and implementation of policies and procedures as outlined in Part 2.2.

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

(iii) providing the AEC with an institutional triennial plan for the implementation and resourcing of institutional responsibilities, including goals and strategies for achieving the 3Rs. The institution should, on an annual basis, review its triennial plan, and provide a report to the AEC on outcomes against the plan.

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

(v) addressing concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action

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

(vii) promotion and implementation of policies, procedures and guidelines approved by the AEC for animal care and use within the institution (see 2.3.3 (v))

(viii) appointment of an officer with veterinary, or other appropriate, qualifications who is authorised by the AEC to ensure that projects are proceeding in compliance with the Code and the decisions of the AEC

2.1.8 Institutions must identify clear lines of responsibility, communication and accountability and ensure that the person responsible for the wellbeing of animals at any given time is clearly identifiable so that

(i) animal wellbeing is monitored by competent persons 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

(ii) all actions required to deal with unexpected adverse events (see definition), including reporting, timeframes, and management, are developed in consultation with the AEC and undertaken as approved by the AEC

(iii) appropriate actions are taken in cases of emergency that require welfare interventions, such as treatment or humane killing of an animal

(iv) there is prompt detection and effective management of disease outbreaks and emergencies such as fire, power failure and biosafety issues.

2.1.9 Institutions must ensure all persons involved in the care and use of animals understand their responsibilities and the requirements of the Code, are competent or are under the direct supervision of a competent person, and have access to appropriate education programs and resources, by:

With respect to investigators

(i) ensuring that investigators are well-informed of their ethical and legal responsibilities under the Code and are either competent in the procedures they perform, or supervised by a competent person
(ii) provision of adequate resources for appropriate education and 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 institutional practices and procedures that concern the supply, breeding, transport, housing and husbandry of animals are based on recognised standards of good practice, informed by evidence of the potential impact on the wellbeing of those animals and include strategies to minimise such effects.

(iv) ensuring that the care and management of animals is under the direction of suitably qualified and experienced personnel.

(v) employment of adequate numbers of appropriately trained and skilled personnel to care for animals.

(vi) ensuring availability and access to veterinary services with relevant experience to assist in the proactive management and oversight of a program of veterinary care, quality management and project design to safeguard animal wellbeing.

(vii) ensuring access to diagnostic services.

*With respect to Occupational Health and Safety*

(viii) 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 complaints and non-compliance*

(ix) developing procedures for addressing complaints, and non-compliance related to the care and use of animals for scientific purposes (see Section 5).

**Reporting by institution**

2.1.10 Institutions must ensure that reports are provided to Commonwealth, State and Territory Government authorities as appropriate.

2.1.11 Institutions should consider making publicly available:

(i) an annual report of compliance with the Code

(ii) a summary of the external review report (see 2.1.12, Section 6).

**External Review**

2.1.12 Institutions must ensure the conduct an external review which enables assessment of its compliance with the Code, identifies matters that should be addressed and informs future planning. The external review should be undertaken every three years and must be undertaken at least every four years (see Section 6, External review of the operation of institutions and their animal ethics committees).

**Projects involving more than one institution and/or AEC**

2.1.13 For projects to be conducted at more than one institution, procedures must be in place to ensure that:

(i) animals will receive appropriate care at all sites and during transport between them

(ii) each AEC will inspect the parts of the project for which they are responsible, such that all phases of the project including any inter-institutional transport and associated care requirements are monitored.
(iii) respective AECs are permitted to visit the phases of the project conducted at other institutions
(iv) no work commences before the respective AECs have approved, or delegated approval of, activities to be conducted by members of their institutions
(v) the respective AECs are aware when considering the application of the cumulative effect on the animals of the proposed procedures
(vi) clear communication channels are established between all AECs and all investigators
(vii) letters of understanding are signed by AEC chairpersons on behalf of their respective institutions to formalise the arrangement.

2.1.14 One AEC may approve the entire project provided all institutions involved agree to delegate the responsibility for decision making to, and support the necessary actions of, that AEC.

Projects conducted by Australian investigators and institutions in other countries

2.1.15 Investigators employed by Australian institutions who wish to use animals overseas must ensure they obtain approval from their AEC for such use.

2.1.16 At the time of application, the investigator should provide the respective Australian AEC with a statement of intent from the associated overseas institution regarding compliance with local requirements. The Australian AEC may accept approval granted by a local AEC or its equivalent if satisfied that outcomes would be equivalent to those expected through application of the Code.

2.1.17 The Australian AEC must be assured of adequate monitoring of animal use and that facilities will be inspected at least annually. The AEC may appoint an agent or delegate to conduct the monitoring and inspection on its behalf.

2.1.18 In the case of an Australian institution operating facilities that use animals for scientific purposes in another country, projects conducted at those facilities must comply with the Code as a minimum, provided such compliance does not conflict with relevant local legislation.

Use of an external AEC or sharing of AECs

2.1.19 The institution may consider using an external AEC or sharing an AEC with another institution (see 2.2.11).
2.2 Responsibilities of Institutions for the governance of an Animal Ethics Committee

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this part:

- **Institution**: any organisation or agency involved with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural institutions, commercial companies, wildlife groups, farms.

- **Governing body of the institution**: the body responsible for the administration and governance of the institution (for example, University Council or Senate, Board of an organisation) and where appropriate its delegated officer.

- **Animal Ethics Committee**: a committee established in accordance with the terms of reference and membership described in this Code.

This section describes the responsibilities of institutions regarding the governance of an Animal Ethics Committee (AEC). Section 2.1 describes the responsibilities of institutions regarding the care and use of animals for scientific purposes. Section 2.3 describes the responsibilities of AECs regarding ethical review, approval and monitoring of animal care and use.

2.2.1 The institution must establish one or more AECs or access an external AEC, and may consider sharing an AEC with another institution (see also 2.2.11).

2.2.2 Institutions must:

(i) ensure that the AEC is established in accordance with the Code

(ii) ensure and support the effective operation of the AEC in the ethical review, approval and monitoring of animal care and use in accordance with the Code.

2.2.3 The Institution must ensure that the AEC is directly responsible to the governing body of the institution(s) for which it acts.

2.2.4 The Institution must ensure that the AEC membership will allow the committee to fulfill its terms of reference. For institutions that operate or maintain animal facilities, the AEC must comprise at least five persons, one from each of the five categories of membership (A, B, C, D, E). For institutions that do not operate or maintain animal facilities, the AEC must comprise at least four persons, one from each of four categories of membership (A, B, C, D) (see 2.2.14).
2.2.5 The Institution must provide the AEC with the resources required to carry out its responsibilities, and to maintain the AEC. The 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.

2.2.6 The Institution must, in consultation with the AEC, establish and document policies and procedures for the effective governance and operation of the AEC that will enable compliance of the AEC with the Code and relevant institutional policies, and promote good ethical review of animal care and use.

2.2.7 The Institution must ensure that the terms of reference of the AEC are publicly available and include the following provisions:

(i) responsibilities, including delegation of responsibilities to an executive or subcommittee (see 2.2.13–14)

(ii) membership (composition; responsibilities of the chairperson; appointment, reappointment, and retirement of members; the management of any conflict of interest in making appointments; orientation and training of new members (see 2.2.15, 2.2.22)

(iii) conflict of interest (see 2.2.3–24)

(iv) confidentiality (see 2.2.25)

(v) operating procedures that will enable compliance with the Code and relevant policies of the institution. In particular, such procedures should cover

(a) meeting procedures including management of conflict of interest (see 2.2.26–28)

(b) review procedures, and decision making (see 2.2.29-33)

(c) projects conducted in other countries (see 2.1.15-18)

(d) 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.

(iv) communication (see 2.2.34–37)

(vii) monitoring of care and use of animals (see 2.3.10–16)

(viii) complaints and non-compliance (see 2.2.38–39)

(ix) records (see 2.2.40)

(x) documentation (including applications form, reports) (see 2.2.41–49)

(xi) reporting to the institutions(s) (see 2.2.50–51)

(xii) performing all other duties required by the Code.

2.2.8 The Institution must ensure that the AEC approves policies, procedures and guidelines for animal care and use (Responsibilities of AECs, 2.3.3 (v)).

2.2.9 The Institution must, in consultation with the AEC, develop documentation for the presentation and reporting of information on the care and use of animals in a manner that complies with the requirements of the Code and facilitates ethical review by the AEC (see 2.2.41).

2.2.10 The Institution must conduct an annual review of the operation of the AEC to ensure that AEC operations are effective and consistent with the Code and institutional policies, including an assessment of the AEC’s Annual Report (see 2.2.49) and a meeting with the AEC chairperson.
2.2.11 Institutions may be approached by individuals who lack access to an AEC (the second party) requiring AEC approval for the care and use of animals for scientific purposes, or by other institutions (the second party) seeking to access an external AEC or share an AEC (see 2.1.19). In such cases, the institution may recommend to their AEC to oversee the consideration, approval and monitoring of such projects. In such instances, formal agreements between the institution and the second party, developed in consultation with the AEC, must be in place, and must include:

(i) where the second party is an institution, mechanisms for ensuring the second party can meet its responsibilities regarding the AEC as outlined in this section
(ii) mechanisms for communication between the AEC and the second party including governance and reporting
(iii) an undertaking by the second party that they or their investigators and other relevant personnel will abide by the directions of the AEC
(iv) an undertaking by the second party to abide by the AEC’s policies and procedures regarding non-compliance
(v) the circumstances under which either party may withdraw from the agreement.

Provisions under the AEC Terms of Reference

The following clauses (2.2.12–49) provide details under the AEC terms of reference (see 2.2.7).

Responsibilities

2.2.12 The responsibilities of an AEC are outlined in Section 2.3.

2.2.13 An AEC may establish an executive that:

(i) must include at least one member from Category C or D (see 2.2.15)
(ii) may approve minor modifications to projects for ratification at the next AEC meeting (see definition of ‘minor amendment’)
(iii) may not approve new applications.

2.2.14 AEC procedures should include the appointment of, and delegation of functions to, an executive.

AEC Membership

Composition

2.2.15 The institution must establish and maintain an AEC that has a membership that will allow it to fulfill its terms of reference (see 2.2.7). For institutions that operate or maintain animal facilities, the AEC must comprise at least five persons, one from each of the five categories of membership (A, B, C, D, and E). For institutions that do not operate or maintain animal facilities, the AEC must comprise at least four persons, one from each of four categories of membership (A, B, C, D). In the latter situation, a member from Category E is recommended but not mandatory:

(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 activities of the institution. Veterinarians whose experience is not current or who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animals used.
(ii) Category B – a suitably qualified person with substantial and recent (i.e. within the last three years) experience in the use of animals for scientific purposes relevant to the institution. The experience must entail 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 current 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.

(v) Category E – a person employed by the institution with responsibility for the routine care of animals.

2.2.16 If the committee has more than four members (or five members for committees that have a Category E member), Categories C plus D must represent at least one third of total membership.

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

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

2.2.19 The chairperson should either hold a senior position in the institution or, if an external appointee, must be given a commitment by the institution to provide the necessary support and authority to carry out the role. The Chairperson should be an additional appointment to Category A to E members.

**Responsibilities of the chairperson**

2.2.20 The chairperson must:

(i) ensure that the AEC operates in accordance with the principles and requirements of the Code, and institutional and AEC policies and procedures

(ii) oversee the development and promulgation of all written procedures relating to the operation of the AEC to ensure that the AEC and the institution comply with the Code

(iii) ensure that applications are considered by the AEC and the outcomes conveyed to investigators in a timely manner

(iv) advise institutional management on the level of resourcing required for the effective functioning of the AEC

(v) represent the AEC in any negotiations with management in consultation with members of the AEC

(vi) oversee all requirements of the AEC to report and review its operation in consultation with the AEC
(vii) ensure AEC records are maintained and made available for review by the institution and authorised external reviewers.

2.2.21 The chairperson should have the following skills and attributes to ensure the successful operation of the AEC in compliance with the Code, and institutional and AEC policies and procedures:

(i) an ability to bring impartiality to the task
(ii) the skills to manage the business of the AEC
(iii) an ability to communicate, negotiate and resolve conflict
(iv) an understanding of the ethical and animal welfare issues involved in the use of animals for scientific purposes.

Membership – appointment

2.2.22 AEC members must be appointed, re-appointed, and retired in accordance with procedures developed by the institution in consultation with the AEC. These procedures must include the management of any conflict of interest in making appointments.

Conflict of interest

2.2.23 Members must declare any conflict of interest that could interfere with objective decision making at the time of appointment, during meetings, and in any situation that may arise.

2.2.24 The AEC must develop procedures for the management of conflicts of interest involving members, expert advisors and all persons attending meetings. Any person with a conflict of interest regarding an activity or project must remove themselves from the review and deliberations of the AEC.

Confidentiality

2.2.25 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, including how advice may be sought without breaching confidentiality.

Operating procedures

Meeting procedures including management of conflict of interest

2.2.26 At least one member from each of the membership categories (A, B, C, D, and when relevant, E) must be present at meetings to establish a quorum. If more than four AEC members are present (or five members for those AECs with a Category E member), Categories C plus D should represent not less than one third of the number of members present.

2.2.27 Documented meeting procedures should include:

(i) distribution of papers to AEC members in a timely manner
(ii) the conduct of quorate AEC meetings in exceptional circumstances where a face-to-face meeting is not possible (for example, through the use of video-linking or teleconferencing)
(iii) resolution of any conflict of interest that may arise (see 2.2.23–24).

2.2.28 Meetings should be held at least quarterly to allow interaction of AEC members and effective functioning of the AEC.
Review procedure and decision-making

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

2.2.30 The AEC must consider and approve applications for new projects and the renewal of approval for existing projects only at quorate meetings of the AEC.

2.2.31 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. (see 2.3.4-9).

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

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

Communication

Good ethical review requires open communication between the AEC and those involved with the care and use of animals. Misunderstandings are more likely to arise when the only form of communication is the written word.

2.2.34 The AEC should encourage informal communication with applicants, and consider face-to-face meetings for issues that remain unresolved after written or telephone communication.

2.2.35 The AEC must clearly communicate its decisions to investigators in writing as promptly as possible.

2.2.36 Requests by the AEC for amendments to an application should include reasons. If an application is rejected the reasons for the rejection should refer to specific elements of the Code.

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

Monitoring of care and use of animals (see 2.3.10–16)

Complaints and non-compliance

2.2.38 AECs must have procedures for dealing with complaints and non-compliance with the Code and grievances related to the AEC process. Procedures must be effective, ensure confidentiality, accord with procedural fairness and the principles of natural justice, give the wellbeing of the animals the highest priority, and ensure appropriate reporting to the institution (see Section 5 Complaints and non-compliance).

2.2.39 The AEC must refer irreconcilable differences between it and an investigator to the governing body of the institution for review of the due process. The ultimate decision after such review lies with the AEC and must not be overruled.

Records

2.2.40 The AEC must maintain:

(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 that include the names of those who attended, observations, any identified problems, follow-up and outcomes.
2.2.41 The AEC in consultation with the institution must develop documentation for the presentation and reporting of information on the care and use of animals in a manner that complies with the requirements of the Code and facilitates ethical review by the AEC.

2.2.42 Documentation must be developed for:

(i) application for AEC approval to commence an activity (see 2.2.43)

(ii) follow-up review at scheduled times and when circumstances trigger additional follow-up review including:

(a) proposed amendment to the approved activities (see 2.2.45)

(b) review of annual progress of ongoing activities (see 2.2.46-7)

(c) unexpected adverse events (see 2.2.48)

(iii) reporting on activities that have been completed or discontinued (see 2.2.49).

2.2.43 *Application for approval to commence an activity.* The design of an application for approval to commence an activity must facilitate both the provision of appropriate information by the applicant as required by the Code, and the judgment by the AEC as to whether the proposed use of animals is ethically acceptable (see 2.4.15-17). Such judgment is informed by evidence that the proposed use of animals is justified and takes into consideration the predicted benefits and potential effects on the wellbeing of the animals involved (see 1.4, 2.3.3 (i)).

2.2.44 *Standard operating procedures.* Reference to standard operating procedures (SOPs) can facilitate the preparation of applications, but make it more difficult for the AEC to apply rigour to the evaluation of procedures. SOPs should only be referred to under the following conditions:

(i) SOPs must not be used until approved by the AEC

(ii) SOPs must include in the title the date of approval or last review

(iii) SOPs lapse and cannot be used if not reviewed by the AEC within three years

(iv) SOPs must be available to AEC members

(v) investigators named on an application must have the competence to apply the relevant SOP

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

2.2.45 *Application for amendment to an approved project.* An application for an amendment to an approved project must meet all of the requirements outlined for application for approval to commence an activity (see 2.2.43).

2.2.46 *Annual reporting of an activity.* Annual reports to the AEC for ongoing projects to allow review of progress should advise on:

(i) what progress has been achieved or reasons for lack of progress

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

(iii) the number and type of animals used at the time of reporting against the total number approved

(iv) whether the wellbeing of the animals was consistent with that anticipated in the application

(v) whether any changes are envisaged and the reasons for them

(vi) whether the project is meeting its aims.
2.2.47 The AEC should develop documentation to facilitate the annual reporting of activities related to the housing conditions, practices and procedures involved in the care of animals.

2.2.48 **Adverse event report.** Reports regarding unexpected adverse events should provide sufficient information to allow the AEC to:

(i) review and evaluate the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies

(ii) review the approved activity in light of the information provided.

2.2.49 **Final report.** Reports on projects that have been completed or discontinued should advise on:

(i) whether the stated aims were achieved and the reasons if they were not

(ii) the number and type of animals used at the time of reporting against the total number approved and the reason for any major discrepancies.

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

(iv) how procedures in future projects could be modified to reduce adverse impacts on animal wellbeing

(v) details of outcomes from the project, including publications and presentations arising.

**Reporting by the AEC**

2.2.50 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.

2.2.51 The report should advise on:

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

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

(iii) actions that have supported the educational needs of AEC members, and personnel 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 the provision of suitable recommendations.
2.3. Responsibilities of Animal Ethics Committees

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.
- **Animal**: means any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife), and octopus and squid.
- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this part:

- **Institution**: any organisation or agency involved with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural institutions, commercial companies, wildlife groups, farms.
- **Animal Ethics Committee**: a committee established in accordance with the terms of reference and membership described in this Code.
- **Activity**: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transport, production, housing, care, use and fate of animals.
- **Project**: an ‘activity’ or activities that form a discrete piece of work outlined in an application to an Animal Ethics Committee (AEC). An approved application is an approved project.

This section describes the responsibilities of Animal Ethics Committee (AECs) regarding ethical review, approval and monitoring of animal care and use in accordance with the Code. Section 2.1 describes the responsibilities of institutions regarding the care and use of animals for scientific purposes. Section 2.2 describes the responsibilities of institutions regarding the governance of an AEC.

2.3.1 The primary responsibility of an AEC is to ensure, on behalf of the institution for which it acts, through ethical review, approval and monitoring, that all care and use of animals is conducted in compliance with the Code.

2.3.2 An AEC must approve and monitor housing conditions, practices and procedures involved in the care of animals in the facilities of institutions.

2.3.3 The AEC must:

   (i) ensure that the use of animals is ethically acceptable based upon evidence provided to support a case that such use is justified, and takes into consideration predicted benefits and potential effects on the wellbeing of the animals involved (see 1.4)

   (ii) determine the compliance, and continuing compliance, of an activity with the Code, and approve, withhold or withdraw approval, or take appropriate actions with respect to non-compliant activities

   (iii) approve only those activities that conform to the requirements of the Code

   (iv) monitor the care and use of animals (see 2.3.10–16)
(iv) approve on behalf of the institution policies, procedures and guidelines for the care and use of animals, including
   (a) clear identification at all stages of animal care and use of the person responsible for animals, and of the association of that person with the institution
   (b) reporting, timeframes and management of, and other actions required for, unexpected adverse events
   (c) authorisation at each site where animals are used including for fieldwork of at least one person to respond to emergencies, including unexpected adverse events, in the absence of the responsible person
   (d) authorisation of the emergency treatment or humane killing of any animal
   (e) how disease outbreaks and emergencies such as fire, power failure and biosafety issues will be detected and managed promptly and effectively

(iv) provide advice and recommendations to the institution regarding strategies required to ensure the requirements of the Code are maintained, and matters affecting animal wellbeing are addressed.

Decisions of the AEC

2.3.4 The AEC must base decisions on the information it receives from the applicant in the documentation (see 2.2.41-49), and any direct discussions with the applicant. The AEC may use information in addition to that obtained from the applicant in making decisions.

2.3.5 The AEC may decide that:
   (i) an application to commence an activity, or amend an approved activity, is approved, deferred subject to modification, or not approved
   (ii) following review of the annual report for a project and possible consultation with the investigator, the approval for the project is continued, suspended, modified or discontinued
   (iii) any approval is suspended or withdrawn.

2.3.6 Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by members of the AEC, and should be made only by those present throughout the discussion (see 2.2.23–24; 2.2.29-33).

2.3.7 Decisions should be made on the basis of consensus.

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

2.3.9 When considering approval for the re-use of animals, the AEC must take into account:
   (i) the pain or distress and any potential long-term or cumulative effects caused by previous procedures
   (ii) the total time over which an animal will remain part of a project
   (iii) the pain and/or distress subsequent procedures are likely to cause
   (iv) the time allowed for recovery of the animals between procedures
   (iv) whether an animal has fully recovered from the previous procedure.
Monitoring of animal care and use

The AEC monitors animal care and use activities by the inspection of animal housing and laboratories and/or in the review of records and reports.

2.3.10 The AEC must monitor all activities related to the care and use of animals (including the acquisition, transport, production, housing, care, use and fate of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC, and to ensure that identified problems receive appropriate follow-up.

2.3.11 The AEC should ensure that activities likely to cause pain and/or distress are subject to early monitoring by the AEC (for example, the study of pain, responses to stressors, certain animal models of human diseases, and attempts to change behaviour by physical or chemical means). This requirement should be a condition of approval for the activity.

2.3.12 Members of the AEC must inspect all animal housing and laboratory areas at least annually and preferably more frequently. A Category C or D member of the AEC who is external to the institution should participate in animal facility inspections.

2.3.13 The frequency and timing of inspections will be determined by factors such as the number and accessibility of sites, the number and types of research and teaching activities, and whether inspections can be combined with scheduled AEC meetings. In addition, the AEC may decide that certain facilities or projects require more frequent inspection than others.

2.3.14 The AEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended remedial actions, ongoing outstanding issues and final outcomes.

2.3.15 The AEC must ensure that, when detected, activities that are in breach of the Code cease immediately, remedial action is initiated, and the requisite reporting occurs.

2.3.16 AEC procedures should cover the delegation of authority to inspect sites and monitor projects at remote sites (for example, fieldwork, activities at other institutions or overseas), and how the resulting information is presented to the AEC, such as by still or video images.
2.4 Responsibilities of investigators

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where.

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ defined above. Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this part:

- **Activity**: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transport, production, housing, care, use and fate of animals.

- **Project**: an ‘activity’ or activities that form a discrete piece of work outlined in an application to an Animal Ethics Committee (AEC). An approved application is an approved project.

Unless otherwise stated, this part relates to the responsibilities and activities of investigators – that is, researchers, teachers (at primary, secondary, tertiary and postgraduate levels including supervisors of research students), undergraduate and postgraduate students involved with research projects, persons involved with product testing, environmental testing, production of biological products and wildlife surveys.

**Part A. Key principles and responsibilities**

2.4.1 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) promoting 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) persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities.

2.4.2 Investigators have responsibilities based on their obligation to treat animals with respect. They must be aware of and accept their responsibilities and act in compliance with the Code.

**Using animals only when justified**

2.4.3 Investigators must use animals for a scientific activity only when that use is justified (Clause 1.1).
Promoting the wellbeing of animals and avoiding or minimising harm

2.4.4 During the planning, conduct and review of activities involving the use of animals investigators must take all possible steps to promote animal wellbeing and anticipate, avoid and minimise any risks to animal wellbeing from both intended and unforeseen consequences, including through the application of the principles of Replacement, Reduction and Refinement (see 1.10).

2.4.5 Investigators must adhere to the requirements of clauses 1.20–35 regarding:
   (i) the Replacement of animals with other methods
   (ii) the Reduction in the number of animals used
   (iii) the Refinement of techniques used to reduce the adverse impact on animals.

Applying high standards of scientific integrity

2.4.6 Investigators must adhere to the requirements of clauses 1.11 and 1.12.

Accepting responsibilities

2.4.7 Investigators are responsible for all matters that relate to the wellbeing of animals that they propose to use in an activity. For the period from allocation of an animal to a project until the future of the animal upon completion of the activity is finalised, investigators have personal responsibility for all matters related to the wellbeing of the animal, including the housing, husbandry and care. Investigators must ensure that animal care can be provided by an adequate number of competent personnel. Investigators may act as animal carers (see Section 2.5) during this period.

2.4.8 Investigators must:
   (i) ensure that all persons involved in the use of animals understand and accept their role and responsibilities in the project. For students undertaking research activities that use animals, this responsibility rests with the student’s supervisor.
   (ii) consider the application of the 3Rs to all aspects of the care and use of animals (see 1.20–35)
   (iii) submit an application to an AEC before the commencement of any activity that uses animals, and before commencement of an amendment to an approved activity (see 1.18 (ii); this section Part B ‘Planning projects’ and Part C ‘Application to the AEC’).
   (iv) not commence an activity involving the use of animals before receipt of written approval from an AEC (see 1.18 (ii))
   (v) conduct an activity involving the use of animals in accordance with the conditions and requirements of the AEC approval, and have procedures in place to ensure that this occurs (see 1.18 (iii); this section, Part D ‘Conduct of projects’)
   (vi) report to the AEC as required (see 1.18(iii); this section, Part E ‘Reporting’)
   (vii) maintain records of the care, use and monitoring of animals and make such records available for audit by the institution, the AEC and authorised external reviewers
   (viii) notify the AEC in writing if they are involved with collaborative studies using animals at another institution or named in an application to the AEC of another institution (see 2.1.13–18)
   (ix) liaise with animal care staff on all matters relevant to the wellbeing of the animals.

2.4.9 Additional investigator responsibilities for specific types of activities are outlined in Part F.
Part B. Planning projects

Part B should be read in conjunction with Section 1 Principles for the care and use of animals for scientific purposes and Section 3 Animal wellbeing of the Code

2.4.10 When planning projects, and before submission of an application to the AEC, investigators must:

(i) be satisfied that the use of animals can be justified (see 1.1, 2.4.1)

(ii) consider the necessity to demonstrate to the AEC the satisfactory application of the 3Rs (see 1.20–35)

(iii) be satisfied the project can be conducted to high standards of scientific integrity, and is feasible (see 1.11–12)

(iv) ensure that all persons involved in the care and management of animals understand and accept their role and responsibilities (see 1.13–14)

(v) give particular consideration to activities that are of special ethical concern because of the potential risks to animal wellbeing (see 2.4.47).

2.4.11 From the outset, when planning projects, investigators must not consider using animals unless they are satisfied that there is evidence to support the case that:

(i) the project has scientific or educational merit, and

(ii) the goals cannot be achieved without the use of animals

and, if there is evidence to support consideration of the use of animals, then investigators must be satisfied that such use would be ethically acceptable taking into consideration the potential benefits and the predicted impact on the wellbeing of the animals.

2.4.12 When planning projects, investigators must take into account the need to demonstrate to the satisfaction of the AEC that the principles of the 3Rs have been applied (1.20–35), notably that:

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

(ii) the proposed activities are designed to use the minimum number of animals to give statistically valid results or achieve educational objectives

(iii) the choice of species and procedures are appropriate for the goals of the project

(iv) factors that may contribute to variability of results are taken into account including determinants of biological status such as the genetic, nutritional, microbiological and general health status of the animals, and the physical, environmental and social determinants of their living conditions

(v) the potential adverse impact of any aspect of the application on the wellbeing of animals is identified

(vi) strategies to identify, minimise and manage risks to the wellbeing of animals from both intended and unforeseen consequences are developed

(vii) circumstances that could result in unintended harm to animals and confound experimental data are eliminated or minimised and managed

(vii) a pilot study is incorporated into the project design 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 development of strategies to manage any negative impact

(ix) procedures will be conducted by persons competent in the procedure or under the direct supervision of a competent person, and that provisions will be made for the supervision and training of students nominated on the application to an authorised level of competence in the relevant procedures
(x) the wellbeing of the animals will be regularly assessed by persons with the necessary skills and experience
(xi) arrangements made for animals at the completion of their use will ensure the wellbeing of those animals.

2.4.13 Before submitting an application to the AEC, investigators must be satisfied, after consultation with the animal facility manager if appropriate, that the conduct of the proposed project is feasible, taking into consideration:

(i) the source and availability of animals
(ii) requirements for animals of a particular age, weight or sex
(iii) requirements for animals of a particular health, genetic or nutritional status
(iv) availability of suitable housing facilities that meet the physiological and behavioral needs of the species and include any special requirements for the species or the proposed project
(v) availability of suitable equipment for the handling and care of animals in the conduct of the project
(vi) any special requirements related to the capture and handling of animals, particularly those involved in wildlife studies
(vii) any special requirements in the husbandry and care of the animals such as diets, containment facilities, exercise regime
(viii) procedures for monitoring animal health during the project and strategies to respond to identified diseases
(ix) resources for monitoring animal wellbeing during the conduct of the project
(x) the need for permits and licences (for example, AQIS, OGTR, wildlife permits, state and Commonwealth)
(xi) the need for appropriate approvals for projects that involve hazards to other animals and humans (for example, viruses, bacteria, fungi, parasites, radiation, radioactivity, corrosive substances, toxins, allergens, carcinogens, recombinant DNA, anaesthetic gases and physical injuries). Any potential pathogenic effects of these hazards when used in projects must be explained as far as possible to all personnel. Tests before, during and after the project may be required for personnel.
(xii) the acquisition of documentation from the supplier to certify the biological status of animal if the biological status of animals must conform to defined requirements
(xiii) the necessary arrangements for projects conducted at more than one institution (see 2.1.13–14).

2.4.14 Before submitting an application to the AEC, investigators must ensure that all persons involved in the care and management of animals understand and accept their role and its relationship to that of other personnel involved with the proposed project and have agreed to participate.

Part C. Application to the AEC

2.4.15 Investigators must submit an application to the AEC before commencing an activity, or commencing an amendment to an approved project (see 1.18 (ii)).

2.4.16 Investigators must use plain English in the application to ensure that all AEC members are provided with sufficient information to participate in the assessment of applications.
2.4.17 Investigators must provide the following information in the application:

(i) name of the project, personnel involved and the technical competence of personnel for all procedures they will undertake using animals

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

(iii) the scientific or educational merit of the activity, the expected benefits of the outcomes, and the evidence that supports the use of animals

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

(v) details of why the use of animals is essential to achieve all the stated aims

(vi) a clear description of the steps taken to consider and apply the principles of the 3Rs (see 1.20–35)

(vii) details of animals required

(a) species chosen and the reason for this choice

(b) number of animals required and the justification for this number

(c) source of animals, details of housing and care.

(viii) assessment of the potential negative impact on animal wellbeing for the duration of the project including

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

(b) identification of all circumstances that are likely to have a negative impact on the wellbeing of an animal and how such an impact will be minimised. Experimental and non-experimental factors must be addressed.

(ix) details of how the wellbeing of animals will be monitored and assessed throughout the project, actions to be taken if problems are identified, intervention points and humane end-points

(x) justification for the proposed use of animals in the project, taking into consideration the scientific or educational merit and predicted benefits and the potential impact on the wellbeing of the animals

(xi) particular justification for activities that are of special ethical concern because of the potential risks to animal wellbeing (see 2.4.47), including

(a) unrelieved pain and distress including where the planned end-points will allow severe adverse effects to occur (see 2.4.47 (i))

(b) death as the end-point (see 2.4.47 (ii))

(c) re-use and repeated use of animals (see 2.4.47 (iii))

(d) prolonged restraint or confinement (see 2.4.47 (iv))

(e) production of monoclonal antibodies by ascites method (see 2.4.47 (v))

(f) use of non-human primates (see 2.4.47 (vi))

(xii) for teaching projects, details as outlined in (see 4.5.1)

(xiii) details of any participation in the proposed project of staff from other institutions and if and how the facilities of another institution will be used (see 2.1.13–18)

(xiv) any additional administrative details as required by the institution and the AEC, for example details of collaborations, permits and licences, occupational health and safety considerations

(xv) 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.
Part D. Conduct of projects

Part D is to be read in conjunction with Section 3 (Animal Wellbeing).

2.4.18 Once an animal is allocated to a project, investigators have personal responsibility for all matters related to the wellbeing of that animal including their housing, husbandry and care. These responsibilities extend during the period of use approved by the AEC until the future of the animal upon completion of the activity is finalised.

2.4.19 Investigators must:
   (i) conduct a project only as approved by the AEC (see 1.18 (iii))
   (ii) ensure that animals are suitable for their proposed use at the time they are allocated to a project
   (iii) implement and review strategies to identify, minimise and manage adverse impact on animal wellbeing including pain and/or distress from both intended and unforeseen consequences (see 1.10; Section 3 ‘Animal wellbeing’)
   (iv) ensure the ongoing consideration and application of the 3Rs (see 1.20–35)
   (v) provide prompt notification of any unexpected adverse events (see definitions) that may have a negative impact on the wellbeing of an animal in their care (see 1.34 (vii))
   (vi) maintain records of all aspects of the use and monitoring of animals and make them available for audit by the institution, the AEC and authorised external reviewers.

Monitoring and record keeping

The term ‘monitoring’ covers observation of animals for deviations from normal behaviour and signs of pain and/or distress, maintaining records of observations, assessment of observations, and taking appropriate actions based on this assessment.

2.4.20 Persons named on an application as being responsible for animals in a project must ensure that animal wellbeing is appropriately monitored at all stages of the project. The scope of day-to-day monitoring must be clearly outlined and communicated to all parties. Monitoring must be undertaken in accordance with the agreed strategy approved by the AEC.

2.4.21 Investigators must provide the AEC access to their records of monitoring of animal wellbeing. Such records must be 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 (see definitions) as a basis for future prevention strategies.

2.4.22 Monitoring records should include:
   (i) the origin and fate of the animals
   (ii) the frequency and method(s) used to assess animal wellbeing
   (iii) details of procedures, including dates, analgesia, anaesthesia and any unexpected outcomes
   (iv) the condition of the animal, any negative impact on animal wellbeing and actions taken as a consequence
   (v) any additional information requested by the AEC
   (vi) names of personnel entering the records
   (vii) names and contact details of personnel responsible for monitoring and emergency incidents.

2.4.23 Investigators must make records regarding animal care and use available for audit by the institution, the AEC and authorised external reviewers.
Detecting and minimising pain and distress

2.4.24 Investigators must take all possible steps to anticipate, avoid and minimise pain and/or distress, and conduct ongoing review of such steps (see 1.10, 1.30).

2.4.25 Investigators must:

(i) use methods that cause the least pain, distress, or lasting harm
(ii) ensure the competence and technical skills of all personnel involved in animal care and use on the project
(iii) ensure that strategies are in place to detect, minimise and manage any pain and/or distress of the animals
(iv) ensure relevant personnel are knowledgeable about the normal behaviour and signs of pain and/or distress for the species they will use
(v) observe and assess animals to detect deviations from normal behaviour that are often the first indications of pain and/or distress, and for overt signs of pain and/or distress. Such observation and assessment must be conducted at a frequency sufficient to detect such signs at an early stage as determined by the procedure
(vi) take prompt action to treat animals with signs of pain and/or distress not anticipated in applications to the AEC. Alleviation of such pain and/or distress must take precedence over an individual animal’s reaching the planned end-point of the activity, or the continuation or completion of the project. If necessary, animals must be humanely killed without delay. Actions must be in accordance with intervention points and humane end-points as approved by the AEC
(vii) use non-pharmacological means to minimise pain and/or distress including acclimatisation of animals to the environment in which the project will be conducted, conditioning animals to procedures and personnel involved in the project, and the nursing and care provided during and after procedures
(viii) use anaesthetic, analgesic and sedating agents appropriate to the species and the scientific aims. Use of such agents should at least be consistent with current medical or veterinary practice
(ix) use anaesthesia for activities that are likely to cause pain of a kind and degree for which anaesthesia would normally be used in medical or veterinary practice
(x) assess and review throughout the course of the project the implementation of refinement of procedures and the criteria for early intervention and humane end-points
(xi) conduct studies over the shortest time practicable.

2.4.26 Deviations from normal behaviour may include changes in patterns of sleeping, feeding, drinking, grooming, exploration, performance in learning or discriminatory tasks, social interaction and reproduction, that are often the first indications of pain or distress.

2.4.27 Overt signs of pain or distress may include aggressive or abnormal behaviour (for example, some species may become unduly submissive), abnormal stance or movements, abnormal sounds, altered cardiovascular or respiratory function, abnormal appetite, rapid loss of body weight, altered core temperature, vomiting and abnormal defecation or urination. Indicators of chronic pain or distress include loss of body weight, failure to thrive, impaired reproductive ability and reduced resistance to disease.

2.4.28 Actions that may be taken in response to observation of signs of pain and/or distress in animals may include an increase in the frequency of observation, consultation with a veterinarian, administration of analgesic agents or other appropriate medication, removal from the project and humane killing.
Specific procedures

Information regarding specific procedures that may be used during the conduct of projects is provided in Section 3 “Animal wellbeing”.

2.4.29 Investigators must ensure that practices and procedures involving animals are based on recognised standards of good practice. These standards must take into consideration relevant aspects of species-specific biology, physiology and behaviour, be informed by evidence of the potential adverse impact on the wellbeing of the animals and include strategies to minimise such impacts.

Issues that involve potential risk to animal wellbeing

2.4.30 Investigators must give special consideration and attention to the conduct of activities of special ethical concern because of the potential risks to animal wellbeing (2.4.47). Such activities include:

(i) unrelieved pain and distress including planned end-points that will allow severe adverse effects to occur (see 2.4.47 (i))
(ii) death as an end-point (see 2.4.47 (ii))
(iii) re-use and repeated use of animals (see 2.4.47 (iii))
(iv) prolonged restraint or confinement (see 2.4.47 (iv))
(v) production of monoclonal antibodies by the ascites method (see 2.4.47 (v))
(v) use of non-human primates (see 2.4.47 (vi)).

Duration of scientific activities

2.4.31 Investigators must conduct studies over the shortest practicable time that is compatible with maintaining animal wellbeing and will meet the objectives of the project (see 1.35 (vii), 4.3.3 (vi)).

2.4.32 Investigators must obtain AEC approval to hold animals for prolonged periods before their use as part of an approved project, and for the continued long-term use of individual animals.

Future of animals at the completion of their use

2.4.33 At the end of their use in a project, investigators must take prompt action regarding the future of animals in accordance with the protocol approved by the AEC (see 3.9).

2.4.34 When it is necessary to kill an animal, investigators must use humane procedures appropriate to the species and circumstances (see 3.5).

2.4.35 Where possible, in accordance with the principle of reduction, tissues from dead animals should be shared with other investigators or deposited in a tissue bank for subsequent distribution.

2.4.36 Any re-use of animals must comply with the Code (see 2.4.37 (iii)).

Necropsy

2.4.37 When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, investigators should ensure that a necropsy is performed by a person with appropriate qualifications and/or experience and that the AEC is notified promptly (see 2.4.38 (ii)).
Part E. Reporting

2.4.38 Investigators must provide the following reports to the AEC in accordance with AEC and institutional policies and procedures (see 1.18 (iii)):
   (i) annual reporting for all projects, regardless of the duration of approval (see 2.2.46)
   (ii) prompt notification of any unexpected adverse events (see definitions) that may impact on the wellbeing of an animal in their care (see 2.2.48, 2.4.37)
   (iii) a final report on outcomes as soon as practicable after completion or discontinuation of a project (see 2.2.49)
   (iv) audit reports regarding the conduct of an approved activity or the monitoring of the wellbeing of animals used
   (v) audit reports regarding the conduct of an approved activity or the monitoring of the wellbeing of animals used

Part F. Additional investigator responsibilities for specific activities

Teaching activities

2.4.39 Additional responsibilities for projects involving teaching activities are outlined in Section 5.

Wildlife studies

2.4.40 For projects involving the use of wildlife or vertebrate pest animals, investigators must:
   (i) avoid taking animals from natural habitats unless animals bred in captivity are unavailable or unsuitable for the scientific purpose
   (ii) ensure that risks to animal wellbeing in both target and non-target species and populations are identified, assessed, and avoided or minimised, and managed. Risks may arise from:
       (a) direct effects from activities such as capture (including inadvertent capture of non-target species and inadvertent recapture of animals), handling, holding, restraint, transport, sedation and anaesthesia, identification, sampling, release, techniques associated with observational studies, humane killing
       (b) indirect effects from disturbance to the habitat.
   (ii) ensure that equipment is managed, and techniques and methods conducted in a way that minimises the risk of transmission of disease.

Use of privately owned animals

2.4.41 For projects involving the use of privately owned animals (for example, livestock or companion animals), investigators must:
   (i) identify and make known to all involved personnel their responsibilities relating to those animals
   (ii) ensure that personnel responsible for the daily management of the animals are familiar with, and understand, the Code and are competent to carry out the proposed procedures
   (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 their responsibilities, the acceptance of which the owner should acknowledge in writing.
Projects involving hazards to other animals and humans

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

(i) ensure all personnel are aware of any potential pathogenic effects of these hazards. Tests may be required for personnel before, during and after the project.

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

Toxicological studies

2.4.43 For projects involving toxicological studies, investigators must:

(i) use suitable non-animal tests if they are available, in particular in vitro methods for initial screening

(ii) use end-points that are as early as is compatible with reliable assessment of toxicity (see 3.2.8–11, 2.4.47 (ii)).

Cloning of animals

2.4.44 The cloning of animals may or may not involve genetic modification. When genetic modification is involved, clauses 3.7.44-3.7.55 must apply when such projects are considered. The Prohibition of Human Cloning Act 2002 (the Act) strictly prohibits the combination of human and animal gametes.

Xenotransplantation

In the context of xenotransplantation:

‘Recipient Animal’ is an animal that receives a transplantation, implantation 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.

‘Source animal’ is an animal from which body fluids, cells, tissues, or organs for use in xenotransplantation are obtained.

2.4.45 Xenotransplantation should be conducted in accordance with relevant legislation and guidelines. Measures must be 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 the collection and retention of tissue samples from source and recipient animals. (See also Section 3 ‘Animal wellbeing’.)

Collaborative studies in Australia or overseas

2.4.46 For projects involving collaborative studies in Australia or overseas, additional responsibilities are outlined in (see 2.1.13–18).
Issues requiring special consideration

2.4.47 During the planning of projects, investigators must give particular consideration to activities that are of special ethical concern because of the potential risks to animal wellbeing and hence require special justification. These include:

(i) unrelieved pain and/or distress, including where the planned end-points will allow severe adverse effects to occur

(a) if a project requires animals to experience pain and/or distress that will not be alleviated, the planned end-point of the project must be as early as is feasible to avoid or minimise pain and/or distress to the animals. Investigators must monitor and assess animals to ensure that the planned end-points are detected, and take action in accordance with the approved protocol

(b) Investigators must promptly treat or humanely kill without delay animals that develop signs of pain and/or distress not anticipated in the application to the AEC. Alleviation of such pain or distress must take precedence over an individual animal’s reaching the planned end-point of the project, or the continuation or completion of the project. Where necessary, the animal must be humanely killed without delay (see 3.5).

(ii) Death as the end-point

‘Death as an end-point’ is defined as “when the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects, that is, the investigator or teacher will not intervene to kill the animal humanely before death occurs in the course of a scientific activity”. Death as an end-point does not cover the death of an animal by natural causes or accidents, or when an animal is humanely killed as planned in a project, or when an animal is humanely killed because of its condition.

(a) Investigators must not use death as an end-point in a project unless no other end-point is feasible to achieve the aims of the project, and the goals of the project are the prevention, alleviation, or cure of a life-threatening disease or situation in humans or animals (see 1.35 (vi)). Where possible, investigators should replace death as an end-point with early and humane end-points.

(b) Where death as an end-point is accepted as essential for the purpose of the project, investigators must:
   • design the project to minimise the number of animals that will die
   • consider and implement as far as possible strategies to prevent or minimise pain or distress, including early and humane endpoints.

(iii) Re-use and repeated use of animals

(a) Investigators must not use individual animals in more than one scientific activity whether in the same or different projects, without approval from the AEC (see 1.25, 1.26, 2.3.9). Appropriate re-use of animals may reduce the total number of animals used in a project and result in better experimental design. However, the investigator must take into account:
   • the pain and/or distress and any potential long-term or cumulative effects caused by previous procedures
   • the total time over which an animal will remain part of a project
   • the pain or distress likely to be caused by subsequent procedures
   • the time allowed for recovery of the animals between procedures
   • whether an animal has fully recovered from the previous procedure.

(b) The number of animals used must not be reduced to the detriment of an
individual animal (see 1.25).

(iv) Prolonged restraint or confinement
If prolonged restraint or confinement of animals is proposed, such as maintenance in metabolic cages, investigators must consider the animal’s biological (including behavioural) needs, and ability to exercise. Investigators must ensure that restrained or confined animals are assessed regularly by a veterinarian or other qualified person not otherwise involved in the project. If any negative impact is detected, investigators must release the animal, or modify the method of restraint to minimise that impact.

(v) Production of monoclonal antibodies by the ascites method
Investigators must not use the ascites method for the production of monoclonal antibodies unless an in vitro method is unsuitable for the production of the specific antibody required for the proposed project (see NHMRC Guidelines for monoclonal antibody production).

(v) Use of non-human primates
Special ethical and welfare concerns arise in the use of non-human primates for scientific purposes. Investigators must demonstrate that predicted outcomes justify the use of these species (see NHMRC Policy on the care and use of non-human primates for scientific purposes).
2.5 Responsibilities of animal carers

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ defined above. Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this part:

- **Activity**: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transport, production, housing, care, use and fate of animals.

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

- **Facility manager**: the person responsible for the overall management of animal acquisition, breeding and holding facilities.

- **Animal carer**: person involved with the care of animals that are bred, supplied or held for scientific purposes.

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

Unless otherwise stated, this section relates to the responsibilities and activities of persons involved with the care of animals that are bred, supplied or held for scientific purposes.

An important factor contributing to the provision of high quality animal care is the number, and training and competence, of animal carers.

Institutions responsible for the acquisition, breeding, supply and holding of animals must ensure that animal care is provided by an adequate number of competent personnel.

For the period following allocation of an animal to a project until the future of the animal at the completion of an activity is finalised, investigators must ensure that animal care can be provided by an adequate number of competent personnel. Investigators may act as animal carers during this period.

**Key principles**

2.5.1 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) promoting 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) persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities.

2.5.2 Animal carers have responsibilities based on their obligation to treat animals with respect. They must be aware of, and accept, their responsibilities, and act in accordance with all requirements of the Code.

2.5.3 Animal carers must, within the scope of their responsibilities:
(i) ensure the wellbeing of animals is an essential consideration
(ii) take all possible steps to promote animal wellbeing and anticipate, avoid and minimise any risks to animal wellbeing, including through the application of Replacement, Reduction and Refinement (the 3Rs) (see 1.10, 1.30, Section 3 ‘Animal wellbeing’).

Responsibilities

General

2.5.4 Animal carers must:
(i) be competent in the duties they perform, or under the supervision of a person competent in those duties
(ii) be knowledgeable about the normal behaviour and signs of pain and/or distress for the species under their care
(iii) consider the application of the 3Rs in all aspects of the care of animals for which they are responsible. Animal carers should coordinate planning and operations and share resources and information to promote and facilitate adoption of the 3Rs
(iv) ensure that they use procedures and practices that are based on recognised standards of good practice. Such practices and procedures must take into consideration relevant aspects of species-specific biology, physiology and behaviour, be informed by evidence of the potential adverse impact of conditions and procedures on the wellbeing of the animals and include strategies to minimise such impacts. Further information is provided in Section 3 “Animal wellbeing”.
(v) ensure that animals are provided with accommodation, physical and social environmental conditions, food, water and care to meet species-specific or strain-specific physical and behavioural needs, and compatible with animal wellbeing and good health
(vi) ensure that housing conditions, practices and procedures involved in the care of animals in the facilities of institutions are approved by an AEC
(vii) ensure they take appropriate actions to maintain the health and biosecurity of animals under their care (see 2.5.5, 3.3.3)
(viii) ensure prompt detection and effective management of disease outbreaks and emergencies such as fire, power failure and biosafety emergencies
(ix) liaise with investigators and research team staff on all matters relevant to the wellbeing of the animals involved.
Animal health

2.5.5 Animal carers must ensure that the health status of animals is maintained in a manner that safeguards animal wellbeing and meets the requirements of their proposed use (see 3.3.3), including:

(i) monitoring and assessment of animals at least daily by a competent person to ensure that sick or injured animals are identified, and that appropriate action is taken

(ii) seeking veterinary clinical care and advice

(iii) a mechanism to ensure prompt detection and effective management of disease outbreaks and emergencies such as fire and power failure

(iv) implementation of appropriate preventative protocols including animal biosecurity, quarantine, and disease surveillance, diagnosis, treatment and control.

Monitoring of animals

2.5.6 Animal carers must ensure that animal wellbeing is monitored on a day-to-day basis until animals are allocated to an approved project, when investigators are responsible for ensuring the day-to-day monitoring of animal wellbeing (see 2.4.20). Monitoring involves:

(i) observation of animals for deviations from normal behaviour and signs of pain and/or distress

(ii) maintaining records of observations

(iii) assessment of observations

(iv) taking appropriate actions based on the assessment, including liaison with investigators and seeking veterinary advice.

2.5.7 Animal carers must provide the AEC access to their records of monitoring of animal wellbeing. Such records 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 (see definition) as a basis for future prevention strategies.

2.5.8 When emergency welfare interventions are required for an animal allocated to a project (for example, treatment or humane killing of an animal), animal carers must take all reasonable steps to first consult with 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 provide a report to the responsible investigator that includes the reasons for emergency interventions and is confirmed in writing. A copy of the report must also be supplied to the AEC.

Records and reports

2.5.9 Animal carers must:

(i) maintain records of the care and monitoring of animals and make them available for audit by the institution, AEC and authorised external reviewers

(ii) provide reports to the AEC as required, including

(a) prompt notification of any unexpected adverse events (see definitions) that may have a negative impact on the wellbeing of an animal in their care

(b) an annual report of activities.
Future of animals at completion of their use and disposal of carcasses and waste material

2.5.10 Animal carers must take prompt action regarding the future of animals at the end of their use in an activity in accordance with approved procedures and protocols (see 3.9).

2.5.11 When it is necessary to kill an animal, animal carers must use humane procedures appropriate to the species and circumstances (see 3.5).

2.5.12 Unless needed as part of a project or for the investigation of a disease outbreak, all carcasses and tissues from animals that have died or been humanely killed must be disposed of in a sanitary and appropriate manner.

2.5.13 If practicable, in accordance with the principle of reduction, tissue samples from dead animals should be provided or made available to investigators for their work, or deposited in a tissue bank for subsequent distribution.

Persons managing and supervising animal acquisition, breeding and holding facilities

2.5.14 Persons supervising the care, husbandry and health of animals and biosecurity in facilities must be competent and hold appropriate veterinary qualifications, training and/or experience.

2.5.15 The person responsible for the overall management of animal acquisition, breeding and holding facilities (the Facility Manager), with support as required from the institution and other staff members, and advice from veterinarians, must:

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

(ii) manage the day-to-day care of animals including arranging for experienced veterinary services in a timely manner

(iii) ensure the development and regular review of procedures for the supply, breeding, transport, housing, husbandry and care of animals (see 3.3)

(iv) ensure that all housing conditions, practices and procedures are approved by an AEC and are implemented as approved. Procedures must be promoted to all personnel involved in the care and use of animals, and be the subject of ongoing staff training and regular review

(v) ensure that the necessary permits, approvals and licences are in place (for example, AQIS, OGTR, wildlife permits, state and Commonwealth)

(vi) ensure training and supervision of staff as appropriate, including instructions on how their actions may affect animal wellbeing and the outcomes of scientific activities

(vii) ensure staff compliance with veterinary advice regarding care, husbandry and health of animals and biosecurity in facilities, including the maintenance of high standards of personal hygiene and the avoidance of eating, drinking or smoking in animal areas

(viii) liaise between investigators and facility staff

(ix) inform investigators of any intended changes to the conditions under which animals are held and that may affect their studies

(x) communicate with the AEC regarding the management of the facility
(xi) ensure the provision of reports as required by the AEC, including
   (a) prompt notification of unexpected adverse events that may impact on the wellbeing of an animal in their care
   (b) an annual report of activities
(xii) ensure that animals are suitable for proposed use, and identify suitable animals for allocation to a project
(xiii) ensure promotion of a high quality of management in the facility through the systems and procedures in place.

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 The Facility Manager must ensure that animal wellbeing is monitored on a day-to-day basis by a competent person knowledgeable about the signs of pain, distress and illness specific to each species under their care, and that appropriate actions are taken (see 2.5.6, 2.5.8). After animals are allocated to an approved project, investigators are responsible for the day-to-day monitoring of animal wellbeing.

2.5.18 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
   (ii) establish procedures that ensure the receipt of, and 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 conduct of a necropsy by a veterinarian, a competent and experienced person or a person under veterinary supervision, and access to diagnostic services when samples are collected for ancillary testing.

2.5.19 The Facility Manager must ensure regular assessment of the health status and breeding performance of all animals and keep records of the assessment that should include:
   (i) the source, care, allocation, movement between locations, use and fate of the animals
   (ii) details of all diseases in the facility
   (iii) the fertility, morbidity and mortality rates of breeding colonies
   (iv) the health status, genetic constitution and physical environment of the animals.

2.5.20 The Facility Manager must make records of the health status and breeding performance of all animals available to investigators, the AEC and authorised external persons on request.

**Consideration of occupational health and safety**

2.5.21 The Facility Manager must ensure that staff:
   (i) are advised of the occupational health and safety issues associated with the animals under their care and the precautions they must take
   (ii) have access to appropriate protective clothing
   (iii) have received necessary vaccinations
   (iv) are provided with a comfortable and safe work environment. In facilities where access and movement between areas is restricted, animal care staff and other personnel must be given reasonable access to amenities to ensure their comfort during normal working hours and outside these times.

2.5.22 The Facility Manager should ensure that regular health checks of animal carers are performed, in the interests of both personnel and animals.
Section 3: Animal wellbeing

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.
- **Animal**: means any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife), and octopus and squid.
- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this chapter:

- **Animal wellbeing**: an animal’s present state with regard to its relationship to all aspects of its environment, both internal and external. Wellbeing implies a positive mental state, successful biological function, positive experiences and freedom from adverse conditions.
- **Distress**: the state of an animal that has not completely adapted to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.
- **Facility**: any place where animals are kept, held or housed including yards, paddocks, tanks, ponds, buildings, cages, pens and containers.
- **Pain**: an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.
- **Phenotype**: the observable physical, behavioural, physiological and biochemical characteristics of an organism, as determined by genetic makeup and environmental influences. The phenotype may influence an animal’s ability to cope with its circumstances and affect its suitability for use.
- **Wildlife**: free-living animals of native or introduced species including those that are captive-bred and those captured from free-living populations.

This section applies to all species of animals used, and to all activities and situations involving their use. It outlines the principles for the promotion of the wellbeing of animals used for scientific purposes in terms of the animal’s lifetime experience. These principles underpin the NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals.

Information provided includes:

- general principles related to animal wellbeing
- strategies to minimise adverse impact on animal wellbeing
- animal supply, housing and care
- handling and restraint
- humane killing
- conduct of projects – general consideration and specific procedure
• wildlife and field techniques
• future of animals at the conclusion of their use.

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.
• Other NHMRC guidelines and policies (insert website)
• Best-practice guidelines regarding supply, breeding, transport, housing, husbandry and care of animals.

3.1 General principles

3.1.1 The wellbeing of an animal must be considered over the whole of the animal’s life, irrespective of the source of the animals.

3.1.2 All circumstances with the potential to have an adverse impact on the wellbeing of an animal must be identified and any potential impact minimised, including through the application of the principles of Replacement, Reduction and Refinement (the 3Rs).

3.1.3 Identification of potential pain and/or distress requires knowledge of the husbandry and handling of a particular animal, its normal behaviour and level of cognitive development, and what can be expected if the proposed procedures have a negative impact on the animal’s wellbeing.

3.1.4 The planning and conduct of projects must include strategies to identify, minimise and manage risks to the wellbeing of the animals involved that take into consideration both intended and unforeseen consequences.

3.1.5 Many factors other than experimental procedures may have a negative impact on the wellbeing of an animal. Other potential sources of pain, stress and distress must be considered, such as capture, transport, handling, restraint, housing and husbandry, social and physical environment, and phenotype.

3.1.6 Practices and procedures involving animals must be based on recognised standards of good practice. These standards must take into consideration relevant aspects of species-specific biology, physiology and behaviour, be informed by evidence of the potential adverse impact on the wellbeing of the animals and include strategies to minimise such impacts. Such practices and procedures include those used in the acquisition, capture, breeding, supply, transport, housing, husbandry, care and use of animals.

3.1.7 Procedures, husbandry and care must be performed by competent personnel or by persons under the direct supervision of competent personnel.

3.1.8 Assessment of the wellbeing of the animals must be undertaken by persons with the necessary skills and experience.

3.2 Strategies to minimise negative impact on animal wellbeing

Identifying potential negative impact on wellbeing

3.2.1 all aspects of animal care and use that could have a negative impact on the wellbeing of an animal must be identified. In each instance, investigators and animal carers should consider the factors that might contribute to the level and duration of such impacts and assess the risk of such occurrences taking into account the predicted likelihood and consequences.
3.2.2 If pain and/or distress are predicted or unavoidable consequences of a procedure, strategies to minimise or control them must be incorporated into the experimental design. The duration and magnitude of pain and/or distress should be no more than required to meet the aims of the project.

3.2.3 If there is uncertainty as to the potential risk of animals experiencing pain and/or distress or the time course and effects are not well defined, investigators must consider conduct of a pilot study to identify risks, and inform the development and validation of strategies to minimise such pain and/or distress.

3.2.4 If the potential cause of an animal experiencing pain and/or distress is not part of the experimental design of a project, all contributing factors should be eliminated or controlled so as to minimise the adverse impact on wellbeing and the risks to quality of data.

**Strategies to minimise and manage the negative impact on wellbeing**

3.2.5 Each application to an AEC must include an assessment of the likelihood that animals will experience pain and/or distress.

3.2.6 Applications must include a strategy to minimise and monitor potential pain and/or distress that should include documentation of the following:

   (i) the clinical signs or observations that will be used to assess wellbeing based on criteria for the species and evidence of predicted changes as a result of the proposed activity

   (ii) the criteria that will be used to determine the level and frequency of monitoring and the point at which an intervention will occur

   (iii) actions that will be taken when predicted effects are evident

   (iv) actions that will be taken if unforeseen complications are detected

   (v) the persons responsible for monitoring and their level of training and competence

   (vi) the methods for recording observations, treatments and actions.

3.2.7 The strategy developed to minimise and manage the adverse impact on wellbeing should be:

   (i) developed to ensure that any changes in an animal’s condition are detected early

   (ii) flexible, to ensure a rapid and effective response to changes during the course of the activity

   (iii) developed so as to foster good communication and co-operation between all parties involved.

**Setting intervention points and humane end-points**

3.2.8 Before the commencement of projects in which an animal is predicted to experience pain and/or distress as a result of a procedure, investigators must prepare a plan to manage animal wellbeing based on validated criteria appropriate for the species and the nature and time course of the predicted effects to ensure that:

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

   (ii) valid data are obtained preferably before pain and/or distress occur, or at the earliest time point possible following the onset.

3.2.9 Criteria for minimising pain and/or distress should be used to identify:

   (iii) the earliest time point at which data can be obtained and the study completed

   (iv) indicators that intervention is necessary to ameliorate the effects of a specific treatment
3.2.10 The investigator must assess and modify the plan as necessary throughout the course of the study.

3.2.11 If uncertain as to the validity and efficacy of criteria for intervention, investigators should undertake a pilot study.

**Review**

3.2.12 The investigator or animal carer must review strategies to minimise adverse impacts on animal wellbeing at least annually but preferably more regularly during the course of an activity, or in the light of adverse outcomes, to ensure the effectiveness of the strategy and identify necessary changes and opportunities for refinement of procedures.

### 3.3 Animal supply, housing and care

3.3.1 Animals sourced, bred or held for scientific purposes must be suitable for the proposed use.

3.3.2 The supply, breeding, transport, housing, husbandry and care of animals must be based on recognised standards of good practice that take into consideration relevant aspects of species-specific biology, physiology and behaviour, are based on evidence of the potential adverse impact of conditions and procedures on the wellbeing of the animals and include strategies to minimise such impacts.

#### Animal health

3.3.3 Procedures must be in place at all stages of animal supply, housing and care to ensure maintenance of a health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use, including:

- monitoring and assessment of animals at least daily by a competent person to ensure that sick or injured animals are identified, and that appropriate action is taken.
- provision of veterinary clinical care and advice
- a mechanism to ensure prompt detection and effective management of disease outbreaks and emergencies such as fire and power failure
- implementation of appropriate preventative protocols including animal biosecurity, quarantine, and disease surveillance, diagnosis, treatment, control.

#### Acquisition and breeding

3.3.4 When animals are specifically bred for scientific purposes:

- the breeding program must be managed in accordance with recognised best practice to ensure the wellbeing of the colony, herd or flock; that specified requirements for genetic constitution and health status are met and certified; and that overproduction of animals is avoided
- records must be maintained and monitored to ensure the wellbeing of all animals involved. To assist in monitoring the effective management of a breeding program, an assessment of reproductive performance should include data relevant to fertility, fecundity, morbidity and mortality
- records of animals culled and the reasons for their cull should be maintained and reviewed to identify overproduction and implement steps to avoid this occurrence.
3.3.5 When animals are obtained from outside an institution:
   (i) they should be acquired from sources including dedicated breeding and supply facilities that maintain conditions consistent with the Code or relevant species-specific codes
   (ii) the health status of the animal colony from which 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 animal facility.

3.3.6 Wildlife animals are particularly susceptible to stress in captivity and should not be removed from their natural habitat unless animals bred in captivity are unavailable or unsuitable for the scientific purpose. Practices to minimise transmission of pathogens between animals and between sites must be implemented.

3.3.7 Information regarding the generation and breeding of genetically modified animals is provided in clauses 3.7.44–55.

Transport of animals

Transport can cause distress to animals due to containment, movement, noise, disruption of social groupings, and changes in the environment and personnel.

The extent of any distress may depend on 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.

3.3.8 The conditions and duration of the transport must be consistent with the factors necessary for the wellbeing of the animals and ensure that any adverse impact on animal health and welfare is minimised.

3.3.9 Containers must be secure and escape-proof. They should contain adequate nesting or bedding material and provision for refuge if appropriate for the species. Containers must protect the animals from movement that could cause injury or distress, and extremes of climate.

3.3.10 Food and water (or other appropriate source of fluids such as palatable gel) must be provided when necessary.

3.3.11 Transport by air must be in accordance with International Air Transport Association (IATA) regulations as in place from time to time, and any relevant codes of practice for the species.

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

3.3.13 Personnel responsible for monitoring animals during transport should be able to recognise signs of pain and/or distress in the species under their care.

Admission of new animals to facilities

3.3.14 New animals admitted to holding areas should be held separately and their health and wellbeing assessed by a qualified person. If necessary, they should be quarantined and given preventive or other health treatment if appropriate.

3.3.15 Appropriate accommodation must be available at the new facility and unnecessary delays when transferring animals to housing should be avoided.

3.3.16 The suitability of the animals for their intended scientific purpose should be assessed, including, as appropriate, confirmation of genetic constitution, health status and clinical history.
3.3.17 Animals should be acclimatised to the facility and personnel before they are used. Those that do not adapt satisfactorily should be returned promptly to normal husbandry conditions or their natural habitat if appropriate and permitted, or, if necessary, humanely killed.

Housing and care

3.3.18 Animals must be provided with accommodation, physical and social environmental conditions, food, water and care to meet species-specific or strain-specific needs (physical and behavioural) and be compatible with animal wellbeing and good health.

3.3.19 The Facility Manager should consult the AEC and investigators in advance of planned changes to the housing conditions of animals, which can affect both the welfare of animals and results of the scientific and teaching activities.

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

3.3.21 The design and management of facilities will depend on the type of animals kept and the studies undertaken. The overall condition and management of facilities must be compatible with the needs of the animals that are housed and the projects in which they are used.

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

3.3.23 Investigators must obtain AEC approval before deviating from the requirements for an animal’s living conditions.

Indoor facilities

3.3.24 Indoor facilities should be designed and operated to:

(i) control environmental factors appropriately
(ii) enable appropriate segregation of species or activities that might impact on other animals held in the same facility
(iii) exclude vermin
(iv) limit contamination associated with the keeping of animals, the delivery of food, water and bedding
(v) prevent the entry of unauthorised people and other animals.

3.3.25 Indoor facilities must be in good repair, clean and tidy. 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.

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

3.3.27 Indoor facilities must have effective ventilation is essential for the comfort of animals and the control of temperature, humidity and odours. Ventilation systems should distribute air uniformly and achieve adequate air exchange. The distinction between air conditioning and ventilation should be understood by relevant personnel.
3.3.28 Noxious odours, particularly ammonia, must not exceed a level compatible with the health and comfort of the animals and personnel. The adequacy of the ventilation system, design, construction and placement of cages and containers; population densities within the cages and within a room; effectiveness of cleaning and the frequency of bedding changes will all influence the level of noxious gases. Attention should be given to the balance between the need for cleanliness and the potential for cleaning procedures to have a negative impact on the wellbeing of animals.

3.3.29 Procedures for monitoring and managing emergencies such as the breakdown of lighting, heating, cooling or ventilation must be documented.

3.3.30 Investigators, teachers and the AEC should be informed in advance of planned changes to the environmental conditions under which the animals are held as environmental factors have the potential to affect the welfare of animals and the results of scientific and teaching activities.

3.3.31 Chemicals used in a facility including detergents, disinfectants, deodorisers and pesticides must be appropriate for the purpose, and avoid contamination of the animals’ environment. They should be used in consultation with the relevant investigators who use the facility.

**Pens, cages and containers**

3.3.32 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.

3.3.33 The number of animals in, and placement of, cages, pens or containers should enable maintenance of social and environmental conditions for the species. If it is necessary to house individually animals of a species that normally exists in social groups, the adverse impact and time of social isolation must be minimal.

**Food and water**

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

3.3.35 Investigators must obtain AEC approval before deviating from the requirements for an animal's food and water.

3.3.36 If possible, animals should be given variety in the composition and presentation of food in a manner suitable for the species. Uneaten perishable food should be removed promptly unless contrary to the needs of the species.

3.3.37 Clean, fresh drinking water should be available at all times as suitable for the species.
Routine husbandry procedures

Routine husbandry procedures are practices or procedures performed in relation to the housing and care of animals with the primary purpose of maintaining their health and wellbeing. Routine husbandry procedures are not part of a project and include, for example, clipping coats and nails, and vaccinations.

3.3.38 Routine husbandry procedures must be performed by competent personnel or by staff being trained under the direct supervision of competent personnel.

3.3.39 For special breeding programs that are integral to a project, such as the creation of a new strain of genetically modified animal, procedures applicable to breeding must be regarded as part of the project and should be included by the investigator in the application to the AEC.

3.3.40 For a special breeding programs integral to maintenance of a line of animals in the facility, the facility manager must document the program in facility management procedures, and the procedures must be approved by the AEC.

Identification of animals

3.3.41 Animals must be marked so as to be identifiable individually or in groups using a method appropriate for the species and the circumstances, compatible with the aims of the project and associated with the least pain and/or distress to the animals.

3.3.42 If possible, animals should be identified by the attachment of a label to the cage, container, pen, yard or paddock in which they are kept. Alternatively, a physical mark such as a tattoo, a neckband or individual tag, or an electronic numbering device, such as a microchip should identify individual animals.

3.3.43 Invasive identification procedures must be performed by person competent in performing the procedure, or under the direct supervision of a person competent in the procedure.

3.3.44 Specific advice on the appropriate means of identification of wildlife is provided in clauses 3.8.19–21.

3.4 Handling and restraint of animals during experiments

3.4.1 Handling and restraint can cause animals to experience stress that may lead to distress. To minimise the adverse impact on an animal’s wellbeing, methods for handling and restraint must be appropriate for the species, conform to recognised standards of good practice and be performed by persons competent with the necessary skills and training. If possible, animals should be conditioned to handling and restraint.

3.4.2 If the period of restraint is likely to cause stress to the animals, the use of chemical restraint, for example sedatives, should be considered.

3.4.3 Electroimmobilisation should not be used for restraint unless evidence shows that it causes less distress than traditional methods (see 3.7.11).

3.5 Humane killing

3.5.1 When it is necessary to kill an animal, the procedures used must be humane and:

(i) avoid pain or distress
(ii) produce rapid loss of consciousness until death occurs
(iii) result in reliable and reproducible effects
(iv) be compatible with the scientific or educational aims.
3.5.2 Methods of killing must be appropriate to the species, age, developmental stage and health of the animal.

3.5.3 Death must be established before disposal of the carcass.

3.5.4 When choosing a method for humane killing, the method that is likely to cause least pain and/or distress to the animal should be used whenever possible.

3.5.5 Methods of killing should require minimum restraint of the animal and minimise the distress and anxiety experienced by the animal before loss of consciousness.

3.5.6 Animals should be killed in a quiet, clean environment away from other animals.

3.5.7 If there is reason to believe, but no supportive evidence that a method of killing will influence data and the proposed method has a higher risk of negative impact on the animal’s wellbeing, a pilot study should be undertaken to validate the use of the proposed method and investigate opportunities to refine techniques.

3.5.8 Appropriate provision must be made for the care of the dependent offspring of animals to be killed. Alternatively, the dependent offspring must be killed using methods appropriate for their stage of development.

3.5.9 Disposal of fertilised eggs, foetuses and embryos must not occur until death has been confirmed.

3.5.10 Procedures for the humane killing of animals that are sick or injured, or in an emergency, must be developed and disseminated and the necessary resources for implementing them made available.

3.5.11 If practicable, tissue from dead animals should be shared in keeping with the principle of reduction or deposited in a tissue bank for subsequent distribution (see 1.28)

3.6 Conduct of Projects – General Considerations

Acclimatisation and conditioning

3.6.1 If there is any change in the conditions of housing, husbandry and/or care at the time an animal is allocated to a project, animals should be allowed time to acclimatise before the study commences.

3.6.2 To minimise any negative impact on animal wellbeing, the persons who will conduct the study should, before commencing an activity, condition the animals to handling and particular experimental conditions such as restraint devices or procedures and testing equipment.

3.6.3 An animal that appears not to have acclimatised to the conditions of a study should not be used.

Animal housing and care requirements

3.6.4 If the proposed conditions of housing and care for a project differ from recognised standards of good practice, the application to the AEC should describe those differences, explain why they are necessary, identify any potential negative impact on wellbeing and describe how such an impact will be managed and minimised.

3.6.5 If alterations to housing and care involve the following circumstances, evidence of an appropriate level and frequency of monitoring should be provided:

(i) changes to an animal’s social and/or physical environment

(ii) the use of single housing or isolation

(iii) changes to diet and/or access to food and water

(iv) limiting opportunities to perform a range of species-specific behaviours including exercise.
3.6.6 When changes to an animal’s living conditions are proposed, consideration should be given to:

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

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

(iii) the need to provide ready access to food and water

(iv) the need to clean the pen, cage or container

(v) protection from spread of pests, disease and predators

(vi) the need to observe and monitor the animals readily.

3.6.7 The housing, care and husbandry of animals administered infectious organisms must take into account risks to other animals and to humans, and include the implementation of appropriate procedures to minimise such risk.

3.7 Conduct of projects – Specific Procedures

Anaesthesia and the management of pain and distress

3.7.1 The use of anaesthetics, analgesics and sedatives should form part of a plan to manage pain and/or distress that includes strategies to anticipate and prevent or alleviate pain and/or distress.

3.7.2 The choice and administration of anaesthetics, analgesics and sedatives must be suitable for the species and the aims of the project, and must take into consideration the age and physiological status of the animal, the type of procedure and the scientific or educational aims. The use of such agents should at least be comparable with their use in current medical or veterinary practice.

3.7.3 It must be assumed that foetuses have comparable requirements for anaesthesia and analgesia as adult animals of the species. Pain management strategies for the foetus must be designed accordingly.

3.7.4 The efficacy of all anaesthetics, regardless of their mechanism of action, must be adequately monitored throughout a procedure.

3.7.5 The induction of general anaesthesia must be effectively managed to ensure an adequate plane of anaesthesia with minimal physiological disturbances. The appearance of potential side effects, such as hypothermia, and cardiovascular and respiratory depression must also be monitored and managed. Records must be kept of all use of anaesthetics and monitoring of anaesthesia.

3.7.6 If an animal is to recover from an anaesthetic, procedures must conform to accepted standards in medical or veterinary practice. An animal must be monitored until it has recovered from the effects of the anaesthetic to ensure its airways are not obstructed and that body temperature and cardiovascular and respiratory function are maintained. Care should be taken to ensure that the animal does not injure itself by uncoordinated movements and that it is safe from disturbance or attack by other animals in the same enclosure.

3.7.7 If it is expected that an animal will experience pain and/or distress due to an approved procedure, a management plan aimed at the prevention or alleviation of such pain and/or distress and appropriate for the procedure and the species must be developed, implemented and reviewed as necessary.
3.7.8 If an animal develops signs of pain and/or distress of a kind or to a degree that was not foreseen in the approved project, immediate steps must be taken to identify the cause and alleviate and manage such pain and/or distress. The efficacy of the actions taken must be closely monitored, reviewed and modified as necessary.

3.7.9 The administration of anaesthetics, analgesics and sedatives, and the management of anaesthesia, must be performed by competent personnel, or under the direct supervision of competent personnel.

3.7.10 Neuromuscular blocking agents may only be used with adequate general anaesthesia or an appropriate surgical procedure that eliminates sensory awareness. Immobilisation of an animal solely with a neuromuscular blocking agent is not acceptable. When neuromuscular blocking agents are used, specialist advice should be obtained. Special care must be taken to ensure the maintenance of an adequate plane of anaesthesia. Since the usual criteria for monitoring anaesthesia, such as character of respiration and corneal and flexor withdrawal reflexes, cannot be used, continuous or frequent monitoring of physiological variables such as heart rate, blood pressure, pupil size and the electroencephalogram, together with the effects on these of mild sensory stimuli should be employed.

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

Injections, blood sampling and non-surgical procedures

3.7.12 Procedures should be performed using recognised standards of good practice relevant to the species and based on guidelines that are informed by evidence of the potential negative impact on the wellbeing of the animals and include strategies to minimise such effects.

3.7.13 The least invasive method compatible with the aims of the investigation should be used.

3.7.14 The methods used should be those that minimise the risk of an animal experiencing pain and/or distress and developing complications.

3.7.15 Any procedure that has the potential risk of causing an infection must be performed under aseptic conditions.

3.7.16 Procedures such as injections, collection of blood, tissue and other biological samples, identification techniques and non-surgical implantation of devices could result in animals experiencing transient pain and/or distress and may result in complications such as infection, haematoma or bleeding.

3.7.17 For procedures that involve the transplantation of cells or tissues by non-surgical methods, special care is needed in the management of the effects of tissue rejection and immunosuppression.

Surgical procedures

3.7.18 Personnel performing surgery must be competent to perform the procedure, or be under the direct supervision of a person competent to perform the procedure.

3.7.19 Surgical procedures must be carried out under appropriate local and/or general anaesthesia.

3.7.20 If the animal is expected to recover from surgery, aseptic procedures must be used. In addition, all procedures must conform to accepted standards in medical or veterinary practice as appropriate for the procedure and circumstances.

3.7.21 The impact of a surgical procedure on an animal’s wellbeing should be minimised by prior identification of the associated risks and development of strategies to manage effectively hypothermia, dehydration, blood loss, tissue trauma, metabolic disturbances, poor tissue perfusion and cardiovascular and/or respiratory failure. Similarly, strategies should be developed to prevent or minimise post-operative complications such as infection, delayed wound healing or impaired function.
3.7.22 For any surgical procedure, effective pain management involves a plan to ensure effective
anaesthesia as well as the prevention and management of post-operative pain and/or
distress. A management plan which is appropriate for the procedure and the species must
be developed, implemented and reviewed, as necessary.

3.7.23 For non-recovery surgery, the animal must remain unconscious throughout the procedure
and death must be confirmed at the end of the procedure.

3.7.24 If an animal will undergo more than one surgical procedure, the time between each
procedure must allow recovery to good general health unless otherwise justified.

3.7.25 Prior to any surgery on a female carrying a foetus or embryo, consideration must be given
to any subsequent requirement for anaesthesia of the foetus or embryo.

3.7.26 If experimentation, including surgery, on foetuses and embryos compromises the ability
of the neonate to survive or causes untreatable pain and/or distress, the animal (foetus/
embryo/neonate) must be killed humanely before or immediately following birth.

Animal models of disease

The scientific validity of animal models of human or animal diseases, whether they occur
spontaneously as the result of genetic modification, or after induction by infectious agents, or
chemical or surgical means, is dependent on how closely the model resembles features of a particular
disease. The induction and progression of pathological changes will have a negative impact on the
wellbeing of an animal due to the pain and/or distress associated with the disease state.

3.7.27 Steps to manage and minimise such pain and/or distress include the establishment of
disease-specific criteria for intervention and for humane end-points. Strategies that will
ameliorate the effects of the disease process must be implemented.

3.7.28 Death as an end-point in the study of animal models of disease should be avoided.

Post-procedure care

Monitoring, and the appropriate treatment and care of animals are essential after any procedure to
manage predicted consequences, identify and respond to unforeseen complications and provide
supportive treatment that will promote wellbeing.

3.7.29 Steps must be taken to ensure the wellbeing of an animal that has undergone a procedure.

3.7.30 Appropriate records of an animal’s condition must be kept. Such records might include
observations and details of administration of any drugs, fluids or other treatments, and must
be accessible to all personnel involved in the post-procedural care of the animal.

3.7.31 The duties of all personnel must be clearly defined and procedures must be established for
the identification of, and response to, emergencies that include the management of pain
and/or distress and veterinary treatment.

3.7.32 If an animal must be housed in isolation or separated from a group following a procedure,
the duration of such housing conditions should be minimal. The animals should receive
visual, auditory and olfactory contact with animals of the same species unless there is
evidence that such contact will interfere with data collection and interpretation.

3.7.33 After an animal has undergone a surgical procedure, the provision of warmth, hydration,
fluid and food intake, and the control of infection require special attention. As part of the
specific plan to manage pain and/or distress, the animals should be given analgesics and
sedatives appropriate to their species, and antibiotics as appropriate to prevent or manage
post-operative infection.
3.7.34 Any post-operative animal observed to be in a state of severe pain and/or distress that cannot be alleviated quickly must be killed humanely without delay.

3.7.35 Surgical wounds must be inspected regularly for evidence of infection and progress of healing and any problems must be attended to without delay.

3.7.36 Animals that have undergone surgery for implantation of recording or sampling devices or creation of a fistula must receive skilled and specialised attention.

3.7.37 If the procedure for the implantation of a recording or sampling device requires an animal to be isolated or restrained for a prolonged period, the animal should be conditioned to such circumstances before the procedure is undertaken.

3.7.38 Animals that have undergone surgery for transplantation of organs or tissues must receive skilled and specialised attention in the management of potential rejection of the transplant and the effects of immunosuppression. Death as an end-point (see definition) should be avoided when determining the survival time of recipients.

**Induction of tumours**

The risks to the wellbeing of animals in studies that involve the induction of tumours are associated with the development and biology of the tumour, including growth rate, invasiveness, potential for ulceration, development of metastases and cachectic effects. Other potential risks in such studies are the effects of therapeutic agents, immunotherapy including irradiation, and surgery involved with transplantation of tumours.

3.7.39 The site for transplantation of tumours must be chosen carefully and should be the anatomically normal site if possible. The footpad, tail, brain or eye may only be used if there is no alternative.

3.7.40 Investigators must monitor animals closely for signs of pain and/or distress, taking particular note of sudden changes in body condition, and other signs of tumour growth and metastases.

3.7.41 Animals should be humanely killed as soon as tumours have reached the minimum size necessary to obtain valid results. Humane killing of animals with induced tumours must occur before predictable death, advanced wasting, or the tumour becomes large enough to cause ulceration or severely limit normal behaviours.

3.7.42 To minimise the adverse impact of a tumour on wellbeing, imaging techniques should be used if possible to measure tumour growth and determine early end-points.

3.7.43 In studies designed to evaluate the efficacy of tumour therapies, end-points compatible with reliable assessment of the therapy must be as early as possible in tumour development. Assessment of animal wellbeing must include close monitoring of changes in body weight and condition. Death from the tumour must not be an end-point.

**Genetic modification of animals**

This section should be read in conjunction with the Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes.

3.7.44 The nature and extent of potential impacts due to genetic modification and the difficulty in predicting them should be considered in the development of strategies to minimise the negative impact of genetic modification on the wellbeing of the animals involved. Both the genetic modification itself and procedures used to create a new line can potentially have a negative adverse impact on the wellbeing of animals.

3.7.45 New animal lines should not be generated by the techniques of genetic modification if a similar, suitable animal model is available.
3.7.46 The methods used to generate a new animal line by genetic modification should be consistent with international benchmarks. The principles of Refinement and Reduction must be used to minimise the adverse impact on the wellbeing of the animals.

3.7.47 For genotyping, the least invasive technique that yields sufficient tissue should be used.

3.7.48 The impact of genetic modification on the wellbeing and genetic stability of newly created genetically modified animals and their offspring must be assessed across a number of generations. Monitoring strategies informed by international benchmarks should take into account the unique features of a particular animal line.

3.7.49 The phenotypic description of genetically modified animals should include the time course and characteristics of indicators of any negative impact on wellbeing. Such documentation can be used to inform the setting of appropriate end-points or management strategies designed to assist the animal in coping with physiological and behavioural changes induced by genetic modification.

3.7.50 In the first instance, AEC approval for the generation of a new genetically modified line should cover the period from the start of the process until data on mortality, morbidity and population health of the new line are available.

3.7.51 The investigator should provide regular reports to the AEC on the monitoring of new lines created through genetic modification at a frequency determined by the AEC (see 2.4.38).

3.7.52 The AEC must be advised when the clinical status of genetically modified animals changes to a kind or degree that was not predicted.

3.7.53 The AEC must approve the final report on the generation of a new line of genetically modified animals before the new line can be treated as breeding stock.

3.7.54 Newly created genetically modified animals and their offspring cannot be sold or transferred to another facility unless the recipient of the animals accepts full responsibility for completion of the phenotype assessment.

3.7.55 Records must be maintained of the number of animals used for the creation and maintenance of the genetically modified animals, and the lineage and health status, and reported to the AEC as required.

Modification of behaviour and neurological function

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

3.7.57 If evidence support a claim that some form of biological stress is required to induce an animal to modify its behaviour or perform a task, the duration and severity of the effect on the wellbeing of the animal must be as mild as possible.

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

3.7.59 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.

3.7.60 Projects involving the withholding or restriction of food or water must be designed such that the animal experiences no continuing detrimental effect. In such studies, changes in fluid balance or body weight must be monitored, recorded and maintained within the limits approved by the AEC.
3.7.61 Animals subjected to neurological impairment (for example by anatomical or chemical lesions of the brain, spinal cord or nerves, or by genetic modification) require special attention. If neurological lesions produce loss of function, including 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, management strategies must meet the special needs of the animals to minimise the negative impact of the defects on their wellbeing. Such animals may also need special animal care, caging and other facilities.

**Immunomodulation and production of antibodies.**

The use of agents to stimulate or suppress an animal’s immune system poses particular risks to the wellbeing of animals and requires special attention.

3.7.62 Agents or treatments such as irradiation that suppress the immune system expose animals to a high risk of developing infections from both recognised pathogens and their normal flora. Special procedures that include regular monitoring of microbiological status must be followed to minimise the risk of infection. Animals must be monitored to identify and manage potential side effects of such agents or treatments.

3.7.63 Immunostimulatory agents are used in the development of an animal model that involves chronic inflammation of specific organs or tissues, and, in combination with an antigen, to produce antibodies. Such agents, particularly adjuvants, may produce an inflammatory response that causes the animal to experience pain and/or distress associated with the route of delivery and possible pathological consequences associated with dispersal of the agent.

3.7.64 If adjuvants are used to produce antibodies, the nature and severity of side effects should be minimised by:

(i) choosing an adjuvant that provides an adequate titre of antibody while causing minimum negative impact on the wellbeing of the animals
(ii) using a ratio of adjuvant to antibody that reduces the probability of adverse reactions
(iii) choosing 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 minimises the potential for pain and/or distress.

3.8 Wildlife and field techniques

**General considerations**

3.8.1 Free-living wildlife and vertebrate pest animals (see definition), 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.

3.8.2 Animals captured in the wild are particularly susceptible to the stress of trapping, transport, handling, holding and release, the effects of which can be cumulative. All reasonable steps must be taken to minimise such stress.

3.8.3 The application to the AEC must include an assessment of all potential sources of stress, the risk of cumulative effects and the methods for their elimination or minimisation.

3.8.4 Wildlife studies and work in the field must be conducted by appropriately skilled personnel.
3.8.5 All materials and equipment used in the capture, holding, transport and manipulation of wildlife must be:
   (i)  appropriate for the species and the purpose
   (ii) cleaned and maintained in a way that minimises
        (a)  risk of injury to the animal
        (b)  transmission of parasitic or infectious diseases between animals and between sites
        (c)  stress from the inadvertent exposure of the captured animals to the scent or
             smell of another animal.

3.8.6 Animal wellbeing must be protected by regular assessment of signs of pain and/or distress
and remedial action taken as necessary.

Studies in the natural habitat

3.8.7 Observational studies of free-living animals using techniques such as spotlighting,
approach, camera traps and playback calls have the potential to cause adverse effects
because of interference with normal behaviour, particularly if there is an effect on the
rearing of young or increased risk of predation.

3.8.8 Steps should be taken when designing field studies to minimise changes to the landscape,
noises, and smells that the animal normally detects in its habitat as such disturbances can
adversely affect the resources available to both target and non-target species and have a
negative impact on the wellbeing of the animals.

Capture and handling

3.8.9 Capture is stressful and steps must be taken to minimise distress experienced by the
captured animals and the populations from which they are taken.

3.8.10 Captured free-living animals must be handled by skilled personnel using techniques and
timing appropriate to the species. Procedures must incorporate the following to minimise
the risk of injury or stress-induced disease:
   (i)  the use of sufficient competent persons to restrain animals in a quiet environment
        and prevent injury to animals and handlers
   (ii) chemical restraint such as by the use of sedatives where appropriate, if the period of
        handling is likely to cause undue stress to animals
   (iii) restraint and handling of animals for the minimum time needed to achieve the
        scientific or educational objectives
   (iv)  recording, if possible, the long-term and short-term consequences of capture,
        handling and restraint.

Use of traps

3.8.11 The inherent randomness of most methods of trapping will cause the capture of both
target species and many animals of non-target species. Investigators must account for and
effectively manage the wellbeing of the non-target animals in the same way as they do that
of target species.

3.8.12 If trapping is to be used for capture, the application to the AEC must cover issues such as:
   (i)  design of the trap, including its size and construction (for example, conformation of
        the walls, lids, covers or grids)
(ii) management of traps to minimise any negative impact on animal wellbeing, including consideration of:
   (a) the time animals will spend in traps
   (b) protection of trapped animals from predators and parasites
   (c) protection of trapped animals from environmental factors such as lack of water, high and low temperatures, and drowning
   (d) lack of food and water.

(ii) minimising the number of days of continuous trapping and deactivating traps that are not in use or no longer required

(ii) ways of minimising the potential negative impact caused by disruption of social structure and on dependent young, for example by avoiding trapping in breeding season if possible

(ii) minimising the numbers of non-target species trapped and implementing a management plan for captured non-target species that complies with the Code.

3.8.13 All trapping activities must be monitored in a way that takes into account the conditions under which they take place:

(i) traps and nets used to capture animals in water must be set and monitored to prevent drowning

(ii) wet pitfall traps must not be used for the capture of vertebrate animals. If wet pitfall traps are used for the capture of invertebrates, they should 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

3.8.14 Stress caused by transport of wildlife must be minimised by:

   (i) the use of transport containers of the appropriate size, design and construction

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

   (iii) providing, if appropriate for the species, shelter within the transport container

   (iv) ensuring that animals of incompatible species, age, size, sex or reproductive status are separated

   (v) avoiding unnecessary handling

   (vi) the administration of sedatives by skilled personnel if appropriate.

3.8.15 If animals are to be held in captivity, the time of holding must be minimal and consistent with the achievement of scientific or educational objectives. If animals are to be released, all possible steps must be taken to avoid their becoming habituated to human activity.

3.8.16 Animals must be held in a way that minimises stress and injury. Management practices for captured animals should be based on current information about the normal behaviour of the species and the likely response of the animals to captivity.

3.8.17 Holding areas and containers must:

   (i) allow animals to rest comfortably

   (ii) minimise the risk of escape and injury

   (iii) be adequately ventilated

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

   (iv) minimise the risk of disease transmission.
3.8.18 Any release of animals must occur at the site of capture unless the AEC has approved an alternative site. The time of release must coincide 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. All reasonable steps must be taken at the time of release to protect animals from injury and predation.

Identification and tracking the movement of wildlife

3.8.19 The method chosen to distinguish individual animals must be that which causes the least distress and interference with the normal functioning of the animal, is consistent with the scientific aims, and does not increase the risk of predation or injury. Examples of identification of individual wildlife animals include leg banding, ear tagging, marking, microchipping, and radio-tracking devices.

3.8.20 Investigators must justify the weight, design and positioning of attached devices, which must be selected so as to minimise interference with the normal survival requirements of the animal.

3.8.21 Toe clipping must not be used unless it can be demonstrated that alternatives are unsuitable or impracticable. Toe clipping is not appropriate for marking wildlife solely for the purpose of identification but might be approved by an AEC if adequately justified (for example, when used to sample and mark an animal simultaneously, as may be required to collect a DNA sample from a very small animal).

Field techniques

3.8.22 Procedures in the field often involve only capture and release of animals, possibly facilitated by sedatives or short-acting anaesthetics. Such procedures, which include identification, examination, measurement and sampling (for example, hair, feathers, scales, blood, and stomach contents of birds), may be carried out only if the following requirements are met:

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

(ii) the potential effects on mating and survival in general are effectively accounted for and the potential negative impact of the procedures on dependent young is minimised

(iii) before release, animals that are sedated or anaesthetised must be allowed to recover to full consciousness in an observation area where they are able to maintain normal body temperature and are protected from injury and predation

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

(v) interference activities such as call playback, spotlighting, tiling, rock turning, investigation of a nest box and disturbance of nest sites must be conducted in a manner that minimises any risk to the wellbeing of the wildlife.

Voucher specimens

Voucher specimens are usually but not always whole animals that are killed humanely, and preserved and retained in a natural history collection as a permanent reference. They are used in biological survey work to validate records of the distribution of a species and as a reference specimen in case of future need for verification and taxonomic revisions. Animals are collected as voucher specimens because field identification is difficult.
3.8.23 Alternatives to collecting vouchers such as tissue samples or digital photography must be considered where appropriate.

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

(i) if it is anticipated that voucher specimens may be taken or animals destroyed to obtain samples, the need to do so must be justified in the application to the AEC

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

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

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

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

3.8.25 For some species, for example large and/or uncommon animals, tissue samples may be an acceptable alternative to whole bodies. Investigators should consult with the appropriate specialists to facilitate development of a collecting strategy that minimises the number of voucher specimens taken and maintains the scientific rigour of, and ability to verify, the research data.

**Wildlife interaction studies**

Studies of wildlife interaction may involve work in the field or the laboratory and can include interaction between species (for example, predator-prey), within species (for example, competition) and between species and habitat. The primary ethical considerations for studies of wildlife interaction are the degree of manipulation required to set up the interaction and the effect of the observer(s) on the interaction.

3.8.26 Investigators must make efforts to reduce animal usage (for example, by employing modelling theory or using museum collections).

3.8.27 Field studies must include an assessment of the wellbeing of animals that are not the prime interest of the project, including other species that may be influenced by the conduct of the project.

3.8.28 In studies of predatory encounters, natural (that is, unstaged) encounters in the field must be used if possible.

3.8.29 If staging is required in studies of predatory encounters, model predators must be used instead of live animals if possible.

**Studies involving vertebrate pest animals**

3.8.30 All principles set out in the Code must be applied equally to animals considered to be pests.

3.8.31 The primary purpose of studies involving pest species often involves methods of capture, killing or control. Applications to an AEC to perform such studies must include sufficient information for the AEC to assess the potential benefits in relation to the adverse impact on both the target and non-target animals and to maximise humane outcomes.

3.8.32 Captive feral and pest species must be killed humanely unless the objectives of a project require their release, and if the study does not involve death as an end-point.
3.9 Future of animals at the completion of their use

3.9.1 When the involvement of an animal in an activity has finished, a decision must be made as to its future, and acted upon promptly (see 2.4.33, 2.5.10).

3.9.2 Decisions regarding future of an animal should take into account the potential impact on its wellbeing and future management.

Re-housing (re-homing)

3.9.3 Opportunities to re-home animals should be considered, especially when in the course of an activity the impact on their wellbeing 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.

3.9.4 Students in primary and secondary schools must not take animals home at the completion of their use unless there are adequate safeguards in place to ensure their ongoing wellbeing, and such an outcome has been approved by the AEC (see 4.3.7). Safeguards may include a written undertaking from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal.

Return to natural environment or normal husbandry conditions

3.9.5 Animals may be either returned to normal husbandry conditions that comply with the Code or, if permitted, to their natural habitat.

3.9.6 If release of wildlife animals is permitted:

   (i) investigators must release them at the site of capture unless the AEC has approved their release at a different site

   (ii) Their time of release must coincide with the period of usual activity for the species, unless the AEC has approved a different time, in which case steps to achieve safe release, such as into appropriate cover, must be described

   (iii) the investigator must take all reasonable steps at the time of release to protect the animals from injury and predation.

Humane killing

3.9.7 When necessary, animals must be killed in accordance with the requirements of the Code (see 3.5.1-3.5.11).

Re-use

3.9.8 Any re-use of animals must comply with the Code (see 2.3.9, 2.4.47 (iii)).

Tissue sharing

3.9.9 Investigators must indicate clearly in the application to the AEC whether there is an opportunity for the sharing of tissues or animals, in accordance with the principle of reduction.

3.9.10 If possible, tissue samples from animals that have died or been humanely killed in the facility or at the completion of their use in a project should be shared among other investigators or deposited in a tissue bank, for subsequent distribution.
Section 4. The use of animals in teaching

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and post-graduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this section:

- **Teacher**: confines the meaning of ‘investigator’ to person in charge of a teaching activity involving the use of animals in primary, secondary and tertiary institutions, including vocational, veterinary, post-graduate and researcher training.

- **Activity**: any undertaking required to achieve the ‘scientific purpose’, including acquisition, transportation, production, housing, care, use and fate of animals.

- **Teaching activity**: confines the meaning of ‘activity’ to one that is intended to impart or demonstrate knowledge or techniques in any area of science. For a teaching activity, the proposed aims are the educational outcomes specified by the relevant curriculum.

- **Routine husbandry**: practices or procedures which are performed in relation to the housing and care of animals with the primary purpose of maintaining their health and wellbeing.

Section 4 covers the care and use of animals in primary, secondary and tertiary educational institutions, and includes vocational, veterinary, postgraduate and researcher training. It describes the different processes that apply in different situations, the relevance of institutional, regional and state Animal Ethics Committees (AECs) and the responsibilities of persons involved in the use of animals in teaching activities.

It is expected that animals used in teaching activities in such institutions will receive a high standard of care, that their wellbeing will be promoted according to the principles of the Code (see Section 1) and that their use will occur only in accordance with approval from an AEC.

All parts of the Code are applicable to the care and use of animals for any teaching activity. This section must be read in conjunction with other parts of the Code, in particular, Section 2 ‘Responsibilities’ and Section 3 ‘Animal Wellbeing’.

### 4.1 Key principles and responsibilities

The principles outlined in Section 1 apply to the care and use of animals for teaching activities:

4.1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes (which include teaching activities). This respect is demonstrated by:
(i) using animals only when it is justified
(ii) promoting 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) persons involved with any aspect of the care and use of animals for scientific purposes knowing and accepting their responsibilities.

4.1.2 Institutions, investigators and animal carers must be aware of and accept clearly defined responsibilities (see Section 2) and act in accordance with the Code.

From this point, the following terms will be used to clarify the applicability of this section:

• **Teacher**: confines the meaning of ‘investigator’ to person in charge of a teaching activity involving the use of animals in primary, secondary and tertiary institutions (including vocational, veterinary, postgraduate and researcher training)

• **Teaching activity**: confines the meaning of ‘an activity’ to one that is intended to impart or demonstrate knowledge or techniques involving the use of animals. For a teaching activity, the proposed aims are the educational outcomes specified by the relevant curriculum or competency requirements.

4.2 Responsibilities of teaching institutions

The responsibilities of tertiary teaching institutions are as outlined in Sections 2.1 and 2.2. Specific institutional responsibilities in the primary and secondary sectors (including secondary agricultural colleges) are outlined in this section.

4.2.1 Schools that use animals in teaching activities to achieve educational outcomes must have access to an AEC, preferably an institutional, regional, or state AEC.

4.2.2 The head of the school is ultimately responsible for all teaching activities involving animals being conducted in compliance with the Code.

4.2.3 Schools must develop procedures that support compliance with the Code and require that the school community be informed of such use. Mechanisms should include:

   (i) the development and implementation of comprehensive, inclusive and continuing processes for risk and quality management that cover all aspects of animal care and use, ranging from routine husbandry and the conduct of various procedures to emergency humane killing

   (ii) the establishment of a policy committee and/or appointment of an animal welfare officer

   (iii) the development of detailed guidelines for animal care and use, including animal husbandry, to be followed by all personnel

   (iv) the appointment of personnel responsible for the monitoring and care of animals at all times, including weekends and holidays

   (v) appropriate teacher training.

4.2.4 Detailed animal care guidelines and complete animal care records must be available in schools for inspection by AEC members and authorised external persons.

4.2.5 Facilities for holding and housing animals must operate in accordance with Part 3.3. In particular, facilities must:

   (i) provide a comfortable physical and climatic environment appropriate to the species
(ii) provide security at all times from environmental hazards and human and animal interference.

### 4.3 Responsibilities of teachers

4.3.1 Teachers are responsible for all matters that relate to the wellbeing of animals used for teaching activities. For the period of use of animals approved by the AEC until the future of the animal at the completion of an activity is finalised, teachers have personal responsibility for all matters relating to the wellbeing of animals used for teaching activities.

4.3.2 Teachers must adhere to the requirements outlined in Section 2.4 ‘Responsibilities of investigators’, including the requirement to consider the application of Replacement, Reduction and Refinement (the 3Rs) (see 1.20–35) in all aspects of their activities. Section 2.4 outlines responsibilities related to:

(i) planning of a teaching activity
(ii) submitting an application to the AEC
(iii) conduct of a teaching activity in accordance with the AEC approval
(iv) reporting to the AEC as required, including annual and final reports, and reports of unexpected adverse events.

4.3.3 In addition to responsibilities outlined in Section 2.4 “Responsibilities of investigators”, teachers must:

(i) obtain written AEC approval before commencing any activity that requires the use of animals, and conduct and direct activities as approved by the AEC. In some educational systems, the AEC may grant pre-approval, or the equivalent, for designated activities of a routine nature and of generally low impact to the wellbeing of the animal

(ii) be competent in the procedures they perform or under the direct supervision of a person competent in those procedures

(iii) arrange for supervision of students at all times during activities by a person who is competent in the procedures involving the use of animals. Teachers must ensure that the level of supervision of students takes into account the competency and responsibilities of each student

(iv) provide their contact details to all relevant personnel in the event that an animal becomes ill or is injured

(v) arrange treatment of any ill or injured animal, ranging from a minor intervention to humane killing, by qualified and/or competent personnel

(vi) ensure that animals are not kept beyond the period approved by the AEC.

4.3.4 When interaction with animals is required, alternatives to the temporary introduction of animals to the school or college, such as observing animals in purpose-built facilities, in their natural environment or under field conditions, should be considered.

4.3.5 Teachers must ensure that responsibility for animal wellbeing at each stage of the project is clear. If teaching involves the care and after-care of animals as part of professional training, the name of the person responsible for animal wellbeing, and contact information for all relevant personnel, must be clearly documented in the animal’s clinical record (see also 4.4.16).

4.3.6 Teachers must ensure that animals are not released to primary or secondary level students, or to teachers, for care overnight, or during weekends and holidays unless:
(i) adequate safeguards approved by the AEC are in place to ensure their ongoing wellbeing (see Section 3 'Animal wellbeing'). In the case of students, safeguards may include a written undertaking from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal

(ii) transport of animals between sites is in accordance with clauses 3.3.8–13 (“Transport”, Animal wellbeing section)

(iv) the housing and care away from the school is of a standard at least equal to that at the school.

4.3.7 Teachers must ensure that primary and secondary level students are not permitted to take animals home at the completion of their use unless there are adequate safeguards in place to ensure the ongoing wellbeing of the animals, and the AEC has given approval for re-homing (see 3.9.4). Safeguards may include a written undertaking from a parent or guardian for the provision of adequate, ongoing and responsible care for the animal.

4.3.8 The person in charge of the animals that are bred, supplied, held or transported for teaching activities must treat those animals with respect, and, within the scope of their responsibilities, ensure that the wellbeing of the animals is an essential consideration. They must adhere to the requirements outlined in Section 2.4 ‘Responsibilities of animal carers’.

4.4 Additional responsibilities in the various sectors

Primary level

4.4.1 Heads of primary schools must ensure that activities with animals in schools:

(i) are justified within the curriculum or have other legitimate educational purposes
(ii) occur only under conditions that do not compromise animal wellbeing
(iii) have been advised to the school community
(iv) provide a good example to students of responsible animal care.

4.4.2 The following activities using animals must not be demonstrated to, or carried out by, students in primary schools:

(i) any activity that results in a negative impact on the wellbeing of the animals
(ii) the performance or demonstration of humane killing of animals
(iii) animal breeding that does not achieve legitimate educational outcomes and fails to provide for the lifetime welfare of animals and their offspring if relevant
(iv) any use that entails conflicts of interest arising from external sponsorship or brand naming.

4.4.3 Teachers must ensure that primary-level students are aware of the special considerations applicable to the involvement of animals in classroom activities and given the opportunity to talk about the ethical and social issues involved at a level appropriate to their learning ability and comprehension.

4.4.4 Teachers must ensure that the following conditions apply when primary level students engage in activities with animals:

(i) the physical environment and resources provide safety for students and animals
(ii) the students understand the different nature and needs of animals compared with humans
(iii) a stepwise approach is taken to the handling of animals that minimises risks to animals during the development of confidence and skills by the students.
4.4.5 Teachers must keep a record of the number of students involved and the number of animals used in each activity, including animal offspring if relevant, and animal welfare outcomes. Negative impacts on animal wellbeing, deaths and actions taken must be included in records of the activity and communicated to the AEC.

Secondary level

4.4.6 The following activities using animals must not be demonstrated to, or carried out by, students in secondary schools or agricultural colleges:

(i) the performance or demonstration of humane killing of animals
(ii) surgical, invasive and other harmful procedures other than normal animal husbandry procedures (see definition)
(iii) induction of an infectious disease or illness
(iv) production of nutritional deficiency to an extent that causes distress
(v) exposure to conditions that would cause an animal to experience pain and/or distress
(vi) administration of toxins, ionising radiation and biohazards, unless for therapeutic or diagnostic purposes.

4.4.7 Teachers must ensure that the following conditions apply when secondary-level students engage in activities with animals:

(i) the physical environment and resources provide safety for students and animals
(ii) a staged program of instruction in methods of handling and caring for animals equips the students to perform the necessary tasks with care and competence.

4.4.8 Teachers must ensure that secondary-level students are given the opportunity to discuss the ethical and social issues involved in the use of animals.

4.4.9 At secondary level, AEC approval is not required for the training and application of agricultural extension work practices to achieve competency-based outcomes in routine procedures if all of the following apply:

(i) the animals are at their home property or a licensed veterinary facility
(ii) the procedures would normally occur as part of routine management
(iii) the animals are subjected to no procedures additional to what would normally occur in routine management
(iv) the trainer is competent to carry out the procedure.

4.4.10 Teachers must keep a record of the number of students involved and the number of animals used in each activity, including animal offspring if relevant, and animal welfare outcomes. Adverse impacts, deaths and actions taken must be included in records of the activity and communicated to the AEC.

4.4.11 Humane killing may be carried out as an emergency procedure by a qualified/competent person, but should not be demonstrated to students.

Tertiary level (including vocational, veterinary, postgraduate and researcher training)

4.4.12 Teachers must ensure that the following conditions apply when tertiary-level students engage in activities with animals:

(i) the appropriate physical and pharmaceutical resources are available for the handling and care of animals
(ii) a staged program of instruction in methods for handling and caring for animals equips the students to perform the necessary tasks with care and competence.

4.4.13 Teachers must ensure that tertiary-level students discuss the ethical and social issues involved in the use of animals before the use of animals commences.

4.4.14 Institutions must ensure that tertiary-level students are informed if their choice not to participate in the use of animals as part of a course would prevent them from achieving the educational outcomes due to the lack of suitable alternatives to the use of animals.

4.4.15 At the tertiary level, 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 licensed veterinary facility
(ii) the procedures would normally occur as part of routine management or veterinary clinical management of the animal
(iii) the animals are subjected to no procedures additional to what would normally occur in routine management or veterinary clinical management of the animal
(iv) the trainer is competent to carry out the procedure.

4.4.16 When teaching activities involve the attainment of professional competencies, case records must include identification of the students involved in any procedure performed (see also 4.3.5).

4.4.17 Humane killing may be carried out as an emergency procedure in tertiary institutions by a qualified/competent person, and if possible should be demonstrated to students in veterinary and nursing training settings.

4.5 Applications for teaching activities to an AEC

4.5.1 In addition to information outlined in clause 2.4.17, all applications for the use of animals in teaching in which students are to interact with, or handle, animals or carry out a procedure on an animal must include:

(i) the ratio of students to animals based on the principles of the 3Rs
(ii) the number of times that each animal will be used in each class, and/or handled per day and/or per week
(iii) the manner in which the attainment of educational outcomes will be assessed, including as applicable national learning outcomes, required Vocational Education and Training (VET) package competency achievements, endorsed program outcomes and other curriculum-related outcomes
(iv) the arrangements for animals at the end of the project (see Section 3.9 Future of animals at the end of their use).

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

(i) teachers must not vary the project without AEC approval
(ii) such approval may be granted for a maximum of three years conditional on an annual report to the AEC.

4.5.3 If a project is the subject of repeated applications to the AEC, the teacher must continue to implement the 3Rs or justify why this cannot be done.
Section 5: Complaints and non-compliance

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers, teachers, undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this section:

- **Institution**: any organisation or agency involved with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural institutions, commercial companies, wildlife groups, farms.

5.1. The institution must have procedures for addressing complaints and non-compliance related to the care and use of animals for scientific purposes (see 2.1.69 (ix), 2.2.38–39), including:

   (i) mechanisms for responding to enquiries or complaints concerning the care and use of animals within the institution and ensuring that personnel and students may voice concerns without jeopardising their employment, careers or coursework

   (ii) procedures developed in consultation with the AEC to deal with grievances related to the AEC process, including resolution of disagreements between AEC members, between the AEC and investigators or teachers, or between the AEC and the institution

   (iii) procedures developed in consultation with the AEC to deal with non-compliance with the Code by any party or person involved with the care and use of animals including investigators, animal carers, research governance officials, and external parties subject to agreements described in Clause 2.2.11.

   (iv) procedures to deal with AEC non-compliance with the Code.

5.2. The procedures must:

   (i) clearly define the mechanisms for reporting and addressing complaints and non-compliance

   (ii) clearly define the responsibilities of all parties

   (iii) ensure fair, effective, confidential processes that accord with procedural fairness and the principles of natural justice, give priority consideration to the wellbeing of the animals, and ensure appropriate reporting to the institution, AEC, and any other relevant bodies including State and Territory Government authorities.

5.3. The welfare of the animals must always be the priority where non-compliance has the potential to adversely affect animal wellbeing.
5.4. The AEC must refer irreconcilable differences between it and an investigator to the governing body of the institution for review of the due process. The ultimate decision after such review lies with the AEC and must not be overruled.

5.5. Any person who has a reasonable belief that a breach of the Code has occurred should report the matter to the AEC. The AEC must ensure that remedial action is initiated if necessary and the requisite reporting of the incident occurs. If the AEC believes the breach to be potentially serious, the AEC must alert the CEO or their delegate and ensure that activities related to the breach cease immediately, remedial action is initiated, and the requisite reporting of the incident occurs.

5.6. The AEC should ensure that an investigation into complaints and non-compliance is conducted by appropriately skilled persons following written procedures. The investigation process must at least ensure the following:

(i) all disclosures to the AEC must accord with any institutional policies on protected disclosures

(ii) all complaints/concerns must be dealt with confidentially and in accordance with procedural fairness and the principles of natural justice

(iii) the actual or potential effect of a non-compliant activity on wellbeing of the animals will determine the level of seriousness of the non-compliance and subsequent action taken by the AEC or the institution. If the level of seriousness of the non-compliance on animal wellbeing is disputed, the ultimate decision by the AEC must not be overruled by the institution

(iv) if a non-compliant activity is found by the AEC to constitute a case of research misconduct under the Australian Code for the Responsible Conduct of Research, subsequent processes must accord with the institution’s procedures for dealing with research misconduct and the full findings of the AEC inquiry must be made available to that process.

5.7. An AEC investigation of a complaint or non-compliance might include recorded interviews with the complainant, the person(s) implicated in the breach, and any witnesses; inspection of the facility or animals concerned, and advice from independent experts within or external to the institution. Depending on institutional policy, the AEC may recommend taking action against the person(s) liable for the breach, or may refer its decisions to the institution for subsequent action. The institution should make available any funds or resources required by the AEC to undertake or direct the investigation.

5.8. The institution should ensure that, if appropriate, serious breaches are reported to the relevant State or Territory Government authority as soon as possible after they are detected.

5.9. The institution should maintain a register of breaches of the Code.

5.10. For projects involving more than one AEC (see 2.1.13–14) in which an incidence of non-compliance occurs, the AEC associated with the site of the non-compliant activity should institute an inquiry in accord with this Section and provide the complete report of that enquiry to the AEC(s) of the other institution(s).
Section 6: External review of the operation of institutions and their animal ethics committees

This Code applies to all aspects of the care and use of animals for ‘scientific purposes’ where:

- **Scientific purposes**: means 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, diagnosis, product testing, and the production of biological products.

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

- **Investigator**: means any person who uses animals for ‘scientific purposes’ (defined above). Includes researchers; teachers; undergraduate and postgraduate students, persons involved with product testing, environmental testing, production of biological products, wildlife surveys.

Additional definitions specifically relevant to this section:

- **Institution**: any organisation or agency involved with the care and use of animals for scientific purposes, including universities, hospitals, teaching organisations, vocational training organisations, agricultural institutions, commercial companies, wildlife groups, farms.

### 6.1 Introduction

The Code embodies a system of self-regulation by which each institution must put in place processes to ensure that the care and use of animals for scientific purposes is undertaken in an ethical and humane manner. In keeping with the notion of self-regulation, the Code defines areas of responsibility and sets out the principles that guide these activities to ensure the expected goals are met.

A key component of any institutional process is the Animal Ethics Committee (AEC), which determines whether a proposed use of animals is justified according to the principles of the Code, and then monitors the ongoing scientific activities. Importantly, through the membership of the AEC, the Code requires input from the wider community in the oversight of these activities. Thus, the effective operation of the AEC in all aspects of its responsibilities is central to ensuring that an institution meets its responsibilities under the Code.

The information in Section 6 is intended to assist institutions in structuring the external review to best meet their specific needs and achieve the desired outcomes.

6.1.1 Institutions must ensure the conduct of an external review (see 2.1.12) which enables assessment of its compliance with the Code, identifies matters that should be addressed and informs future planning (see 2.1.7 (iii)). Such an external review should be undertaken every three years and must be undertaken at least every four years.

6.1.2 Existing government compliance processes carried out under the administration of State and Territory animal welfare legislation may achieve the outcomes set out in this section. Information on inspection, review and other government compliance processes is available from the relevant government departments. External reviews by funding bodies, regulatory bodies and institutions should if possible be coordinated to minimise time and costs.
6.2 Scope and outcomes of the external review

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

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

6.2.3 The external review should enable the institution to evaluate and, if necessary, modify processes to ensure it meets its responsibilities under the Code. To this end, the report of an external review should contain recommendations for improvement.

6.2.4 Potential additional benefits include:

(i) assisting scientific and animal care personnel to identify opportunities to promote animal wellbeing

(ii) identification of areas in need of improvement

(iii) provision of a strong impetus for improvement through recommendations for institutional support of AECs, animal houses and their staff

(iv) through an impartial critique, improved public acceptance that the institution, through its AEC, is providing effective oversight of the welfare of the animals in its charge.

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

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

(i) the AEC is operating effectively according to the requirements of the Code

(ii) AEC processes are fair and transparent to all involved

(iii) there is effective communication between the AEC and senior management of the institution/s, and the AEC and all responsible parties involved with animal use within the institution’s scope of operation

(iv) the AEC is a committee of standing within the institution

(v) the AEC receives necessary support to meet its responsibilities

(vi) the involvement of external members in AECs is actively supported and facilitated

(vii) there are effective strategies to promote and monitor the implementation of the 3Rs by the institution

(viii) there is effective monitoring of the welfare of animals

(ix) any facilities used to house animals are managed to achieve high standards of animal wellbeing

or be provided with recommendations on how these outcomes may be met.
6.3 Conduct of the external review

6.3.1 There are many acceptable models for the conduct of an external review, some of which are already in place. The approach taken will vary with particular institutional needs; however it is recommended that the review team consists of three or four people to ensure that different perspectives are considered as a part of the process.

6.3.2 Members of the review team must be external to the institution and the AEC under review. The review team may include persons who have relevant and appropriate qualifications or experience such as knowledge of animal welfare matters pertaining to research and teaching institutions, a demonstrated interest in animal welfare or experience in the administration of animal welfare and animal ethics, a background in veterinary science or experience in animal care appropriate to the institution.

6.3.3 The ways in which the review team accesses information and conducts its enquiries will vary but should include review of documentation, observation of activities and procedures, and discussions with involved parties, including those who may wish to speak with the review team in confidence. Elements of the external review should include:

(i) review of paperwork (for example, the AEC terms of reference, applications for scientific and teaching activities, procedures, minutes and reports, reports of previous reviews, approved standard operating procedures (SOPs) and records of monitoring animal wellbeing)

(ii) attendance at an AEC meeting to view the normal running of the meeting

(iii) inspection of animal teaching and research areas and animal holding facilities

(iv) discussions with the chairperson and members of the AEC, and representatives of animal users and animal carers.

6.3.4 As a way of understanding how the processes work in a given institution, the review team should consider tracking particular applications and projects from the time of application to the time of completion of a project.

6.3.5 The institution and the review team should establish an agreed timetable and approach for the conduct of the external review that includes access to information and confidentiality. The institution should facilitate involvement of personnel in the external review process.

6.3.6 The review team should refer the draft report to the AEC chairperson for comment. After consideration of all comments made by the AEC, the review team should send the completed report to the Head of the relevant institution(s). The report should include recommendations to address any problems identified with the operation of the AEC or with the application of the principles of the Code.

6.3.7 The institution should publish a summary of the external review report, possibly at an institutional annual report or web site and consider making the summary report available to the relevant regulatory authority and funding bodies of the institution (see 2.1.11).

6.3.8 Guidelines for the effective conduct of external reviews consistent with the requirements of the Code are available at relevant NHMRC and state and territory websites.