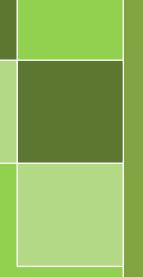


# MINISTRY OF HIGHER EDUCATION AND SCIENTIFIC RESEARCH AL-NAHRAIN UNIVERSITY

**COLLEGE OF PHARMACY** 





# College of pharmacy code for the care and use of animals for scientific purposes

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# Introduction

# Purpose of the college of pharmacy/ Al-Nahrain University for the care and use of animals for scientific purposes (the Code)

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

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

#### Scope of the Code

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

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

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

# المقدمة

تم أعداد المدونة الأخلاقية في أستعمال الحيوانات المختبرية أستناداً الى المدونة الأخلاقية الأسترالية لرعاية وأستعمال الحيوانات للأغراض العلمية بشكل أساسي. تضمنت هذه المدونة مجموعة من التعليمات والمبادئ لتوجيه الأساتذة والباحثين في المؤسسات التعليمية والبحثية لرعاية الحيوانات وفقاً لأحدث المقاييس العالمية لغرض الحصول على أفضل النتائج البحثية وفي نفس الوقت التقليل قدر الأمكان من الأثار الضارة للمواد المؤثرة بأنواعها والبيئة المحيطة على الحيوانات المختبرية.

#### Aim of this code of ethics

- 1. To ensure that the animals not exposed to harm or waste or to bad treatment.
- 2. These codes of ethics ensure the right of those scientists who are working in the laboratories.
- 3. To ensure that the scientist are fill filling the standard requirements of other global codes.

## Avoid or minimize harm, including pain and distress, to animals

#### **Animal carers must:**

- (i) ensure that their duties are performed competently, and be
- (a) competent for the duties they perform, or
- (b) under the direct supervision of a person competent to perform those duties
- (ii) monitor and assess the wellbeing of animals for which they are responsible with sufficient frequency to ensure that harm, including pain and distress, is promptly detected and managed. Where animal carers are involved in the monitoring and assessment of animals after they have been supplied to an approved project, the investigator must ensure that the scope and responsibilities for day-to-day monitoring are clearly outlined and communicated to all parties
- (iii) maintain records of monitoring and assessment of animal wellbeing
- (iv) take prompt actions based on the monitoring and assessment of animal wellbeing and in response to unexpected adverse events and emergencies, in accordance with institutional policies and procedures, and procedures approved by the AEC, including liaising with investigators and seeking veterinary advice.

# **Section 1**

# College of pharmacy principles

- 1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:
- (i) using animals only when it is justified
- (ii) supporting the wellbeing of the animals involved
- (iii) avoiding or minimising harm, including pain and distress, to those animals
- (iv) applying high standards of scientific integrity
- (v) applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:
  - (a) the Replacement of animals with other methods
  - (b) the *Reduction* in the number of animals used
  - (c) the Refinement of techniques used to minimise the adverse impact on animals
- (vi) knowing and accepting one's responsibilities.
- 1.2 The care and use of animals for scientific purposes must be subject to ethical review.
- 1.3 The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

#### Use animals only when justified

#### 1.4 Evidence to support a case to use animals must demonstrate that:

- (i) the project has scientific or educational merit, and has potential benefit for humans, animals or the environment
- (ii) the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available
- (iii) the project involves the minimum number of animals required to obtain valid data
- (iv) the project involves the minimum adverse impact on the wellbeing of the animals involved.

#### 1.5 Projects must only be undertaken:

- (i) to obtain and establish significant information relevant to the understanding of humans and/or animals.
- (ii) to maintain and improve human and/or animal health and welfare.
- (iii) to improve animal management or production.
- (iv) to obtain and establish significant information relevant to the understanding, maintenance improvement of the natural environment.
- (v) to achieve educational outcomes in science, as specified in the relevant curriculum competency requirements.

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

# Support the wellbeing of animals

- 1.7 The wellbeing of animals used for scientific purposes must be considered in terms of the cumulative effects of an animal's lifetime experience. At all stages of the care and use of an animal, measures should be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal, and support the animal's wellbeing.
- 1.8 Practices and procedures used for the care and management of animals must be based on current best practice that:
- (i) takes into consideration the relevant aspects of species-specific biology, physiology and behaviour
- (ii) is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals
- (iii) includes strategies to minimise adverse impacts.

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

# **Section 2**

#### Responsibilities

#### 2.1 Investigators

- 2.1.1 Investigators have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use.
- 2.1.2 Investigators should seek advice and information from relevant experts, including other experienced scientists, veterinarians, animal care staff, or specialists in laboratory animals, livestock or wildlife, when necessary.

#### 2.1.3 Investigators must:

- (i) Follow all Islamic roles regverdig to animals (high or/low). Treated in all aspects of the care and use of animals, including planning, conducting and reviewing projects
- (ii) apply for and obtain written approval from an AEC before commencing a project that involves the use of animals, or an amendment to an approved project
- (iii) conduct a project involving the use of animals in accordance with the conditions and requirements of the AEC approval, and cease the project if approval from the AEC is suspended or withdrawn
- (iv) undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures
- (v) ensure that procedures using animals are performed competently
- (vi) maintain records of the care and use of animals
- (vii) report to the AEC as required.
- (viii) follow relevant policies and procedures established by the institution and the AEC.
- 2.1.4 A person must be identified who has ultimate responsibility for the care and use of animals in a project. This person must:
- (i) ensure that all people involved in the project understand and accept their roles and responsibilities
- (ii) ensure that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities, including their education, training and supervision, as appropriate
- (iii) be competent with respect to the wellbeing of animals used in the project.
- This person does not relieve the individual responsibility of each investigator working with animals in the project.

#### Use animals only when justified

- (i) the project has scientific or educational merit
- (ii) the aims of the project cannot be achieved entirely or in part without the use of animals
- (iii) the potential benefits justify the potential effects on the wellbeing of the animals involved
- (iv) particular justification is provided for activities that involve severe compromise to animal wellbeing and for which the 3Rs cannot be fully applied for the activity to proceed, and for activities that involve the use of non-human primates.

#### Apply high standards of scientific integrity

- (v) the choice of species, source of the animals and biological status of the animals (e.g. genetic, nutritional, microbiological and general health status) are suited to the purpose of the project
- (vi) factors that may contribute to variability of results are taken into account, including the biological status of the animals and their living conditions (e.g. physical, environmental and social conditions)
- (vii) unintended adverse impacts on animal wellbeing that may confound experimental data are avoided or minimised
- (viii) the methods and procedures to be used accord with current best practice and are appropriate for the purpose of the project.

#### Avoid or minimise harm, including pain and distress

- (ix) known and potential causes of adverse impact on the wellbeing of animals are identified, and strategies to avoid or minimise harm, including pain and distress, are developed. Experimental and non-experimental factors must be considered
- (x) a pilot study is incorporated into the design of the project if the potential impact on the animal cannot be predicted on the basis of available evidence, to allow staged assessment of the impact on animal wellbeing and the development of strategies to avoid or minimise any adverse impact
- (xi) the wellbeing of the animals is regularly monitored and assessed by competent people

#### Accept responsibilities

- (i) all people involved in the proposed project understand and accept their roles and responsibilities in the project and the relationship of their roles and responsibilities to those of other people involved in the project
- (ii) procedures are performed competently, by people competent for the procedures or under the direct supervision of a person competent to perform the procedures, and provisions are made for the education, training and supervision of people nominated on the application, as appropriate
- (iii) the conduct of the proposed project is feasible, after consultation with the facility manager if appropriate, and taking into consideration the available resources (e.g. funding, personnel, physical, equipment), the type and availability of animals required, and requirements to support the wellbeing of the animals
- (iv) appropriate approvals, and any administrative requirements of the institution and the AEC, are in place. These could include permits and licences, documentation to certify the biological status of animals, biosafety, work health and safety considerations, and arrangements for projects conducted at more than one institution.
- 2.1.2 Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution.

#### Obtaining approval from an animal ethics committee

- 2.1.3 Before commencing a project, or an amendment to an approved project, investigators must:
- (i) submit an application to the AEC
- (ii) obtain written approval from the AEC.
- 2.1.4 Investigators must use plain English in the application to the AEC to ensure that all AEC members are provided with sufficient information to participate effectively in the assessment of the application.

#### Apply high standards of scientific integrity

- 2.1.5 Investigators must:
- (i) confirm that animals are suitable for their proposed use at the time they are supplied or procured for that use
- (ii) ensure that procedures involving animals accord with current best practice

#### Support animal wellbeing

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

#### Accept responsibilities

- 2.1.7 Investigators must:
- (i) act in accordance with their role and responsibilities in the project
- (ii) ensure that the scope of monitoring the wellbeing of the animals at all stages of their care and use in the project is clearly outlined and communicated to all parties. Depending on the type of project, this may include monitoring by animal carers.

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

- 2.1.8 Investigators must take prompt action regarding provisions for animals at the conclusion of their use, in accordance with procedures and protocols approved by the AEC.
- 2.1.9 Investigators must use humane procedures for killing an animal that are appropriate to the species and circumstances.
- 2.1.10 Unless otherwise required, investigators must ensure that all carcasses and tissues from animals that have died or been humanely killed are disposed of in a sanitary and appropriate manner.
- 2.1.11 Investigators should ensure that, if practicable, tissue samples from animals that have died or been humanely killed are provided or made available to other investigators for their work, or deposited in a tissue bank for subsequent distribution.

#### **Projects involving hazards**

- 2.1.12 For projects that involve hazards to other animals and humans, investigators must ensure that:
- (i) all personnel are aware of these hazards, and any potential pathogenic effects from these hazards
- (ii) appropriate procedures are implemented for quarantining and handling animals that pose a risk to other animals and to humans because of naturally acquired or experimentally induced infectious disease.

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

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

#### 2.1.14 Investigators must:

- (i) not generate a new animal line using genetic modification if a similar, suitable animal model is available to the investigator or a relevant in vitro method can be used to achieve the aims of the project
- (ii) ensure that AEC approval is in place from the start of the process until the impact of the genotype on wellbeing is known, and data on mortality, morbidity and population health of the new line are available. Procedures used for creating and breeding these animals must be regarded as part of a project and must be included in the project application to the AEC
- (iii) use methods to support and safeguard the wellbeing of the animals involved.
- (iv) advise the AEC when the clinical status of the animals changes to a kind or degree that was not predicted
- (v) maintain records of the number of animals used to create and maintain the new animal line, and the lineage and health status of the animals. Following approval from the AEC for the new animal line to be treated as breeding stock, the facility manager or animal carer is responsible for records of the maintenance of the animal line.
- (vi) ensure that reports are provided to the AEC, including:
- (a) regular reports on the monitoring of a new animal line at a frequency determined by the AEC
- (b) a final report on the generation of the new animal line
- (vii) ensure that animals and their offspring are not sold, or transferred to another facility, unless the recipient of the animals accepts full responsibility for completion of the phenotype assessment.

#### Using privately owned animals

- 2.1.15 For projects involving the use of privately owned animals (e.g. livestock or companion animals), investigators must:
- (i) ensure that all people involved in the care and use of such animals are aware of and accept their responsibilities relating to the animals
- (ii) ensure that people responsible for the daily management of the animals during the project are familiar with and understand the Code, and are competent.

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

#### Xenotransplantation

In the context of xenotransplantation:

- a 'recipient animal' is an animal that receives a transplant, implant or infusion of either live cells, tissues or organs from another species, or body fluids, cells, tissues or organs that have ex vivo contact with live cells, tissues or organs from another species
- a 'source animal' is an animal from which body fluids, cells, tissues or organs for use in xenotrans- plantation are obtained.
- 2.1.16 For projects involving xenotransplantation, investigators must ensure that measures are in place to minimise the potential for xenosis, including the appropriate screening of source animals, management of biohazardous waste and emergency plans for the management of adverse outcomes. Investigators should consider collecting and retaining tissue samples from source and recipient animals.

#### **Maintaining records**

- 2.1.17 Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers.
- 2.1.18 Investigators must ensure that records include:
- (i) the origin/source of the animals and provisions for the animals at the conclusion of their use
- (ii) the number of animals used
- (iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes
- (iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result
- (v) any additional information requested by the AEC
- (vi) names of people performing the procedures and entering the records
- (vii) names and contact details of people responsible for monitoring and emergency incidents.
- 2.1.19 When activities involve genetically modified animals, records must include:
- (i) the number of animals used for the creation and maintenance of genetically modified animals
- (ii) the lineage and health status of the animals.

# **Section 3**

# **Animal wellbeing**

This section applies to all species of animals used for scientific purposes, and to all activities and situations involving their care and use. It outlines the principles for supporting and safeguarding the wellbeing of animals used in terms of the animal's lifetime experience.

### College of pharmacy principles

- (i) The wellbeing of animals used for scientific purposes must be considered in terms of the cumulative effects of the animal's lifetime experience. At all stages of the care and use of an animal, measures should be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal, and support the animal's wellbeing.
- (ii) Animals have a capacity to experience pain and distress, even though they may perceive and respond to circumstances differently from humans. Pain and distress may be difficult to evaluate in animals. Unless there is evidence to the contrary, it must be assumed that procedures and conditions that would cause pain and distress in humans cause pain and distress in animals.

Decisions regarding the possible impact of procedures or conditions on an animal's wellbeing must be made in consideration of an animal's capacity to experience pain and distress.

- (iii) Steps must be taken at all times to safeguard the wellbeing of animals by avoiding or minimising harm, including pain and distress, to the animals.
- (iv) The development of strategies to support and safeguard animal wellbeing must include the application of high standards of scientific integrity, and the application of Replacement, Reduction and Refinement.

# 3.1 Identify known and potential causes of adverse impacts on animal wellbeing

- 3.1.1 Circumstances with the potential to have an adverse impact on the wellbeing of an animal must be identified. Experimental and non-experimental causes must be considered, including acquisition and breeding, capture, transport, housing and care, social and physical environment, handling, restraint, sample collection, non-surgical procedures, anaesthesia, surgical procedures, genetic modification, humane killing and provisions for the animal at the conclusion of their use.
- 3.1.2 In each instance, factors that might contribute to the level and duration of harm, including pain and distress, and the risk of such occurrences, must be considered and assessed, taking into account the predicted likelihood and consequences.
- 3.1.3 If the potential impact on the animal, or the validity and efficacy of criteria for intervention to minimise harm, including pain and distress, cannot be predicted on the basis of available evidence, the incorporation of a pilot study into the design of the project must be considered.

# Take steps to avoid or minimize adverse impacts on animal wellbeing Support the animals' wellbeing

- 3.1.4 Animals must be cared for and managed so that species-specific or strain-specific physiological and behavioral needs are met.
- 3.1.5 Practices and procedures used for the care and management of animals must be appropriate for the situation, the species and strain of animal, and the activities to be undertaken, and must be based on current best practice. Where the requirements of a project or activity preclude or modify these conditions, special ethical consideration and specific AEC approval is required.
- 3.1.6 The living conditions in indoor facilities in which animals are bred, held and used must be checked daily.
- 3.1.7 Procedures must be in place at all stages of animal supply, housing and care to ensure that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use.
- 3.1.8 Animals that are sourced, bred or held for scientific purposes must be suitable for their proposed use, taking into account their biological characteristics, temperament, behavioral conditioning, microbiological and nutritional status, and general state of health. Where appropriate, the suitability of animals should be assessed before they are selected.
- 3.1.9 Assessment of animals (e.g. wellbeing, suitability for purpose, health) must be undertaken by a competent person, or under the direct supervision of a competent person.
- 3.1.10 Animals should be acclimatized to the housing/holding conditions, experimental conditions and personnel, and any changes to such conditions, before they are used. Animals that do not adapt satisfactorily should not be used. Prompt provisions should be made for such animals, as appropriate.
- 3.1.11 For animals that normally live in social groups, social isolation or separation from a group must be avoided unless specific justification is provided to, and approval is obtained from, an AEC.
- 3.1.12 Animals must be identified either individually or in groups.

#### Avoid or minimize harm, including pain and distress

- 3.1.13 Animals used must be suited to the purpose of the project or activity, and their suitability must be assessed before they are used.
- 3.1.14 Scientific and educational methods used must accord with current best practice.
- 3.1.15 Procedures, husbandry and care must be performed competently, by people who are competent or by people under the direct supervision of a competent person.
- 3.1.16 Potential causes of pain and distress that are not part of the design of a project or activity should be eliminated or controlled to minimize the adverse impact on animal wellbeing and the risks to quality of data.

- 3.1.17 If pain and distress are predicted or unavoidable consequences of a project, methods for minimizing such pain and distress must be incorporated into the design of the project, including:
- (i) establishing and implementing early intervention points and endpoints.
- (ii) monitoring animals to ensure that the planned endpoints are detected, and taking appropriate action.
- (iii) using pharmacological agents and non-pharmacological measures for avoiding and minimizing pain and distress.
- 3.1.18 Where it is established that the aim(s) of the project involves animals experiencing pain and distress that will not be alleviated:
- (i) the planned endpoint of the project must be as early as feasible to avoid or minimize pain and distress to the animals
- (ii) the animals must be monitored and assessed so that the planned endpoints are detected, and actions must be taken in accordance with the AEC approval for the project.

#### Monitor animals and take appropriate action

- 3.1.19 Animals must be monitored and assessed:
- (i) by a competent person who is knowledgeable about the normal behavior and signs of pain and distress for the species, or a person under the direct supervision of a competent person
- (ii) with sufficient frequency to ensure that any harm, including pain and distress, is promptly detected and managed
- (iii) in accordance with the AEC approval for the project or activity.
- 3.1.20 Methods for monitoring and assessment of animal wellbeing should include:
- (i) the criteria that will be used to assess wellbeing
- (ii) the level and frequency of monitoring to ensure that any changes in an animal's condition are detected early
- (iii) the criteria that will be used to determine when action is required
- (iv) actions that will be taken so that adverse impacts on animal wellbeing, including predicted effects and unforeseen complications, are addressed rapidly and effectively
- (v) the methods for recording observations, treatments and actions
- (vi) flexibility to ensure a rapid and effective response to changes during the course of the project or activity.
- 3.1.21 Records of the monitoring and assessment of animal wellbeing must be:
- (i) sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies
- (ii) accessible to all people involved in the care of the animal
- (iii) available for audit by the institution, the AEC and authorized external reviewers.

- 3.1.22 Prompt action must be taken based on the monitoring and assessment of animals, in accordance with:
- (i) institutional and AEC policies and procedures.
- (ii) the intervention points and humane endpoints approved by the AEC for a project, or actions documented in procedures for animal care approved by the AEC.
- 3.1.23 Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress, in accordance with institutional and AEC policies and procedures. Alleviation of pain and distress of a severity that was not anticipated in an approved project or activity must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity. If necessary, animals must be killed humanely without delay.
- 3.1.24 When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person.

#### Set intervention points and experimental humane endpoints

- 3.1.25 If pain and distress are predicted or unavoidable consequences of a project, validated criteria that are appropriate for the species and the nature and time course of the predicted effects must be established to identify:
- (i) the earliest time point at which data can be obtained and the study completed (experimental endpoint[s])
- (ii) when intervention is necessary to minimize pain and distress (intervention point[s])
- (iii) when the animal should be humanely killed, regardless of whether the aims of the study have been achieved (humane endpoint[s]).
- 3.1.26 Intervention points and endpoints must be applied as early as feasible and ensure that:
- (i) the duration and extent of pain and distress are minimized
- (ii) valid data are obtained at the earliest time point before or following the onset of pain and distress.
- 3.1.27 'Death as an endpoint' must be replaced with early experimental and humane endpoints whenever possible. Where death as an endpoint is essential for the aim(s) of the project and cannot be avoided:
- (i) the project must be designed to minimize the number of animals that will die
- (ii) steps to avoid or minimize pain and distress, including early experimental and humane endpoints, must be considered, implemented and reviewed at all stages of the project.

#### 3.2 Animal care and management

#### **Animal health**

- 3.2.1 Procedures for ensuring that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use (see Clause 3.1.8) must include:
- (i) monitoring and assessment of animals by a competent person with sufficient frequency to ensure that sick or injured animals are promptly detected and identified, and that appropriate action is taken
- (ii) provision of veterinary clinical care and advice
- (iii) prompt detection and effective management of disease outbreaks and emergencies such as fire, power failure and biosafety issues
- (iv) preventive protocols under veterinary direction or supervision, as appropriate, including animal biosecurity; quarantine; and the surveillance, diagnosis, treatment and control of diseases.

#### **Transport of animals**

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

#### 3.2.3 Transport methods and arrangements must:

- (i) be appropriate for the species and the circumstances
- (ii) minimise harm, including pain and distress, arising from factors such as containment, movement, noise, disruption of social groups, and changes in the environment and personnel
- (iii) ensure that animals are:
  - (a) provided with appropriate food and water when necessary
  - (b) provided with the physical and social environment appropriate for the species
  - (c) protected from, and treated for, injury and disease.
- 3.2.4 Both suppliers and recipients of animals must ensure that satisfactory delivery procedures are in place, including receipt of the animals by a responsible person, accountability for animal numbers, and adherence to other regulatory codes, such as quarantine.
- 3.2.5 People responsible for monitoring animals during transport must be able to recognise and respond to animal needs during transport.

#### Acclimatization and conditioning

- 3.2.6 If there is any change in the housing/holding conditions at the time an animal is supplied or selected for use in a project, sufficient time should be allowed for the animal to acclimatize before the project commences.
- 3.2.7 Before a project commences, the animals should be conditioned to the handling, experimental conditions and people who will conduct the procedures.
- 3.2.8 Animals that do not adapt satisfactorily after acclimatization and/or conditioning should not be used, and prompt provisions should be made for such animals, as appropriate.

#### Housing and care

- 3.2.9 Animals must be provided with accommodation, physical and social environmental conditions, food, water and care to meet species-specific or strain-specific physical and behavioral needs. If the requirements of a project or activity preclude or modify these conditions, special ethical consideration and specific AEC approval are required.
- 3.2.10 Facilities must be appropriately staffed, designed, constructed, equipped, maintained and managed to achieve a high standard of animal care. Facilities must be suitable for the type of animals kept and the aims of the activities undertaken.
- 3.2.11 Animals held outdoors must be protected from adverse environmental conditions and predation, and provided with access to adequate shelter, food and water.
- 3.2.12 The housing and care of animals that are administered infectious organisms must take into account risks to other animals and to humans, and appropriate procedures to minimize such risks must be implemented.

#### Indoor facilities

- 3.2.13 Indoor facilities should be designed and operated to:
- (i) control environmental factors such as air quality, temperature, humidity, light and noise within limits compatible with the health and wellbeing of the species held. Capacity for control of the microclimate by the caging systems or by the individual animals should be taken into account
- (ii) enable appropriate segregation of species or activities that might affect other animals held in the same facility
- (iii) exclude vermin
- (iv) limit contamination associated with the keeping of animals, and the delivery of food, water and bedding
- (v) prevent the entry of unauthorized people and other animals.
- 3.1.1 Indoor facilities must be clean, tidy and in good repair. Walls and floors should be constructed of safe, durable materials that can be cleaned and disinfected readily. There must be adequate storage areas for food and equipment, a reticulated water supply and proper facilities for drainage, if appropriate.
- 3.1.2 Noxious odors, particularly ammonia, must not exceed a level compatible with the health and comfort of the animals and personnel.
- 3.1.3 Chemicals used in a facility, including detergents, disinfectants, deodorizers and pesticides must be appropriate for the purpose, and contamination of the animals' environment must be avoided during their use. Chemicals should be used in consultation with the relevant investigators who use the facility.

#### Pens, cages and containers

#### 3.2.14 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 minimize injury to animals
- (vii) large enough for the species and the number of animals held
- (viii) compatible with the behavioral needs of the species.
- 3.2.15 The number of animals in, and placement of, cages, pens or containers should enable the social and environmental conditions for the species to be maintained.
- 3.2.16 If an animal of a species that normally lives in social groups must be housed in isolation or separated from a group, the duration of such housing conditions must be minimized. The animal should be able to see, hear and smell animals of the same species unless such contact is precluded by the requirements of the activity.

#### Food and water

3.2.17 Animals must receive, and be able to access, appropriate, uncontaminated, nutritionally adequate food of a quantity and composition that maintain normal growth of immature animals and normal weight of adult animals, and meet the requirements of pregnancy, lactation or other conditions. Clean, fresh drinking water must be available at all times, as suitable for the species.

## 3.3 Specific procedures

#### General requirements that apply to all procedures

- 3.3.1 Procedures must:
- (i) be appropriate for the species and the circumstances
- (ii) accord with current best practice
- (iii) be compatible with the purpose and aims of the project or activity
- (iv) cause the least harm, including pain and distress, to the animals
- (v) be performed competently, and by a person who is competent for the procedures, or under the direct supervision of a person who is competent to perform the procedures.

#### Handling and restraining animals

- 3.3.2 If handling or restraint is likely to cause harm, including pain and distress, to the animal, the use of chemical restraint (e.g. sedatives) should be considered.
- 3.3.3 When handling or restraint is required, the animal should be conditioned to the method used, whenever possible.
- 3.3.4 If prolonged restraint or confinement of an animal is required as part of a project:
- (i) methods used must take into consideration the animal's physiological and behavioral needs, and ability to
- (ii) the animals must be assessed regularly by a person with veterinary, or other appropriate, qualifications who is independent of the project
- (iii) if any adverse impact is detected, the animal must be released, or the method of restraint must be modified to minimize that impact.

#### Routine husbandry procedures

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

#### **Identification of animals**

- 3.3.6 Methods used to identify animals must:
- (i) be appropriate for the species and the circumstances
- (ii) be compatible with the purpose and aims of the project or activity
- (iii) involve non-invasive methods whenever possible. The use of invasive methods must conform with.
- (iv) cause the least harm, including pain and distress, to the animals.

#### Injections, blood sampling and non-surgical procedures

- 3.3.7 When performing injections, blood sampling and non-surgical procedures, procedures used must:
- (i) minimize the risk of an animal developing complications (e.g. tissue damage, infection, haematoma, bleeding)
- (ii) be performed under aseptic conditions if there is a potential risk of infection
- (iii) if the procedure involves the transplantation of cells or tissues, include management of the effects of tissue rejection and immunosuppression.

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

- 3.3.8 The use of local and general anaesthetics, analgesics and sedatives must be considered as part of a plan to manage pain and distress, and such use should at least parallel their use in current veterinary or medical practice.
- 3.3.9 When anaesthetics, analgesics and sedatives are used, the choice of agent and its administration must:
- (i) be appropriate for the species, age, developmental stage and physiological status of the animal
- (ii) be compatible with the purpose and aims of the project or activity, and appropriate for the type of procedure.
- 3.3.10 Unless there is evidence to the contrary, it must be assumed that fetuses have comparable requirements for anaesthesia and analgesia as adult animals of the species. Approaches to avoid or minimize pain and distress in the fetus must be designed accordingly.
- 3.3.11 Regardless of their mechanism of action, the effectiveness of all anaesthetics must be monitored throughout anaesthesia.
- 3.3.12 When general anesthesia is used, procedures must conform with current veterinary or medical practice and ensure that:
- (i) induction is smooth, with minimum distress to the animal
- (ii) the animal and the effectiveness of the anesthetic are monitored to maintain an adequate plane of anesthesia, minimize physiological disturbances, and monitor and manage potential complications (e.g. hypothermia, and cardiovascular and respiratory depression)
- (iii) when an animal is to recover from an anesthetic, the animal is monitored and cared for to avoid and manage complications during the post-anesthetic period (e.g. airway obstruction, hypothermia, cardiovascular and respiratory compromise, injury from uncoordinated movements or other animals)
- (iv) records are maintained of the use of anesthetics and other drugs, monitoring of the animal, and the management of complications.
- 3.3.13 Animals that develop signs of pain and distress must be treated promptly, in accordance with the intervention points and humane endpoints approved by the animal ethics committee (AEC), and institutional and AEC policies and procedures.

- 3.3.14 Neuromuscular blocking agents must only be used in conjunction with adequate general anaesthesia or an appropriate surgical procedure that eliminates sensory awareness. The animal must be monitored to ensure that an adequate plane of anaesthesia is maintained or sensory awareness has been eliminated. Because the paralysis abolishes many criteria for assessing anaesthetic depth and pain perception (e.g. character of respiration, and corneal and flexor withdrawal reflexes), continuous or frequent monitoring of physiological variables (e.g. heart rate, blood pressure, pupil size, electroencephalogram), together with the effects on these of mild sensory stimuli, must be used.
- 3.3.15 Electroimmobilisation must not be used as an alternative to analgesia or anaesthesia.

#### **Surgical procedures**

- 3.3.16 The wellbeing of animals that have undergone surgical procedures must be supported and safeguarded by:
- (i) conducting surgical procedures under appropriate local and/or general anaesthesia. The requirement for anaesthesia of the fetus or embryo must be taken into account before conducting surgery on a pregnant female
- (ii) using aseptic procedures if the animal is expected to recover from surgery
- (iii) ensuring that all procedures conform to accepted standards in veterinary or medical practice, as appropriate for the procedure and circumstances
- (iv) ensuring that potential complications during and after the procedure are avoided or minimised, that animals are monitored for complications, and that any complications that do occur are effectively managed. Potential complications include hypothermia, dehydration, blood loss, tissue trauma, metabolic disturbances, poor tissue perfusion and cardiovascular and/or respiratory failure, infection, delayed wound healing and impaired function
- (v) ensuring that pain management that is appropriate for the species and the procedure is effective, and includes effective anaesthesia as well as avoiding and minimising postoperative pain and distress
- (vi) ensuring that, for non-recovery surgery, the animal remains unconscious throughout the procedure and death is confirmed at the end of the procedure
- (vii) ensuring that animals that undergo more than one surgical procedure have recovered to good general health before any subsequent procedure is performed, unless otherwise approved by an AEC.

### **Post-procedure care**

#### 3.3.17 After any procedure:

- (i) animals must be monitored and assessed with sufficient frequency to ensure that both predicted and unforeseen consequences are detected early. If an animal has undergone a surgical procedure, surgical wounds must be inspected regularly for evidence of infection and progress of healing
- (ii) prompt action must be taken so that predicted and unforeseen consequences, including pain and distress, are addressed rapidly and effectively.
- (iii) appropriate care and supportive treatment that will support and safeguard animal wellbeing must be provided, including nursing of the animal, pharmacological management of pain and distress, provision of fluid and nutritional support, and prevention or control of infection
- (iv) appropriate records must be maintained and made accessible to all people involved in the postprocedural care of the animal.

- 3.3.18 If an animal must be housed in isolation or separated from a group after a procedure, the duration of such housing conditions should be minimized. The animal should be able to see, hear and smell animals of the same species unless such contact will interfere with data collection and interpretation.
- 3.3.19 If an animal is to be isolated or restrained for a prolonged period after a procedure, the animal should be conditioned to the housing or restraint conditions before the procedure is undertaken.
- 3.3.20 Animals that have undergone surgery for transplantation of organs or tissues must be managed to avoid or minimize adverse impacts from potential rejection of the transplant and the effects of immunosuppression.

#### Projects involving the fetus or embryo

- 3.3.21 Where a project involves the fetus or embryo, the requirements for anaesthesia and analgesia of the fetus or embryo must be taken into account.
- 3.3.22 If a procedure conducted on a fetus or embryo would compromise the ability of the animal to survive after birth or causes untreatable pain and distress, the animal (neonate/fetus/embryo) must be killed humanely before or immediately after birth.

#### Induction of tumors

- 3.3.23 For animals in studies that involve the induction of tumors, methods used and endpoints chosen must ensure that valid results are obtained with minimal harm, including pain and distress, to the animal. Animal wellbeing must be supported and safeguarded by:
- (i) considering potential adverse impacts associated with the development and biology of the tumor (including growth rate, invasiveness, potential for ulceration, development of metastases and cachectic effects), effects of therapeutic agents, side effects of immunotherapy including irradiation, and consequences of surgery involved in transplantation of tumors
- (ii) choosing an appropriate implantation site or method of induction of the tumor that causes the least harm, including pain and distress, to the animal. The footpad, tail, brain or eye must not be used unless there is no valid alternative
- (iii) monitoring the growth or impact of the tumor and efficacy of therapy, and using early experimental endpoints, to obtain valid results as early as possible. Death from the tumor must not be an endpoint
- (iv) establishing and implementing early intervention points and humane endpoints.
- (v) wherever possible, using techniques that facilitate measurement of tumor growth and determination of early endpoints
- (vi) monitoring and assessing animals for signs of pain and distress, including changes in body condition and body weight; ulceration; adverse effects of procedures used for induction of the tumor; signs of growth, invasion and metastases of the tumor; and toxic effects of therapeutic agents.

#### Capture and handling

- 3.3.24 To minimize the risk of injury or stress-induced disease, procedures for the capture and handling of wildlife must include:
- (i) the involvement of a sufficient number of competent people to restrain animals in a quiet environment and prevent injury to animals and handlers
- (ii) chemical restraint (e.g. sedatives) where appropriate, if the period of handling is likely to cause harm, including pain and distress, to animals
- (iii) restraint and handling of animals for the minimum time needed to achieve the purpose and aims of the project or activity
- (iv) making provisions for captured animals that are ill or injured, including treatment of pain and distress.

#### Use of traps

- 3.3.25 If trapping is used to capture wildlife, the wellbeing of both target and non-target animals must be considered by:
- (i) selecting a trap that is suited to the species and the circumstances, and designed to ensure protection of trapped animals from injury, predators, parasites and environmental extremes
- (ii) monitoring traps to minimize the time animals will spend in traps, and to avoid or minimize adverse impacts on trapped animals.
- (iii) minimizing the number of days of continuous trapping within an area, and removing or deactivating traps that are not in use or are no longer required
- (iv) minimizing the potential adverse impact caused by disrupting social structure, and adverse impacts on dependent young (e.g. by avoiding trapping in the breeding season)
- (v) minimizing the numbers of non-target species that are trapped, and implementing a management plan for captured non-target species to ensure their wellbeing or ensure that they are humanely killed.
- 3.3.26 Wet pitfall traps must not be used to capture vertebrate animals. If wet pitfall traps are used to capture invertebrates, they must be managed and monitored to minimize the inadvertent capture of vertebrates, including by locating the trap where vertebrate entry is unlikely and using the smallest possible trap diameter.

#### Tracking the movement of wildlife

3.3.27 When devices are used to track the movement of wildlife, the weight, design and positioning of attached devices must minimize interference with the normal survival requirements of the animal.

#### **Interference activities**

Interference activities such as call playback, spotlighting, tiling, rock turning, investigating a nest box and disturbing nest sites must be conducted in a manner that minimizes any risk to the wellbeing of the wildly.

#### Humane killing

- 3.3.28 The method and procedures used for killing an animal must be humane and:
- (i) avoid pain or distress and produce rapid loss of consciousness until death occurs
- (ii) be compatible with the purpose and aims of the project or activity
- (iii) be appropriate to the species, age, developmental stage and health of the animal
- (iv) require minimum restraint of the animal
- (v) be reliable, reproducible and irreversible
- (vi) ensure that animals are killed in a quiet, clean environment away from other animals
- (vii) ensure that death is established before disposal of the carcass, fetuses, embryos and fertilised eggs.
- 3.3.29 Dependent offspring of animals to be killed must be cared for or humanely killed.

#### Rehousing (rehoming)

- 3.3.30 Opportunities to rehome animals should be considered wherever possible, especially when the impact of the project or activity on the wellbeing of the animal has been minimal and their physiological condition and behavioural attributes indicate that they can be introduced to a new environment with minimal, transient impact on their wellbeing.
- 3.3.31 An animal must not be released to a person at the conclusion of their use unless:
- (i) the AEC has approved such release
- (ii) safeguards are in place and approved by the AEC to ensure the ongoing wellbeing of the animal. In the case of primary and secondary level students, safeguards must include a written commitment from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal, and demonstrating an awareness of relevant legislative requirements regarding the animal being rehomed
- (iii) transport of animals between sites.

#### Return to normal husbandry conditions or natural habitat

3.3.32 The return of animals to normal husbandry conditions and the release of wildlife to their natural habitat must be in accordance with current best practice.

# **Section 4**

# The care and use of animals for the achievement of educational outcomes in science

## College of pharmacy principles

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

- (i) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes.
- (ii) The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal on completion of their use.
- (iii) People involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code.
- (iv) All activities, including projects, that involve the care and use of animals for scientific purposes must:
- (a) be subject to ethical review, approval and monitoring by an AEC
- (b) commence only after approval has been granted by an AEC
- (c) be conducted in accordance with the AEC approval
- (d) cease if approval from the AEC is suspended or withdrawn.

# Responsibilities

#### **Institutions**

- 4.1 The responsibilities of institutions involved in the care and use of animals for teaching activities.
- 4.2 The responsibilities of institutions regarding the governance of an AEC overseeing the care and use of animals in teaching activities.
- 4.3 Institutions must ensure that animals are used for teaching only when their use is essential to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements, and suitable alternatives to replace the use of animals to achieve the educational outcome are not available.
- 4.4 Institutions must identify the person with ultimate responsibility for the care and use of animals in teaching activities. This person must:
- (i) ensure that all people involved in the care of animals understand and accept their role and responsibilities.

- (ii) ensure that procedures and resources are in place so that all people involved in the care and use of animals can meet their responsibilities
- (iii) be competent with respect to the wellbeing of animals under their care.

This person does not relieve the individual responsibility of the teacher who is involved in the care and use of animals in teaching activities.

#### Primary and secondary sectors (including secondary agriculture college)

- 4.5 Institutions involved in the care and use of animals in teaching activities in the primary and secondary sectors must ensure that they have access to an AEC. This may be a regional or central state AEC.
- 4.6 Institutions must ensure that the following activities using animals are not demonstrated to, or carried out by, primary or secondary level students:
- (i) animal breeding that does not achieve an educational outcome in science and fails to provide for the lifetime welfare of animals (and their offspring, if relevant).
- (ii) surgical, invasive and other harmful procedures, other than routine husbandry procedures
- (iii) induction of an infectious disease or illness
- (iv) production of nutritional deficiency
- (v) exposure to conditions that would cause an animal to experience pain and distress
- (vi) administration of drugs or chemicals unless for therapeutic or diagnostic purposes
- (vii) administration of toxins, ionising radiation or biohazards.
- 4.7 Institutions must ensure that humane killing of animals is not demonstrated to, or carried out by, primary or secondary level students unless it is required:
- (i) to achieve an educational outcome in science as specified in the relevant curriculum or competency requirement, or
- (ii) as part of veterinary clinical management of an animal, under the direction of a veterinarian.

#### Animal ethics committees

The responsibilities of an AEC overseeing the care and use of animals in teaching activities.

#### Teachers as investigators and animal carers

- 4.8 When teachers use animals for teaching activities, the teacher has the responsibilities of an investigator.
- 4.9 When teachers are responsible for the care of animals that are used for teaching activities, including during their acquisition, transport, breeding, housing and husbandry, the teacher has the responsibilities of an animal carer.
- 4.10 Teachers have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use.
- 4.11 Teachers must ensure that students have the opportunity to discuss the ethical and social issues, and legal responsibilities, involved in the care and use of animals for scientific purposes, at a level appropriate to their learning ability and comprehension, and before the use of animals commences.

- 4.12 Teachers must ensure that the students are supervised by a person who is competent for the procedure being performed, and that the level of supervision of students takes into account the competency and responsibilities of each student.
- 4.13 Teachers must ensure that animals are not released to students, or any other person, for temporary care, or at the completion of the use of the animal, unless:
- (i) the AEC has approved such release
- (ii) safeguards are in place and approved by the AEC to ensure the ongoing wellbeing of the animal. In the case of primary and secondary level students, safeguards must include a written commitment from a parent or guardian for the provision of adequate, ongoing and responsible care of the animal, and demonstrating awareness of relevant legislative requirements regarding the animal.
- (iii) transport of animals between sites.

#### Obtaining approval from an animal ethics committee

- 4.14 Teachers, and the person with ultimate responsibility for a teaching activity, must follow institutional and AEC procedures when submitting an application to an AEC and provide information in the application form. The AEC may be a regional or central state AEC.
- 4.15 AEC approval may be sought to repeat a particular teaching activity that may involve different students, times, locations or animals.
- 4.16 AEC approval is not required for the training and application of agricultural extension work practices, or the training of students in veterinary science, veterinary nursing or animal technology to achieve competency-based outcomes in routine procedures if all of the following apply:
- (i) the animals are at their home property or a premises licensed by a state or territory Veterinary Surgeons Board
- (ii) the procedures would normally occur as part of routine management or veterinary clinical management of the animal
- (iii) the animals are not subjected to anything additional to routine management or veterinary clinical management of the animal
- (iv) the teacher is competent to carry out the procedure.