UMS
UNIVERSITI MALAYSIA SABAH

PEKELILING
TIMBALAN NAIB CANSELOR (PENYELIDIKAN DAN INOVASI)

Tarikh : 27 Julai 2015 Bil: 2/2015 Ruj: UMS/PPI1.3.2/800-1/2/3

RESEARCHER'S GUIDELINES ON CODE OF PRACTICE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES

1.0 TUJUAN

Pekeliling ini dikeluarkan adalah bagi memaklumkan pemakaian *Researcher's Guidelines On Code Of Practice For The Care And Use Of Animals For Scientific Purposes* di Universiti Malaysia Sabah (UMS).

2.0 LATAR BELAKANG

2.1 Mesyuarat Lembaga Pengarah Universiti (LPU) Kali Ke-67 yang bersidang pada 7 Julai 2015 telah mengesahkan cadangan mewujudkan *Researcher's Guidelines On Code Of Practice For The Care And Use Of Animals For Scientific Purposes.*

2.2 Penggunaan haiwan untuk pengajaran, penyelidikan atau kajian haruslah berlandaskan Akta Pencegahan Kekejaman kepada Haiwan 1986. Mengikut kod amalan National Institute of Health (NIH) untuk penjagaan dan penggunaan haiwan bagi tujuan santifik ia perlulah mendapatkan kelulusan daripada Jawatankuasa Etika Haiwan (JEH) Universiti.

2.2 Semua kakitangan Universiti yang ingin menggunakan haiwan untuk pengajaran, penyelidikan atau kajian mesti mendapatkan kelulusan etika dari JEH Universiti sebelum sebarang penggunaan atau penglibatan dengan haiwan, tanpa mengira di mana mereka berada, di mana haiwan boleh ditempatkan atau digunakan, atau sumber pembiayaannya. Semua projek penyelidikan yang dikendalikan oleh pelajar juga mesti menerima pelepasan daripada JEH Universiti.

3.0 PELAKSANAAN

3.1 Garis panduan ini merangkumi perkara-perkara berikut:

a. Dokumen *Researcher's Guidelines On Code Of Practice For The Care And Use Of Animals For Scientific Purposes.*
b. Borang Permohonan Kelulusan Jawatankuasa Etika Haiwan
c. Carta Alir Permohonan Kelulusan Jawatankuasa Etika Haiwan

3.2 Garis panduan ini boleh juga dimuat turun melalui laman web Pusat Penyelidikan dan Inovasi di url **http://www.ums.edu.my/ppi/**

3.3 Sebarang pertanyaan lanjut mengenai garis panduan ini bolehlah menghubungi Bahagian Pengurusan Penyelidikan, Pusat Penyelidikan dan Inovasi.

4.0 TARIKH KUAT KUASA

4.1 Pekeliling ini berkuat kuasa mulai dari tarikh diluluskan oleh Mesyuarat Lembaga Pengarah Universiti (LPU) Kali Ke-67 iaitu pada **7 Julai 2015.**

Sekian, terima kasih.

"BERTEKAD CEMERLANG"

Yang ikhlas,

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UMS
UNIVERSITI MALAYSIA SABAH

RESEARCHER'S GUIDELINES ON CODE OF PRACTICE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES

Adopted and modified from:
UNIVERSITI PUTRA MALAYSIA
CODE OF PRACTICE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES

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INTRODUCTION

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

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

The Code emphasizes the responsibilities of investigators and institutions using animals to:

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

There are difficult ethical judgments to be made regarding the use of animals for scientific purposes. The Code requires IACUCs to determine whether the case for animal use is justified and to ensure adherence to the principles of Replacement, Reduction and Refinement (3Rs). IACUCs apply a set of principles that are outlined in the Code and that govern the ethical conduct of people whose work involves the use of animals for scientific purposes.

SCOPE OF THE CODE

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

The Code provides general principles for the care and use of animals, specifies the responsibilities of investigators and institutions, and details the terms of reference, membership and operation of

IACUCs. It also provides guidelines for the humane conduct of scientific activities, and for the acquisition of animals and their care, including their environmental needs.

DEFINITIONS OF TERMS USED IN THE CONTEXT OF THE CODE

Analgesia: The temporary abolition or diminution of pain perception.

Anaesthesia: A state of controllable, reversible insensibility in which sensor perception and motor responses are both markedly depressed.

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

Institutional Animal Care and Use Committee (IACUC): a committee constituted in accordance with the terms of reference and membership laid down in the Code.

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

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

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

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

Compliance: acting in accordance with the Code.

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

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

Competent Person: someone who has sufficient training and experience or knowledge in handling animals and animal care for research.

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

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

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

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

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

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

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

Institution: Any institution, company, organisation, association, body or person that uses or intends to use animals for Scientific Purposes and is licensed to do so.

Investigator: any person who uses animals for scientific purposes.

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

Manipulation: Any interference with the normal physiological, behavioural or anatomical integrity of the animal by deliberately depriving it of its usual care or subjecting it to a procedure which is unusual or abnormal; when compared with that to which animals of that type would be subjected to under normal management or practice and which involves exposing it to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition or any enforced activity, restraint, nutrition, or surgical intervention.

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

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

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

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

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

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

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

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

Teaching: developing, imparting or demonstrating knowledge or techniques in any area of science at the tertiary level.

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

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

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

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

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

Encapsulated in the Code is the need in scientific and teaching activities to consider:

- the Replacement of animals with other methods;
- the Reduction in the number of animals used; and
- the Refinement of techniques used to reduce the adverse impact on animals.

JUSTIFICATION

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

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

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

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

RESPONSIBILITIES

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

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

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

1.7 The acquisition, care and use of animals for all scientific purposes in Malaysia must be in accordance with the Code and with relevant Federal and State legislation.

REPLACEMENT

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

REDUCTION

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

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

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

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

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

REFINEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 2: RESPONSIBILITIES OF INSTITUTIONS AND THEIR INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

21 RESPONSIBILITIES OF INSTITUTIONS

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

(i) establishing one or more IACUCs directly responsible to the governing body of the institution or its delegate.

(ii) ensuring through the IACUC, that all scientific activities involving the use of animals comply with relevant legislation and the Code (eg. Animals Act, 1953 (Revised 2006)).

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

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

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

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

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

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

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

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

(xi) establishing mechanisms to respond to enquiries or complaints concerning the use of animals within the institution and ensuring that personnel and students may voice concerns without jeopardising their employment, careers or coursework;

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

(xiii) providing personnel and IACUC members with information on potential disease hazards and other Occupational Health and Safety (OSHA) issues associated with the care and use of animals, in accordance to the Occupational Safety and Health Act (OSHA) 1994;

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

2.1.2 To enable the institution to assess whether the care and use of animals by the institution complies with the Code, an external review should be undertaken as determine by the relevant authorities

2.2 RESPONSIBILITIES AND OPERATION OF IACUCs

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

Terms of Reference

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

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

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

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

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

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

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

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

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

(ix) withdraw approval for any project;

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

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

(xii) maintain a record of proposals and projects;

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

(xiv) inspect, at least once every six months, all of the Institution's Housing Facilities (including satellite facilities)

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

Membership

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

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

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

Category C: a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements

of this Category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and nomination by, such an organisation; and

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

2.2.3 In addition to the prescribed membership Categories A to D, the institution shall appoint to the IACUC the competent person responsible for the routine care of animals.

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

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

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

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

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

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

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

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

Responsibilities of the Chairperson

2.2.9 The Chairperson must:

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

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

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

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

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

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

Operating Procedures

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

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

(ii) the presence at meetings of at least one member from each of Categories A, B, and either C or D to establish a quorum;

(iii) the conduct of quorate IACUC meetings in exceptional circumstances where a face-to-face meeting is not possible (for example, through the use of video-linking, teleconferencing or any other method deemed suitable by the IACUC);

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

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

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

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

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

2.2.12 Meetings should be held at least quarterly to allow interaction of IACUC members and effective functioning of the IACUC.

2.2.13 Irreconcilable differences between the IACUC and an investigator must be referred to the governing body of the institution for review of the due process. The ultimate decision of an IACUC after such review must not be over-ridden.

Proposals

2.2.14 Proposals - general

Information provided in proposals must be sufficient to satisfy the IACUC that the proposed use of animals is justified by weighing the predicted scientific or educational value of the proposal against the potential impact on the welfare of the animals. An essential component of this assessment by the IACUC involves consideration of the steps taken by the applicant to comply with the principles of the 3Rs specified in the Code. It is important that all IACUC members are provided with sufficient information to participate in the assessment of proposals. Applicants must ensure that where the use of scientific language is deemed unavoidable, it is supported by a suitable lay description or a glossary of terms.

2.2.15 Proposals - detailed

Proposals should contain the following information as appropriate:

(i) The project title.

(ii) The expected commencement and completion dates of the animal trial.

(iii) The names of all personnel involved with the project, their role and details of the experience and training that qualifies them to perform specific procedures using animals.

(iv) The source of animals and any permits required, details of where the animals will be housed and where procedures will be performed.

(v) Potential benefits of the project description of:

- the broad context of the project;
- maintaining or improving human or animal health and welfare;
- the expected benefits in:
  - increasing our understanding of humans or animals;
  - improving animal management

(vi) Overview of the project.
An outline of how the project is designed in relation to its aims.

(vii) Reduction
A clear description of:

- the number, species and strain of animals required, by treatment groups, where appropriate;
- the reasons why this number is necessary, including whether the proposal is for a repeat of an earlier project and if so, why repetition is necessary; and
- whether there is an opportunity for the sharing of tissues or animals.

(viii) Replacement

Explanation of why animals are needed for the project, including:

- a list of any potential alternatives to animal use;
- whether any of these alternatives would be used, and if not;
- why alternatives are unsuitable.

(ix) Refinement

Proposals must identify and justify the impact of all aspects of the project on an animal's wellbeing from the time it is obtained until the project is completed and detail how that impact will be minimised. The assessment of potential impact should include:

1. A description of what will happen to each animal including:

   (i) transportation, acclimatisation and conditions of housing and handling;
   (ii) experimental and other procedures, including dose and route of any substance or treatment given and method, volume and frequency of samples collected;
   (iii) surgical and related procedures including dose of anaesthetic, analgesic and tranquillising agents and methods of monitoring their adequacy and side-effects;
   (iv) the sequence and timing of events from start to finish for individual or groups of animals; and
   (v) the arrangements for the animal or animals at the completion of the project, including, if applicable, the method of humane killing.

2. Identification of all aspects of animal use and management, including handling and housing, that may adversely impact on the animals' wellbeing, and how this impact will be minimised. The information provided should include details of:

(i) the Refinement of procedures that reduce the adverse impact on animals

(ii) how any impact will be monitored, assessed and managed; and

(iii) procedures to identify and quickly respond to unforeseen complications.

(x) Monitoring of animals

3. Details of how the wellbeing of animals will be assessed throughout the project, including:

- method and frequency of routine monitoring of animals;
- method and frequency of monitoring animals during and after procedures;
- what will be done if a problem is identified including criteria for intervention, treatment, or withdrawal of the animals from the project; and
- names and contact details of personnel responsible for day-to-day monitoring and for dealing with any emergencies.

To inform IACUCs of the extent to which the monitoring of animals and their care has been considered in the project design.

(xi) Justification

Investigators must provide justification for the use of animals / specific species in the project weighing the predicted scientific or educational value against the potential impact on the welfare of the animals. In addition, particular justification must be given for potentially severe or ethically contentious procedures. For example:

- unrelieved pain and distress including where the planned end-points will allow severe adverse effects to occur
- death as the end point;
- reuse of animals;
- prolonged restraint or confinement;
- production of monoclonal antibodies by the ascites method and
- the use of non-human primates

This is the opportunity for the investigator to present their case for the justification of the project on the basis of the proposed benefits, sound experimental design, and the

potential adverse impacts on the animals described in the proposal. The IACUC is then able to decide whether it agrees that the project is justified.

(xii) Practical considerations to assist IACUCs and animal carers. Specify any special risks to other animals or humans arising from the project

(xiii) Declaration

The proposal must include a statement signed by the responsible investigator(s) stating that they and all others involved in the project are familiar, and will comply, with relevant Federal and State legislation and the requirements of the Code. The applicant must assure the IACUC that adequate equipments and resources will be available to undertake the project.

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

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

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

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

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

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

Assessing proposals

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

2.2.18 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 IACUC according to the usual criteria applied to project approval.

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

2.2.20 Decisions must be made as promptly as possible.

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

2.2.22 IACUCs must advise investigators of their decisions in writing as promptly as possible. Projects must not commence until written approval has been received.

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

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

Monitoring

2.2.25 Once an animal is allocated to a project, the investigator is responsible for the day-to-day monitoring of its wellbeing.

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

2.2.27 Investigators and animal facility manager should promptly notify the competent person of any unexpected, adverse events that may impact on the wellbeing of an animal in their care.

2.2.28 When there is non-compliant with the Code, the IACUC has the authority to cease such activities immediately and remedial action is initiated.

2.2.29 On each site where animals are used, including the location where fieldwork is undertaken, the principal investigator should authorise a person to respond to emergencies, including unexpected adverse outcomes, in his/her absence.

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

Projects involving more than one IACUC

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

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

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

(iii) before any work commences, each IACUC approves the scientific and teaching activities being conducted by members of its institution;

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

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

2.2.32 Where parts of a project take place at different institutions, each IACUC may choose to approve and monitor only those parts that take place at their institution. Notwithstanding this

arrangement, it is essential that each IACUC is cognisant of all aspects of the project and ensures that any cumulative impact of procedures on animals is considered. Such arrangements should be part of an understanding between the institutions involved.

Non-institutional applicants and IACUC responsibility

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

(i) who is liable and responsible for the project;
(ii) how the impact of the project on the animals will be monitored and by whom; and
(iii) the qualifications and experience of applicants.

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

Non-compliance with the Code

2.2.35 Institutions, IACUCs and investigators are responsible for compliance with the Code.

SECTION 3: RESPONSIBILITIES OF INVESTIGATORS

3.1 GENERAL

3.1.1 Investigators who use animals for scientific purposes have a moral and professional obligation to treat the animals humanely and consider their welfare when planning projects and conducting experiments.

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

3.1.3 Investigators have the legal and ethical responsibility to ensure that animals being studied are manipulated using medical and surgical techniques, which are consistent with the principles of good practice and scientific knowledge in laboratory animal veterinary medicine. Investigators should consult with veterinarian whenever adverse effects occur, in order that standard veterinary care and treatment regimes are promptly implemented.

3.2 IACUC APPROVAL

3.2.1 Before any projects begins, investigators must submit a proposal to the Institutional Animal Care And Use Committee (IACUC) that indicate that the design of the project complies with the Code and/or relevant legislation(s).

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

3.2.3 Investigators must make reports to the IACUC as requested, including prompt notification of any adverse or unexpected effects that impact on animal wellbeing. Investigators must provide the information required for the annual report of any on-going project

3.2.4 Investigators must inform the IACUC in writing when each project is completed, discontinued.

3.3 PLANNING PROJECT

3.3.1 Choice of animal

3.3.1.1 Investigators must ensure that the choice of species is appropriate for the purpose of the project.

3.3.1.2 Requirement for known genetic constitution, freedom from specific diseases, documented health, nutritional and environmental histories and other relevant factors should be taken into account.

3.3.1.3 When definition of the biological status of animals is necessary, investigators must ensure that the supplier can provide adequate proof that all requirements can be met.

3.3.1.4 Where relevant, species and individual animals should be chosen on the basis that the proposed experiments will result in the least pain and distress. In making the decision, all aspects of the biological nature of the animals including their behavioural characteristics and cognitive development should be taken into account.

3.3.2 Monitoring

3.3.2.1 Investigators should ensure that all intensively managed animals are observed daily (or more frequently if circumstances require it) to assess their health and welfare.

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

3.3.3 Record keeping

3.3.3.1 Investigators must ensure that records of the use and monitoring of animals used for scientific purposes are maintained. Records should include the origin and fate of issued animals AND notation of procedures.

3.3.3.2 Investigators must make these records available for audit by the institution and authorised external reviewers.

3.3.4 Consultation

3.3.4.1 Investigators should consult other experienced scientist, veterinarians or laboratory animal and livestock specialist when necessary.

3.3.4.2 The competent person must be consulted on the following in the planning of any practise or procedure which can cause pain to animals;

(i) the use of tranquilisers, analgesics and anaesthetics

(ii) pre-surgical, surgical and post- surgical care by laboratory workers in accordance with established veterinary medical and nursing procedures

(iii) the use of paralytics without anaesthesia

(iv) the withholding of tranquilisers, anaesthesia, analgesia or euthanasia when scientifically necessary.

3.3.5 Checklist

3.3.5.1 Before submitting a proposal to the IACUC, investigators need to consider the following questions during the planning stages of a project:

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

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

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

(iv) Are the following biological statuses of the animals appropriate?

a. genetic

b. nutritional

c. microbiological d.

general health

(v) Are the following available?

a. animal holding facilities

b. equipment c.

personnel

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

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

(viii) Does this project involve students and are they appropriately supervised?

(ix) Are the following environmental conditions appropriate?

a. type of enclosure

b. noise control c.

photoperiod d.

temperature

e. humidity

f. ventilation

g. density of housing

h. social structures

(x) Are the studies designed so that:

a. statistically valid results can be obtained using the minimum number of animals?

b. educational objectives can be achieved using the minimum number of animals?

(xi) If the potential impact on the animal is unknown:

a. is it appropriate to incorporate a pilot study into the project design to allow a staged assessment of the impact on animal welfare ? b. how it will be managed?

(xii) Will any aspects of the project adversely impact on the:

a. well-being of animals

b. if so what will be done to minimise or avoid this?

c. What arrangements will be made for the regular assessment of the animals' wellbeing?

(xiii) Have any of the studies:
a. been performed previously?
b. If so, why should they be repeated?

(xiv) Have the following relevant permits been obtained:
a. importation
b. capture
c. use
d. treatment
e. humane killing
f. release of the animals

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

3.4 CONDUCT OF PROJECTS

3.4.1 Pain and Distress

In practical terms, it is difficult to evaluate pain and other unpleasant sensation, such as discomfort and distress.

3.4.1.1 The investigator must regularly assess and be aware of the signs of distress in animals under experiment and must limit distress to acceptable levels. Distress may be apparent as aggressive and abnormal behaviour, changes in normal sounds, abnormal appetite, decline in body weight, impaired reproduction and reduced resistance to disease

3.4.1.2 The investigator must assume that the pain experienced by mammals, and possibly other vertebrates is similar to the pain in humans, and hence the indications for

analgesia and anaesthesia should parallel to those accepted in human and veterinary medical practice

3.4.1.3 The investigator must at the beginning of an investigation/research introduce the procedures one at a time, to allow animals to adjust without periods of excessive stress:

- change of location
- changes of feed
- change of experimental procedures

3.4.2 Limiting pain and distress

3.4.2.1 Investigators/ researchers must anticipate and take all possible steps to avoid or minimize pain and distress including:

(i) choosing the most appropriate and humane method for each experiments

(ii) attending and undergoing technical skill courses for competency in the specific animal research

(iii) ensuring the technical skills and competence of all people involved in animal research

3.4.2.2 If ascitic tumour research is to be conducted, investigators must ensure the minimisation of pain and distress to the animals by:

- using the appropriate type and volume of priming agent
- preventing excessive accumulation of ascitic fluid at the site of inducing tumour
- removing ascitic fluid or tissue under anaesthesia
- euthanising animals with severe changes in body weight due to the tumour

3.4.3 Anaesthesia and analgesia

Any procedure which causes pain, distress or injury, apart from brief simple procedures which involve trivial pain, must be performed under general or local anaesthesia or analgesia.

3.4.3.1 Investigators must ensure that the techniques of sedation, anaesthesia and analgesia used are appropriate for the particular species of animal used, and that the techniques are in accordance with latest or current laboratory animal practices available in the institution or veterinary or human clinical practice.

3.4.3.2 Investigators must monitor all anaesthetised animals continuously.

3.4.3.3 Anaesthesia and analgesia must be performed only by the veterinarian, or under the supervision of a veterinarian.

3.4.3.4 Training in surgical or anaesthetic techniques must be under the direct and constant supervision of a veterinarian.

3.4.3.5 Investigator must ensure that the choice and administration of anaesthetic, analgesic and tranquilising agents is suitable for the species and the purpose of the project.

3.4.3.6 These anaesthetic, analgesic and tranquilising agents must be used within the context of the pain management plan.

3.4.3.7 Research personnel should consult the veterinarian or trained personnel in the choice and use of these drugs.

3.4.3.8 If a procedure needs to be conducted without the use of an anaesthetic, analgesic or tranquilizer, the procedure must be supervised directly by the responsible investigator and approved by the institutional IACUC.

3.4.3.9 Muscle relaxant or paralytic drugs that are not anaesthetics must not be used alone for surgical procedures.

3.4.3.10 Muscle relaxant or paralytic drugs must always be used with drugs known to produce adequate analgesia for restraining animals.

3.4.3.11 Electro-immobilisation devices must not be used to produce analgesia.

3.4.3.12 If during an experiment, there is evidence that animals are experiencing severe pain and distress which cannot be alleviated quickly, the investigator must ensure that the animal be humanely destroyed without delay, even if the objective of the investigation has not been achieved.

3.4.3.13 The investigator must ensure the use of analgesics and anaesthetics controlled under the Poisons (Amendment) Act 1988 are in accordance with the specific legal requirements. These drugs must be purchased, stored and documented in accordance to this Act.

3.4.4 Animal welfare monitoring of pain and distress

3.4.4.1 Investigators should be familiar with the normal behaviour patterns of the animal species chosen, be knowledgeable of signs of pain and distress specific to the species and must monitor their animals for these signs.

3.4.4.2 Deviations from normal behaviour patterns are often the first indications that animals are experiencing pain or distress. Any changes in patterns of sleeping, feeding, drinking, grooming, exploratory behaviour, performance in learning or discriminatory tasks, reproduction or social behaviour should be noted, assessed and acted on if appropriate.

3.4.4.2.1 Animals must be monitored appropriately for clinical signs of acute pain or distress. These may include one or more of the following:

(i) aggressive and/or abnormal behaviour (some species may become unduly submissive);
(ii) abnormal stance or movements;
(iii) abnormal sounds;
(iv) altered cardiovascular and/or respiratory function;
(v) abnormal appetite
(vi) rapid decline in body weight;
(vii) altered body temperature viii) vomiting and
(ix) abnormal defecation and urination

3.4.4.3 Indicators of sustained pain or distress may include:

(i) loss of body weight or failure to gain weight;

(ii) failure to display normal grooming behaviour;

(iii) failure to thrive;

(iv) impaired reproductive ability and

(v) reduced resistance to disease

3.4.5 Study end-points

3.4.5.1 The investigator should develop humane study end-points when preparing a project application.

3.4.5.2 Death as an end-point is generally ethically unacceptable and should be fully justified. When death as an end-point cannot be avoided, the experiments must be designed to result in the death of as few animals as possible.

3.4.5.3 Best practise indicates that end-points earlier than the moribund condition should always be used. For the purpose of the code, animals can generally be considered to be in a moribund state when:

(i) they have lost more than 20% of their pre-study body weight; or

(ii) they have lost more than 10% of their pre-study body weight in 24 hrs; or

(iii) a tumour grows to more than 10% of the animal's weight; or

(iv) life-threatening abscesses developed; or

(v) body temperature falls below a pre-set level (as determined by pilot studies which indicate that the level set is predictive of death); or

(vi) animals self-mutilate; or

(vii) animals obviously become incapacitated and are not able to eat, rest or perform normal activity.

3.4.5.4 All animals found in the moribund state must be euthanised unless there is specific justification to do otherwise.

3.4.6 Repeated use of Animals for Scientific Purpose

3.4.6.1 Individual animals must not be used in more than one scientific experiment, without IACUC approval. When considering approval for the reuse of animals, the IACUC must take into account:

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

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

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

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

3.4.7 Handling, restraint and confinement of animal

3.4.7.1 Animals must be handled only by persons authorised and competent in methods which minimise pain and distress and do not cause injury.

3.4.7.2 Restraint devices must be suitable in size, design, and operation to minimize discomfort or injury to the animal.

3.4.7.3 When restraint devices are used, they must be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel. The following are important guidelines for restraint:

- Restraint devices are not to be considered normal methods of housing
- Restraint devices must not be used simply as a convenience in handling or managing animals.
- The period of restraint must be the minimum required to accomplish the research objectives.

- Animals to be placed in restraint devices must be acclimatized to adapt to the equipment and personnel.
- Provisions must be made for the monitoring of the animal at appropriate intervals, as determined by the IACUC.
- Veterinary care must be provided if lesions or illness associated with restraint are observed.

(The presence of lesions, illness, or severe behavioural change often necessitates temporary or permanent removal of the animal from restraint.)

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

3.4.7.5 Prolonged periods of restraint or confinement should be avoided. However, when prolonged restraint or confinement of animals is proposed, such as housing animals in metabolic cages, consideration must be given to the animals' biological and behavioural needs.

3.4.7.6 Animals subjected to prolonged period of restraint and confinement must be assessed regularly by a veterinarian or other person deemed qualified by the institution not otherwise involved in the project. If any negative impact on an animal is detected, the animal must be removed from the restraint or the method of restraint must be modified to minimise the impact.

3.4.8 Withholding of food and water

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

3.4.8.2 When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid must be available to provide for development of young animals and to maintain long-term wellbeing of all animals.

3.4.8.3 Food and water restriction for research purposes should be scientifically justified, and a programme must be established to monitor physiological or behavioural indices, such as weight loss or state of dehydration for temporary or permanent removal of an animal from the experimental protocol.

3.4.8.4 In the case of conditioned-response research protocols, use of a highly preferred food and fluid as positive reinforcement, instead of restriction is recommended.

3.4.9 Animal welfare and animal health research

3.4.9.1 When studying ways to improve the health or welfare of animals, investigators may need to replicate the problem, such as injury, trauma, nutritional disorder, physical exertion, disease or environmental stress. Investigators must ensure that:

- the principal aim of the project is to improve animal welfare or health;
- the outcome of the project cannot be achieved by alternative methods;
- all possible steps are taken to minimise any pain or distress; and
- the end-point of studies conforms to the requirements for toxicological studies

3.4.10 Modifying animal behaviour

3.4.10.1 Positive reinforcement is the preferred method to motivate an animal to modify its behaviour or to perform specific tasks. Inducement used in the form of biological stress must be as mild as possible.

3.4.10.2 Severe deprivation of water, food, social interaction or sensory stimuli must not be used.

3.4.10.3 Painful or noxious stimuli must be avoided. If their use is necessary, the level and duration of the stimulus must be minimised and escape from the stimulus must be available.

3.4.11 Scientific and teaching activities involving hazards to other animals or humans

3.4.10.1 Proposals for the use of animals in teaching must be approved by the IACUC and comply with all relevant legislation and institutional requirements.

3.4.10.2 Animals must not be used when other techniques such as audio-visual aids will achieve the teaching objectives satisfactorily.

3.4.10.3 If animals have to be used, the following principles apply:

- lower orders of life e.g. bacteria, fungi, protozoa and insects should have preference over vertebrates
- The number of animals used should be kept to the minimum to achieve the stated scientific objective
- If animals are handled, manipulated or intervened with in any way by students, there must be close supervision by authorised and trained personnel.

3.4.10.4 Anaesthesia and euthanasia of animals and/or surgical interferences should be carried out by students only if it is absolutely essential for training. Close supervision has to be provided by properly trained and qualified personnel.

3.4.10.5 Students must be trained to handle animals humanely.

3.4.12 Animal models of disease

3.4.12.1 Animal models of disease are only allowed if the investigators can show scientific validity of its resemblance to human disease/conditions. Death as an end-point in these studies should be avoided

3.4.13 Neuromuscular paralysis

3.4.13.1 Neuromuscular blocking agents may only be used with adequate general anaesthesia or an appropriate surgical procedure that eliminates sensory awareness.

3.4.13.2 When the neuromuscular blocking agents are used, specialist advice must be obtained

3.4.13.3 Immobilisation of an animal solely with a neuromuscular blocking agent is not acceptable. When these agents are used in conjunction with general anaesthesia, special care must be taken to ensure the maintenance of an adequate plane of anaesthesia.

3.4.14 Lesions of the Central Nervous System

3.4.14.1 Projects involving anatomical or chemical lesions of the central nervous system demand special consideration when the lesion produces loss of function; including:

- impairment of limb or trunk movements
- loss of sensibility to touch, temperature or pain
- impairment of the animal's awareness of its surroundings
- impairment of appetite or thirst.

Special animal care, caging and other facilities may be needed and the condition of the animals must be closely monitored.

3.4.15 Humane Killing and Euthanasia

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

3.4.15.2 The procedures must be performed only by personnel approved as competent by the IACUC.

3.4.15.3 Animals should be killed in a quiet, clean environment that is away from other animals where possible.

3.4.15.4 Death must be established before disposal of the carcass occurs.

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

3.4.15.6 Methods of killing must be appropriate to the developmental stage and species of the animal. (Report of the AVMA Panel on Euthanasia 2000).

3.4.14.7 Disposal of fertilised eggs, foetuses and embryos must not occur until death is assured.

3.4.16 Implanted devices

3.4.16.1 Skilled and specialised attention is required in the care of animals following operations in which recording or sampling devices are implanted, or fistulae created.

3.4.16.2 Animals must be assessed frequently for any signs of pain, distress or infection and treated immediately if these occur.

3.4.17 Organ and tissue transplantation

3.4.17.1 Skilled and specialised attention is required in the care of animals following organ or tissue transplantation. Animals must be assessed frequently for any signs of pain, distress, infection and tissue rejection and treated immediately if these occur.

3.4.17.2 Special attention must be given to the management of immunosuppression and the disease hazards and adverse outcomes that may be associated with organ and tissue transplantation between species (xenotransplantation).

3.4.17.3 Death as an end-point must avoided when determining recipient survival times.

3.4.18 Cloning of Animals

3.4.18.1 Cloning of animals is subjected to the prevailing legislation on cloning. If cloning of animals involved genetic modifications clauses must be considered.

3.4.19 Genetic modification

3.4.19.1 All projects involving genetic modification of animals must be conducted in accordance with appropriate country legislation, requirements and guidelines of the individual institutions research and ethics committees.

3.4.19.2 Proposal to produce a new strain or hybrid of a genetically modified animal must include sufficient information to allow the ethics committee to consider the potential impact of introducing a new gene, or altering the expression of existing genes on all the animals involved in the breeding program, as well as the reasons to support the creation of the said genetically modified animal.

3.4.19.3 The investigator must state implicitly in the proposal of any potential side- effects due to the genetic manipulation that may impact negatively on the welfare of the parent animal or offspring and also of the means that will be used to deal with such eventualities.

3.4.19.4 The investigator must provide monitoring details for expected and unexpected adverse effects arising from the genetic modification to the ethics committee.

3.4.19.5 Proposals for the creation of genetically modified animals that are expected to cause pain or distress in the animal must contain information of any special needs

and details of specialist care that will be provided to minimise these negative impacts. Humane end-points must also be defined.

3.4.19.6 The breeding procedures used to establish a colony of genetically-modified animals (*from newly-created genetically modified animals or those from an outside source*), must be carried out based on scientific purpose of performing research with these animals.

3.4.19.7 A final report must be submitted to the IACUC at the completion of the project and/or when the strain is regarded as breeding stock.

3.4.19.8 Investigators must assess through detailed monitoring, the welfare and genetic stability of newly created genetically-modified animals and their offspring across a number of generations and forward a summary of these observations to the IACUC. The frequency of reporting should be determined by the IACUC, taking into account the nature of the genetic modification.

3.4.20 Induction of Tumours

3.4.20.1 The site for induction of tumours must be chosen carefully. Subcutaneous sites on the back or flank should be chosen where possible.

3.4.20.2 Implantation of tumours either in the footpad, tail, brain or eye must not be chosen unless there is no alternative.

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

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

3.4.20.5 In tumour therapy studies, end-points compatible with reliable assessment of the therapy must be as early as possible.

3.4.21 Production of Monoclonal Antibody

3.4.21.1 In the immunisation phase, investigators must ensure that there is minimal pain and distress to animals from factors such as:

- type, volume, site and frequency of injection of adjuvant
- method of blood sampling
- frequency of blood sampling

3.4.21.2 Researchers should use *in vitro* methods for the routine amplification of hybridomas for producing monoclonal antibodies.

3.4.21.3 Any investigators wishing to use the *in vivo* (ascites) methods must provide recent laboratory evidence in their proposal to the IACUC to show that *in vitro* methods are unsuitable for the production of specific monoclonal antibody described in their research proposal.

3.4.21.4 If the researcher uses the ascitic tumour method, they must ensure that there is minimal pain and distress to animals from factors such as:

- type and volume of the priming agent
- accumulation of the ascites fluid
- extreme changes in body weight
- removal of ascites fluid.

3.4.22 Post Mortem Examination

3.4.22.1 When an animal dies unexpectedly, or is euthanized due to unforeseen complications, an autopsy must be performed by a person with appropriate qualifications and/or experience

3.4.22.2 Records of post-mortem examination should be kept. Records of digital image or post-mortem findings are encouraged.

3.4.23 Surgery and Post-operative Care

3.4.23.1 Surgery must be performed only by or under supervision of a veterinarian

3.4.23.2 Surgical procedures must be carried out under appropriate local or general anaesthesia.

3.4.23.3 The depth of anaesthesia must be adequately monitored throughout the procedure.

3.4.23.4 There must also be appropriate monitoring and management of potential side effects, such as hypothermia, cardiovascular and respiratory depression.

3.4.23.5 Anaesthetic monitoring records for major surgeries must be kept.

3.4.23.6 The comfort of animals must be promoted throughout the post-operative period.

3.4.23.7 Attention should be given to warmth, hygiene, fluid and food intake, and control of infection.

3.4.23.8 The use of analgesic, tranquillizing and antibiotic agents may be needed to minimize post-operative pain or distress.

3.4.23.9 Care should be taken to ensure that animals recovering from anaesthesia do not injure themselves by uncoordinated movements, and that conditions are such that they are not disturbed, attacked or killed by other animals in the same enclosure.

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

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

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

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

3.4.24 Blood sampling and tissue harvesting from laboratory animals

3.4.24.1 Blood sampling and tissue harvesting from animals slaughtered for food, IACUC-approved experimental intervention procedures, and/or samples obtained during an autopsy investigation to determine the cause of death shall be excluded from this guideline.

3.4.24.2 Exsanguination and/or removal of body organs to result in death without general anaesthesia must not be allowed.

3.4.24.3 Blood removal from laboratory mammals must comply with published guidelines.

3.4.24.4 Efforts must constantly be made to refine scientific techniques so as to reduce the volume of the blood sample.

3.4.24.5 More animals should be used if the animal's welfare is threatened by the volume of the sample required.

3.4.24.6 Tissue harvesting & biopsy procedures must be undertaken by, or under the direct supervision of personnel experienced in the techniques involved, and must utilize proper restraint, surgical and anaesthetic procedures.

3.4.25 Toxicology Studies

3.4.25.1 If suitable non-animal test are available they must be used.

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

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

3.4.26 Experiments involving hazards to humans and animals

3.4.26.1 Hazards may arise from sources that include

(i) viruses; (ii) bacteria;
(iii) fungi;
(iv) parasites; (v) radiation;
(vi) radioactivity;
(vii) corrosive substances
(viii) toxins;
(ix) allergens;
(x) carcinogens;
(xi) recombinant DNA;
(xii) anaesthetic gases; and
(xiii) physical injury

3.4.26.2 Experiments involving hazards to humans or animals shall be in accordance to the relevant country legislation.

3.4.26.3 Protocol should include a subscription of any intended use of hazardous compounds or organisms. They should describe specific safety measures and disposal protocols used to prevent contamination of caging, other animals, research personnel or students.

3.4.26.4 Animals being administered infectious organisms should be isolated, taking into account risks to other animals and to people.

3.4.26.5 Investigators must not allow the experiments to proceed to the painful or distressful or lingering death of animals unless no other experimental end- point is feasible and the goals of the experiments are the prevention, alleviation, treatment or care of a life-threatening disease or situation in human beings or animals. When death as end-point cannot be avoided, the experiment must be designed to result in the death of as few animals as possible. The investigator must also ensure that the animal's suffering or pain is minimised. And use appropriate sedation, analgesia or anaesthesia to relieve the animal's pain and suffering.

3.4.26.6 Precautions, security and emergency plans to contain hazardous agents should be appropriate to a worst-case scenario.

3.2.27 Foetal and Embryonic Experimentation

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

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

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

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

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

Animals should be obtained from breeding and supply facilities that maintain conditions consistent with the Code or relevant industry code.

Housing conditions, practices and procedures involved in the care of animals in breeding and holding facilities of scientific and teaching institutions must be approved and monitored by an Institutional Animal Care and Use Committee.

4.1 ANIMALS OBTAINED FROM INTERSTATE OR OVERSEAS

It is the responsibility of the investigator to consult the relevant authorities (Department of Veterinary Services, Customs, Wildlife Department and Department of Civil Aviation) to ensure compliance with all requirements governing the import, capture, handling and transportation of animals and to include details of this in the proposal. All imported animals must be accompanied with health permits from exporting countries.

4.2 TRANSPORTATION OF ANIMALS

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

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

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

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

4.2.5 Food and water (or their alternatives) must be provided when necessary.

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

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

4.3 ADMISSION OF NEW ANIMALS INTO HOLDING AREAS

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

4.3.2 Animals should be acclimatised to the holding facility and personnel before their use in a project and those that do not adapt satisfactorily should not be used

4.4 CARE OF ANIMALS IN HOLDING AND BREEDING FACILITIES

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

4.4.2 Institutions, Institutional Animal Care and Use Committees and investigators must ensure that facilities are appropriately staffed, designed, constructed, equipped and maintained to achieve a high standard of animal care and fulfil scientific requirements.

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

Outdoor holding areas

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

Indoor Housing

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

4.4.6 Buildings should be designed *(refer to Appendix I for construction guidelines)* and operated to control environmental factors appropriately, to exclude vermin and to limit contamination associated with the keeping of animals, the delivery of food, water and bedding, and the entry of people and other animals.

4.4.7 There should be a pest control program to monitor and control vermin.

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

4.4.9 Buildings must be kept clean and tidy and operated to achieve maximum possible hygiene.

4.4.10 There must be adequate storage areas for food, bedding and equipment.

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

4.4.12 Cleaning practises should be monitored on a regular basis to ensure effective hygiene and sanitation. This can include visual inspection, monitoring water temperature and microbiological testing of surfaces after cleaning.

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

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

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

4.4.16 Animals must be provided with environmental conditions that suit their behavioral and biological needs unless other conditions are approved by the Institutional Animal Care And Use Committee for a particular project.

4.4.17 Air exchange, temperature, humidity, light and noise should be maintained within limits compatible with animal wellbeing and good health *(refer to Appendix II for standards)*.

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

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

4.4.20 Environmental factors potentially affect the welfare of animals and may affect the results of scientific and teaching activities. Investigators and the Institutional Animal Care And Use Committee should be informed in advance of planned changes to the environmental conditions under which animals are held.

Pens, cages and containers and the immediate environments of animals

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

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

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

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

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

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

protection from spread of pests and disease;

(vii) requirements of the project; and

(viii) the need to observe the animals readily.

4.4.22 Pens, cages and containers must:

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

(ii) be kept clean;

(iii) be maintained in good repair; (iv) be

secure and escape-proof;

(v) protect animals from climatic extremes;

(vi) not cause injury to animals;

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

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

4.4.23 Wire floor cages should not be used for rodents unless essential to the Project and only for an approved period. Animals should have a solid resting area when housed in wire floor cages.

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

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

4.4.26 The Institutional Animal Care and Use Committee, investigators should be consulted in advance of planned changes to these conditions, since these may affect both the welfare of animals and results of the scientific and teaching activities.

Food and water

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

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

4.4.29 Any alteration to dietary regimes should be gradual.

4.4.30 Food should be stored such as to minimise deterioration of nutritional value and palatability and to prevent contamination by vermin.

4.4.31 Feed and water equipment should be constructed of materials and be easily and effectively cleaned.

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

4.4.32 Variations to these requirements as part of a project must receive prior Institutional Animal Care and Use Committee approval.

Enrichment and environmental complexity

4.4.33 Most animals used in Projects are housed in environments dissimilar to their natural habitats. Wherever possible, such animals should be provided with stimuli that promote the expression of normal behaviour appropriate to the species.

4.4.34 Almost all species of animals used in Projects have well defined social structures and prefer to live in groups, although care must be taken to ensure that animals are socially compatible. Individual housing is stressful for such animals, and social isolation should be avoided whenever possible and limited to meet specific Project objectives. The effects of physical isolation should be minimised where possible by increasing the complexity of an environment such as with apparatus such as climbing equipment, objects and gnawing sticks as may be appropriate to the species concerned

4.5 MANAGEMENT AND PERSONNEL

Person-in-charge of breeding and holding facilities

4.5.1 Animal acquisition, breeding and holding facilities must be supervised by competent persons with animal care qualifications or experience in handling animals.

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

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

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

(iii) liaising between investigators and facility personnel; and

(iv) communicating with the Institutional Animal Care And Use Committee on management of the facility and any adverse incidents.

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

4.5.4 The person-in-charge must ensure that ill or injured animals that are not assigned to projects are treated promptly and any cause of death investigated if the animals die unexpectedly

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

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

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

(i) transportation, quarantine and disposal of animals;
(ii) routine husbandry;
(iii) prevention, diagnosis and treatment of disease;
(iv) assessment of health status and genetionstitution of the different species; and
(v) physical environmental factors.

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

(i) the source, care, allocation, movement between locations, use and fate of all animals;
(ii) details of any diseases;
(iii) the fertility, fecundity, morbidity and mortality in breeding colonies; and
(iv) the health status, genetic constitution and physical environment of the animals.

4.5.9 Records maintained by the person-in-charge must be made available to investigators and the Institutional Animal Care and Use Committee.

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

Personnel

4.5.11 An important factor contributing to high standards of animal care is the number of well-trained, committed personnel. People working with animals in a holding facility should be instructed in the detailed care and maintenance of the animals, and in how their actions may affect animal wellbeing and the outcomes of scientific and teaching activities.

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

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

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

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

4.6 ROUTINE HUSBANDRY PROCEDURES

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

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

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

4.6.4 When special breeding requirements are integral to a research or teaching project such as in the creation of a new strain of genetically modified animal, then procedures applicable to breeding must be regarded as part of the project and should be included in the proposal to the Institutional Animal Care and Use Committee.

4.7 IDENTIFICATION OF ANIMALS

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

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

4.8 DISPOSAL OF CARCASSES AND WASTE MATERIAL

4.8.1 Prompt, sanitary disposal of carcasses and waste material must be in accordance to the respective biosafety regulations of the institutions.

4.9 NON-HUMAN PRIMATES

4.9.1 Non-human primates are recognised as having highly developed mental and emotional capacities, more so than most other animals. In many ways, they are similar to humans and exhibit many similar external manifestations of emotions such as facial expressions, vocalisations, postures, gestures, and reactions. They have been known to react in ways similar to humans under comparable situations. Investigators, competent persons and staff should familiarise themselves with the references and information in Appendix IV.

SECTION 5: VETERINARY CARE

5.1 COMPETENT PERSONNEL/ SCIENTIST COMPETENT IN ANIMAL RESEARCH

5.1.1 Each Institution must have an competent person for its housing and research facility(ies). The competent person shall advise on the appropriate care and use of animals and provide adequate veterinary care.

5.1.2 The competent person must be engaged under formal arrangements. The competent person can however be engaged on a part-time or full-time basis.

5.1.3 The formal arrangements must include a written program of veterinary care to be provided. In the case of a part-time competent person, the formal arrangements must also set out regularly scheduled visits to the housing and research facility(ies) of the Institution.

5.1.4 If the competent person is on leave or will be otherwise unavailable to provide any general or emergency veterinary care, interim arrangements must be made to ensure that there is always ready access to veterinary care.

5.1.5 The competent person or other veterinarians engaged on a full-time, part-time or ad-hoc basis must be persons with qualifications in veterinary science who are licensed by the Malaysian Veterinary Council.

5.2 COMPONENTS OF VETERINARY CARE

5.2.1 The staff-in-charge and his/her staff managing the animals, as well as the investigators, must have ready access to veterinary care for the animals at all times.

5.2.2 Institutions must establish and maintain adequate veterinary care, overseen by the competent person, that include:

(a) the availability of appropriate facilities, personnel, equipment, and services to comply with the Guiding Principles.

(b) the use of appropriate methods to prevent and control diseases (e.g. vaccination and other prophylaxis, disease monitoring and surveillance, quarantine and isolation), diagnose, and treatment of diseases and injuries.

(c) the availability of 24 hour emergency, weekend and holiday care.

(d) daily observation of all animals to assess their health and well-being: The daily observation of animals may be accomplished by someone other than the competent person provided that there is a mechanism of direct and frequent communication between the competent person and the staff concerned so that timely and accurate information on problems of animal health, behaviour, and well-being is conveyed to the competent person.

(e) guidance to investigators and other personnel involved in the care and use of animals regarding handling, immobilisation, anaesthesia, analgesia, tranquillisation, and euthanasia.

(f) adequate p re -procedural, surgical, and post-procedural care in accordance with current established veterinary medical and nursing procedures.

5.2.3 The IACUC's may direct that certain procedures or other tasks related to the care and use of animals shall be performed only by the competent person or a veterinarian.

APPENDIX I

CONSTRUCTION GUIDELINES

Corridors

Corridors should be wide enough to facilitate the movement of personnel and equipment. Corridors 6-8 ft. (1.8 - 2.4 m) wide can accommodate the needs of most facilities. Floor-wall junctions should be designed to facilitate cleaning. In corridors leading to dog and swine housing facilities, cage- washing facilities, and other high-noise areas, double-door entry or other noise traps should be considered. Wherever possible, water lines, drainpipes, electric-service connections, and other utilities should be accessible through access panels or chases in corridors outside the animal rooms. Fire alarms, fire extinguishers, and telephones should be recessed or installed high enough to prevent damage from the movement of large equipment.

Animal-Room Doors

For safety, doors should open into animal rooms; however, if it is necessary that they open toward a corridor, there should be recessed vestibules. Doors with viewing windows might be preferable for safety and other reasons. However, the ability to cover viewing windows might be considered in situations where exposure to light or hallway activities would be undesirable. Doors should be large enough (approximately 42 x 84 in, (107 x 210 cm) to allow the easy passage of racks and equipment. Doors should fit tightly within their frames, and both doors and frames should be appropriately sealed to prevent vermin entry or harborage. Doors should be constructed of and, where appropriate, coated with materials that resist corrosion. Self-closing doors equipped with recessed or shielded handles, threshold sweeps, and kick plates are usually preferred. Where security room-level is necessary or it is desirable to limit access (as in the case of the use of hazardous agents), room doors should be equipped with locks. Doors should be designed to be opened from the inside without a key.

Exterior Windows

Windows are acceptable in some animal rooms and can constitute a type of environmental enrichment for some species, especially nonhuman primates, dogs, some agricultural animals, and other large mammals. The effects of windows on temperature, photoperiod control, and security should be considered in design decisions. Where temperature cannot be regulated properly because of heat loss or gain through the windows or where photoperiod is an important consideration (as in breeding colonies of rodents), exterior windows usually are inappropriate.

Floors

Floors should be moisture-resistant, nonabsorbent, impact-resistant, and relatively smooth, although textured surfaces might be required in some high-moisture areas and for some species (such as farm animals). Floors should be resistant to the action of urine and other biologic materials and to the adverse effects of hot water and cleaning agents. They should be capable of supporting racks, equipment, and stored items without becoming gouged, cracked, or pitted. Depending on their use, floors should be monolithic or have a minimal number of joints. Some materials that have proved satisfactory are epoxy aggregates, hard-surface sealed concrete, and special hardened rubber-base aggregates. Correct installation is essential to ensure long-term stability of the surface. If sills are installed at the entrance to a room, they should be designed to allow for convenient passage of equipment.

Drainage

Where floor drains are used, the floors should be sloped and drain traps kept filled with liquid. To minimize humidity, drainage should allow rapid removal of water and drying of surfaces. Drainpipes should be at least 4 in (10.2 cm) in diameter. In some areas, such as dog kennels and farm animal facilities, larger drain pipes are recommended. A rim-flush drain or heavy-duty disposal unit set in the floor might be useful for the disposal of solid waste. When drains are not in use for long periods, they should be capped and sealed to prevent backflow of sewer gases and other contaminants; lockable drain covers might be advisable for this purpose in some circumstances.

Floor drains are not essential in all animal rooms, particularly those housing rodents. Floors in such rooms can be sanitized satisfactorily by wet vacuuming or mopping with appropriate cleaning compounds or disinfectants.

Walls

Walls should be smooth, moisture-resistant, nonabsorbent, and resistant to damage from impact. They should be free of cracks, of unsealed utility penetrations, and of imperfect junctions with doors, ceilings, floors, and corners. Surface materials should be capable of withstanding cleaning with detergents and disinfectants and the impact of water under high pressure. The use of curbs, guardrails or bumpers, and corner guards should be considered to protect walls and corners from damage.

Ceilings

Ceilings should be smooth, moisture-resistant, and free of imperfect junctions. Surface materials should be capable of withstanding cleaning with detergents and disinfectants. Ceilings of plaster or fire-proof plasterboard should be sealed and finished with a washable paint. Ceilings formed by the concrete floor above are satisfactory if they are smoothed and sealed or are painted. Generally, suspended ceilings are undesirable unless they are fabricated of impervious materials and free of imperfect junctions. Exposed plumbing, ductwork, and light fixtures are undesirable unless the surfaces can be readily cleaned.

Heating, Ventilation, and Air-Conditioning (HVAC)

Temperature and humidity control minimizes variations due either to changing climatic conditions or to differences in the number and kind of animals in a room. Air-conditioning is an effective means of regulating temperature and humidity. HVAC systems should be designed for reliability, ease of maintenance, and energy conservation. They should be able to meet requirements for animals. A system should be capable of adjustments in dry-bulb temperatures of +1°C (+2°F). The relative humidity should generally be maintained within a range of 30-70% throughout the year. Temperature is best regulated by having thermostatic control for each room. Use of a zonal control for multiple rooms can result in temperature variations between the "master-control" animal room and the other rooms in the zone because of differences in animal densities within the rooms and heat gain or loss in ventilation ducts and other surfaces within the zone.

Regular monitoring of the HVAC system is important and is best done at the individual-room level. Previously specified temperature and humidity ranges can be modified to meet special animal needs in circumstances in which all or most of the animal facility is designed exclusively for acclimated species with similar requirements (for example, when animals are held in a sheltered or outdoor facility).

Brief and infrequent, moderate fluctuations in temperature and relative humidity outside suggested ranges are well tolerated by most species commonly used in research. Most HVAC systems are designed for average high and low temperatures and humidities experienced in a geographic area within +5%. When extremes in external ambient conditions that are beyond design specifications occur, provisions should be in place to minimize the magnitude and duration of fluctuations in temperature and relative humidity outside the recommended ranges. Such measures can include partial redundancy, partial recycling of air, altered ventilation rates, or the use of auxiliary equipment.

In the event of a partial HVAC system failure, systems should be designed to supply facility needs at a reduced level. It is essential that life-threatening heat accumulation or loss be prevented during mechanical failure. Totally redundant systems are seldom practical or necessary except under special circumstances (as in some biohazard areas). Temporary needs for ventilation of sheltered or outdoor facilities can usually be met with auxiliary equipment.

In some instances, high-efficiency particulate air (HEPA) filters are recommended for air supplied to animal- holding, procedural, and surgical facilities. Also, consideration should be given to the regulation of air- pressure differentials in surgical, procedural, housing, and service areas. For example, areas for quarantine, housing, and use of animals exposed to hazardous materials and for housing of nonhuman primates should be kept under relative negative pressure, whereas areas for surgery, for clean-equipment storage, and for housing of pathogen-free animals should be kept under relative positive pressure with clean air. Maintaining air-pressure differentials is not the principal or only method by which cross contamination is controlled and should not be relied on for containment. Few air-handling systems have the necessary controls or capacity to maintain pressure differentials across doors or similar structures when they are opened for even brief periods. Containment requires the use of biologic-safety cabinets and exhausted airlocks or other means.

If recirculated air is used, its quality and quantity should be in accord with recommendation. The type and efficiency of air treatment should be matched to the quantity and types of contaminants and to the risks that they pose.

Power and Lighting

The electric system should be safe and provide appropriate lighting, a sufficient number of power outlets, and suitable amperage for specialized equipment. In the event of power failure, an alternative or emergency power supply should be available to maintain critical services (for example, the HVAC system) or support functions (e.g. freezers, ventilated racks, and isolators) in animal rooms, operating suites, and other essential areas.

Light fixtures, timers, switches, and outlets should be properly sealed to prevent vermin from living there. Recessed energy-efficient fluorescent lights are most commonly used in animal facilities. A time-controlled lighting system should be used to ensure a uniform diurnal lighting cycle. Timer performance and timer- overriding systems should be checked regularly to ensure proper cycling.

Light bulbs or fixtures should be equipped with protective covers to ensure the safety of the animals and personnel. Moisture-resistant switches and outlets and ground-fault interrupters should be used in areas with high water use, such as cage-washing areas and aquarium-maintenance areas.

Storage Areas

Adequate space should be provided for storage of equipment, supplies, food, bedding, and refuse. Corridors used for passage of personnel or equipment is not appropriate storage area. Storage space can be minimized when delivery is reliable and frequent. Bedding and food should be stored in a separate area in which materials that pose a risk of contamination from toxic or hazardous substances are not stored. Refuse-storage areas should be separated from other storage areas. Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal-tissue waste; this storage area should be kept below 7°C (44.6°F) to reduce putrefaction of wastes and animal carcasses.

Noise Control

Noise control is an important consideration in an animal facility. Noise-producing support functions, such as cage-washing, are commonly separated from housing and experimental functions. Masonry walls are more effective than metal or plaster walls in containing noise because their density reduces sound transmission. Generally, acoustic materials applied directly to the ceiling or as part of a suspended ceiling of animal rooms present problems for sanitation and vermin control and are not recommended. However, sanitizable sound-attenuating materials bonded to walls or ceilings might be appropriate for noise control in some situations. Experience has shown that well-constructed corridor doors, sound-attenuating doors, or double- door entry can help to control the transmission of sound along corridors.

Attention should be paid to attenuating noise generated by equipment. Fire and environmental-monitoring alarm systems and public-address systems should be selected and located to minimize potential animal exposure. The much-higher frequencies that are capable of being discriminated by some species make it important to consider the location of equipment capable of generating sound at ultrasonic frequencies.

APPENDIX II

Temperature and Humidity

Regulation of body temperature within normal variation is necessary for the wellbeing of homeotherms. Generally, exposure of unadapted animals to temperatures above 2 9 . 4 °C (85°F) or below 4.4°C (40°F), without access to shelter or other protective mechanisms, might produce clinical effects, which could be life-threatening. Recommended temperature for housing laboratory animals is between 18 to 23 oC. Some conditions might require increased environmental temperatures, such as postoperative recovery, maintenance of chicks for the first few days after hatching, housing of some hairless rodents, and housing of neonates that have been separated from their mothers. The magnitude of the temperature increase depends on the circumstances of housing; sometimes, raising the temperature in the primary enclosure alone (rather than raising the temperature of the secondary enclosure) is sufficient.

In the absence of well-controlled studies, professional judgment and experience have resulted in recommendations for dry-bulb temperatures for several common species. In the case of animals in confined spaces, the range of daily temperature fluctuations should be kept to a minimum to avoid repeated large demands on the animals' metabolic and behavioural processes to compensate for changes in the thermal environment.

Relative humidity should also be controlled, but not nearly as narrowly as temperature; the acceptable range of relative humidity is 30 to 70%.

Ventilation

The purposes of ventilation are to supply adequate oxygen; remove thermal loads caused by animal respiration, lights, and equipment; dilute gaseous and particulate contaminants; adjust the moisture content of room air; and, where appropriate, create static-pressure differentials between adjoining spaces. Establishing a room ventilation rate, however, does not ensure the adequacy of the ventilation of an animal's primary enclosure and hence does not guarantee the quality of the microenvironment.

The guideline of 10-15 fresh air changes per hour has been used for secondary enclosures for many years and is considered an acceptable general standard. Although it is effective in many animal housing settings, the guideline does not take into account the range of possible heat loads; the species, size, and number of animals involved; the type of bedding or frequency of cage- changing; the room dimensions; or the efficiency of air distribution from the secondary to the primary enclosure. To determine more accurately the ventilation required, the minimal ventilation rate (commonly in cubic feet per minute) required to accommodate heat loads generated by animals can be calculated with the assistance of mechanical engineers. The heat generated by animals can be calculated with the average-total-heat-gain formula as published by the American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE, 1993). The formula is species-independent, so it is applicable to any heat-generating animal. Minimal required ventilation is determined by calculating the amount of cooling required (total cooling load) to control the heat load expected to be generated by the largest number of animals to be housed in the enclosure

in question plus any heat expected to be produced by non-animal sources and heat transfer through room surfaces. The total-cooling-load calculation method can also be used for an animal space that has a fixed ventilation rate to determine the maximal number of animals (based on total animal mass) that can be housed in the space.

Even though that calculation can be used to determine minimal ventilation needed to prevent heat buildup, other factors-such as odour control, allergen control, particle generation, and control of metabolically generated gases-might necessitate ventilation beyond the calculated minimum. When the calculated minimal required ventilation is substantially less than 10 air changes per hour, lower ventilation rates might be appropriate in the secondary enclosure, provided that they do not result in harmful or unacceptable concentrations of toxic gases, odours, or particles in the primary enclosure. Similarly, when the calculated minimal required ventilation exceeds 15 air changes per hour, provisions should be made for additional ventilation required to address the other factors. In some cases, fixed ventilation in the secondary enclosure might necessitate adjustment of sanitation schedules or limitation of animal numbers to maintain appropriate environmental conditions.

Caging with forced ventilation that uses filtered room air and other types of special primary enclosures with independent air supplies (i.e., air not drawn from the room) can effectively address the ventilation requirements of animals without the need to ventilate secondary enclosures to the extent that would be needed if there were no independent primary-enclosure ventilation. Nevertheless, a secondary enclosure should be ventilated sufficiently to provide for the heat loads released from its primary enclosures. If the specialized enclosures contain adequate particulate and gaseous filtration to address contamination risks, recycled air may be used in the secondary enclosures.

Filtered isolation caging without forced ventilation, such as that used in some types of rodent housing, restricts ventilation. To compensate, it might be necessary to adjust husbandry practices-including sanitation, placement of cages in the secondary enclosure, and cage densities-to improve the microenvironment and heat dissipation.

The use of recycled air to ventilate animal rooms saves considerable amounts of energy but might entail some risk. Many animal pathogens can be airborne or travel on fomites, such as dust, so exhaust air to be recycled into heating, ventilation, and air-conditioning (HVAC) systems that serve multiple rooms presents a risk of cross contamination. The exhaust air to be recycled should be HEPA filtered (high-efficiency particulate air-filtered) to remove airborne particles before it is recycled; the extent and efficiency of filtration should be proportional to the estimated risk. HEPA filters are available in various efficiencies that can be used to match the magnitude of risk. Air that does not originate from animal use areas but has been used to ventilate other spaces (e.g., some human-occupancy areas and food, bedding, and supply storage areas) may be recycled for animal space ventilation and might require less-intensive filtration or conditioning than air recycled from animal use space. The risks in some situations, however, might be too great to consider recycling (e.g., in the case of nonhuman-primate and biohazard areas).

Toxic or odour-causing gases, such as ammonia, can be kept within acceptable limits if they are removed by the ventilation system and replaced with air that contains either a lower concentration or none of these gases. Treatment of recycled air for these substances by chemical absorption or scrubbing might be effective; however, the use of non-recycled air is preferred for ventilation of animal use and holding areas. The use of HEPA filtered recycled air without gaseous filtration (such as with activated-charcoal filters) can be used but only in limited applications, provided that:

- room air is mixed with at least 50% fresh air (that is, the supply air does not exceed 50% recycled air).
- husbandry practices, such as bedding-change and cage-washing frequency, and the preparation of recycled air used are sufficient to minimize toxic gases and odors.
- recycled air is returned only to the room or area from which it was generated, except if it comes from other than animal housing areas.
- recycled air is appropriately conditioned and mixed with sufficient fresh air to address the thermal and humidity requirements of animals in that space.

Frequent bedding changes and cage-cleaning coupled with husbandry practices, such as low animal density within the room and lower environmental temperature and humidity, can also reduce the concentration of toxic or odour-causing gases in animal-room air. Treatment of recycled air for either particulate or gaseous contaminants is expensive and can be rendered ineffective by improper or insufficient maintenance of filtration systems. These systems should be properly maintained and monitored appropriately to maximize their effectiveness.

Illumination

Light can affect the physiology, morphology, and behaviour of various animals. Potential photostressors include inappropriate photoperiod, photointensity, and spectral quality of the light. Numerous factors can affect animals' needs for light and should be considered when an appropriate illumination level is being established for an animal holding room. These include light intensity, duration of exposure, wavelength of light, light history of the animal, pigmentation of the animal, time of light exposure during the circadian cycle, body temperature, hormonal status, age, species, sex, and stock or strain of animal

In general, lighting should be diffused throughout an animal holding area and provide sufficient illumination for the well-being of the animals and to allow good housekeeping practices, adequate inspection of animals—including the bottom-most cages in racks—and safe working conditions for personnel. Light in animal holding rooms should provide for adequate vision and for neuroendocrine regulation of diurnal and circadian cycles

Photoperiod is a critical regulator of reproductive behaviour in many species of animals and can also alter body weight gain and feed intake. Inadvertent light exposure during the dark cycle should be minimized or avoided. Because some species will not eat in low light or darkness, such illumination schedules should be limited to a duration that will not compromise the well-being of the animals. A time-controlled lighting system should be used to ensure a regular diurnal cycle, and timer performance should be checked periodically to ensure proper cycling.

The most commonly used laboratory animals are nocturnal. Because the albino rat is more susceptible to phototoxic retinopathy than other species, it has been used as a basis for establishing room illumination levels. Data for room light intensities for other animals, based on scientific studies, are not available. Light levels of about 325 lux (30 ft-candles) about 1.0 m (3.3 ft) above the floor appear to be sufficient for animal care and do not cause clinical signs of phototoxic retinopathy in albino rats and levels up to 400 lux (37 ft - candles) as measured in an empty room 1 m from the floor have been found to be satisfactory for rodents if management practices are used to prevent retinal damage in albinos. However, the light experience of an individual animal can affect its sensitivity to phototoxicity; light of 130-270 lux above the light intensity under which it was raised has been reported to be near the threshold of retinal damage in some individual albino rats according to histologic, morphometric, and electrophysiologic evidence. Some guidelines recommend a light intensity as low as 40 lux at the position of the animal in midcage. Young albino and pigmented mice prefer much-lower illumination than adults although potential retinal damage associated with housing these rodents at higher light levels is mostly reversible. Thus, for animals that have been shown to be susceptible to phototoxic retinopathy, light at the cage level should be between 130 and 325 lux.

Noise

Noise produced by animals and animal care activities is inherent in the operation of an animal facility. Therefore, noise control should be considered in facility design and operation.

Separation of human and animal areas minimizes disturbances to both the human and animal occupants of the facility. Noisy animals—such as dogs, swine, goats, and nonhuman primates—should be housed away from quieter animals, such as rodents, rabbits, and cats. Environments should be designed to accommodate animals that make noise, rather than resorting to methods of noise reduction. Exposure to sound louder than 85 dB can have both auditory and non-auditory effects. To the greatest extent possible, activities that might be noisy should be conducted in rooms or areas separate from those used for animal housing.

Personnel should try to minimize the production of unnecessary noise because changes in patterns of sound exposure have different effects on different animals.. Excessive and intermittent noise can be minimized by training personnel in alternatives to practices that produce noise and by the use of cushioned casters and bumpers on carts, trucks, and racks. Radios, alarms, hand phones and other sound generators should not be used in animal rooms unless they are parts of an approved protocol or an enrichment program.

APPENDIX III

TABLE 1: Recommended Space for Commonly Used Group-Housed Laboratory Rodents

Animals	Weight, g	Floor Area/ Animal, in²[a]	Height,[b] in[c]
Mice	<10	6	5
	Up to 15	8	5
	Up to 25	12	5
	>25[d]	>15	5
Rats	<100	17	7
	Up to 200	23	7
	Up to 300	29	7
	Up to 400	40	7
	Up to 500	60	7
	>500[d]	>70	7
Hamsters	<60	10	6
	Up to 80	13	6
	Up to	16	6
	100	>19	6
	>100[d]		
Guinea Pigs		60	7
	<350	>101	7
	>350[d]		

[a] To convert square inches to square centimeters multiply by 6.45.

[b] From cage floor to cage top.

[c] To convert inches to centimeters. multiply by 2.54.

[d] Larger animals might require more space to meet the performance standards (see text).

TABLE 2: Recommended Space for Rabbits, Cats, Dogs, Nonhuman Primates and Birds

Animals	Weight, kg[a]	Floor Area/ Animal, in²[b]	Height,[c] in[d]
Rabbits	<2	1.5	14
	Up to 4	3.0	14
	Up to 5.4	4.0	14
	>5.4[e]	>5.0	14
Cats	<4	3.0	24
	>4[e]	>4.0	24
Dogs[f]	<15	12.0	--
	Up to 30	>24.0	
Monkeys[g,h]			
(including baboons)			
Group 1	Up to 1	1.6	20
Group 2	Up to 3	3.0	30
Group 3	Up to 10	4.3	30
Group 4	Up to 15	6.0	32
Group 5	Up to 25	8.0	36
Group 6	Up to 30	10.0	46
Group 7	>30[e]	15.0	46
Apes (pongidae)[h]			
Group 1	Up to 20	10.0	55
Group 2	Up to 35	15.0	60
Group 3	>35[i]	25.0	84-
Pigeons[j]	-	0.8	----
Quail[j]	-	0.25	--
Chickens[j]	<0.25	0.25	
	Up to 0.5	0.50	
	Up to 1.5	1.00	
	Up to 3.0	2.00	
	>3.0[e]	>3.00	

Table 3 lists recommended space allocations for farm animals commonly used in a laboratory setting. When animals, housed individually or in groups, exceed the weights in the table, more space might be required. If they are group-housed, adequate access to water and feeder space should be provided (Larson and Hegg 1976; Midwest Plan Service 1987).

[a]To convert kilograms to pounds, multiply by 2.2.

[b]To convert square feet to square meters, multiply by 0.09.

[c]From cage floor to cage top.

[d]To convert inches to centimeters. multiply by 2.54.

[e]Larger animals might require more space to meet performance standards.

[f]These recommendations might require modification according to body conformation of individual animals and breeds. Some dogs, especially those toward upper limit of each weight range, might require additional space. These regulations (CFR 1985) □ to look up what is CFR

mandate that the height of each cage be sufficient to allow occupant to stand in "comfortable position" and that the minimal square feet of floor space be equal to "mathematical square of the sum of the length of the dog in inches (measured from the tip of its nose to the base of its tail) plus 6 inches; then divide the product by 144."

[g]Callitrichidae, Cebidae. Cercopithecidae, and Papio. Baboons might require more height than other monkeys.

[h]For some species (e.g., *Brachyreles, Hylobates, Symphalangus, Pongo*, and *Pan*), cage height should be such that an animal can, when fully extended, swing from the cage ceiling without having its feet touch the floor. Cage-ceiling design should enhance brachiating movement.

[i]Apes weighing over 50 kg are more effectively housed in permanent housing of masonry, concrete, and wire-panel structure than in conventional caging.

[j]Cage height should be sufficient for the animals to stand erect with their feet on the floor.

TABLE 3: Recommended Space for Commonly Used Farm Animals

Animals/ Enclosure	Weight. kg[a]	Floor Area/ Animal, ft[2][b]
Sheep and Goats		
1	<25	10.0
	Up to 50	15.0
	> 50[c]	20.0
2-5	<25	8.5
	Up to 50	12.5
	> 50[c]	17.0
>5	<25	7.5
	Up to 50	11.3
	> 50[c]	15.0
Swine		
1	Up to 25	12.0
	Up to 50	15.0
	Up to	24.0
	100 Up	48.0
	to 200	>60.0
2-5	> 200[c]	6.0
	<25	10.0
	Up to 50	20.0
	Up to100	40.0
	Up to200	>52.0
>5	> 200[c]	6.0 9.0
	<25	18.0
	Up to 50	36.0
	Up to100	>48.0
	Up to200	
	> 200[c]	

[a]To convert kilograms to pounds. multiply by 2.2.
[b]To convert square feet to square meters. multiply by 0.09.
[c]Larger animals might require more space to meet performance standards.

TABLE 4: Temperature, Humidity, Ventilation and Lighting

The recommended temperature ranges for the different animals are as provided in the table below.

ANIMAL	DRY-BULB TEMPERATURE °C
Mouse, rat, hamster, gerbil, guinea pig	18 - 23
Rabbit	16 - 22
Cat, dog, non-human primate	18 - 29
Farm animals & poultry	16 - 27

The relative humidity should be 30 - 70%. The ventilation should be 10 - 15 fresh air changes per hour. In some situations, the use of such a broad ventilation guideline might over-ventilate an enclosure that contains few animals or under-ventilate an enclosure that contains many animals. To determine more accurately the ventilation required, the minimal ventilation rate required to accommodate heat loads generated by animals can be calculated with the assistance of mechanical engineers. The minimal required ventilation is then determined by calculating the amount of cooling required to control the heat load expected to be generated by the largest number of animals to be housed in the enclosure plus any heat generated by non-animal sources and heat transfer through room surfaces.

Lighting of 325 lux (30 foot candles) about 1.0 metre (3.3 feet) above the floor should be provided.

APPENDIX IV

ADDITIONAL INFORMATION ON NON-HUMAN PRIMATE HOLDING CARE AND USE

1. Non-human primates (NHP) are recognised as having highly developed mental and emotional capacities, more so than most other animals. In many ways, they are similar to humans and exhibit many similar external manifestations of emotions such as facial expressions, vocalisations, postures, gestures, and reactions. They have been known to react in ways similar to humans under comparable situations, e.g. compare captive NHP and institutionalised humans.

2. Given the greater complexity of the NHP, when managing and caring for them, besides providing a physical environment conducive to their well-being, emphasis should therefore be placed on enhancing their social and behavioural well-being through enrichment of their environment.

3. Researchers should acquaint themselves with the animal's distinctive characteristics and needs. They should be able to recognise abnormal behaviour patterns such as stereotypes, appetite disorders, abnormal social behaviours, etc. and take necessary steps to treat or ameliorate them. They should be familiar with the literature on animal cognition and perception and conduct frequent routine observation of every animal in order to be in a position to provide optimal care and handling of the animals. NHP that are housed improperly or treated inhumanely are likely to yield unreliable data due to the effects of behavioural stress. This can introduce unwanted variables.

4. Most primate species, including the majority of those used in laboratories, are highly social, live in complex social groups and establish long-term bonds, although such bonds may not necessarily be permanent. Because of the bonding, social isolation is likely to adversely affect individual animals. Animals raised in total social isolation could suffer from social deprivation and become withdrawn and develop aberrant social, sexual and exploratory behaviour. It is therefore important to provide the company of compatible conspecifics or other NHP species, and if this is not possible, increased human company.

5. Group or paired housing is preferred but the potential for problems such as wounding, disease transmission, dominance hierarchies, social distress, and undernourishment of a lower ranking partner should be kept in mind. When groups are being formed, observers must adjust group composition so the units show minimal aggression. Where single housing is necessary, the role of

the animal care technician takes on added importance. Familiarity with the handler, surrounding and procedure can significantly reduce anxiety. NHP should never be housed in a restraint chair but the restraint chair may be used to the extent necessitated by the nature of an experiment.

6. NHP form coalitions through which they establish their dominance ranks and compete for food and sexual partners. Removing a monkey from its group may disrupt the existing network of alliances and induce rank changes, which may be associated with vicious fighting resulting in injuries. Animals that are to be reintroduced should be kept away from the group for as short a time period as possible.

7. While enclosure size is an important variable, the primary emphasis should be in providing the animal with the option for species-appropriate activities. Besides providing social peers, an animal's environment can also be enriched by providing food gathering activities, devices such as perches, shelves and swings and artificial appliances, such as audiovisual devices (radio, video, television). These latter appear to be useful in enhancing the wellbeing of NHP, especially if the NHP can turn the equipment on and off at will. It has been reported anecdotally that monkeys are particularly fascinated by visuals depicting their natural environment, animals that are found in their natural habitat or videos of themselves.

8. Most primates show vertical flight reactions. This should be taken into account when arranging their housing. Attempts should be made to cater to their preferred vertical limits in the wild. Because of the importance of vision to the NHP, particularly M. *nemestrina*, cages should be positioned so that the monkeys can see animals of like species. Solid-sided caging prevents visual contact. If physical contact is possible, there must be assurance that the animals are compatible.

9. Interaction between the NHP and the researcher or technician is encouraged but it should not be forced. The interaction, however, must not involve handling other than what is necessary for the maintenance of the animal or for investigational procedures. Direct physical contact between humans and NHP should be evaluated from facility to facility. In many instances it should be kept to a minimum to avoid problems that may arise, for example from breaking of the human / animal bond when staff changes occur or when an animal must be euthanised, as well as the hazards posed by zoonotic diseases. Some of the most significant diseases associated with NHP are *Cercopithecine herpesvirus I* (formerly *Herpesvirus simiae*) infection and infectious haemorrhagic fever viruses.

10. Many NHP have extreme physical strength in relationship to body size and can inflict serious injury on personnel. Humans can also transmit infectious diseases to primates, e.g. measles, tuberculosis. It is recommended therefore that personnel exposed to NHP be provided with such protective items as gloves, arm protectors, masks and face shields. They should be routinely screened for tuberculosis and a procedure established for ensuringulosis and a procedure established for ensuring medical care for bites and scratches.

BORANG PERMOHONAN KELULUSAN JAWATANKUASA ETIKA HAIWAN

UMS
UNIVERSITI MALAYSIA SABAH

MS ISO/IEC 17021: 2006
QS 0212/999 CS 01

CERTIFICATE

ANIMAL ETHICS COMMITTEE UNIVERSITI MALAYSIA SABAH

Application for Approval of a Research Project Involving the Use of Animals, and Approval as an Investigator for the Project

NOTE:

1. Please complete the application form in accordance to the Animal Ethics Committee Guidelines. Incomplete application will result in the return of the application and delay in the granting of the approval.

2. Attach a copy of the proposal (research / elective / teaching / other).

3. Application must be word-processed or typewritten and forwarded to:

   Chairperson, Animal Ethics Committee (AEC),
   Centre for Research & Innovation, Universiti Malaysia Sabah (UMS),
   Jalan UMS, 88400 Kota Kinabalu, Sabah.

4. Please submit the application and direct all enquiries to the following address:
   Secretary, Animal Ethics Committee, Centre for Research & Innovation, Universiti Malaysia Sabah (UMS), Jalan UMS, 88400 Kota Kinabalu, Sabah.
   Tel: **(6)088-320 393; Fax: (6)088-320 127 Email: ric@ums.edu.my**

TYPE OF APPLICATION: [Please tick (/)]

RESEARCH ( ) / ELECTIVE ( ) / TEACHING ( ) / OTHER ( ) please specify: _____

If teaching / elective project, state course name and code:

_____

NAME OF PRINCIPAL INVESTIGATOR / CO-ORDINATOR / CHAIRPERSON:

_____

FACULTY / CENTRE:

_____

PROJECT TITLE:

_____

Received by Secretary, Animal Ethics Committee

AEC File No: **Date:**

1. PROPOSAL

1.1 Project Title:

1.2 Project Objectives:

1.3 Summary of the Project/ Abstract (not more than 250 words):

1.4 State the Ethical Implications of the Project:

i.

ii.

iii.

1.5 Duration

Proposed commencement date :

Estimated duration from : dd/mm/yyyy to: dd/mm/yyyy

1.6 Investigators / Co-ordinators / Chairperson:

Please list the names of persons responsible in handling animals (including students):

No.	Name	Dept/ School	Investigators / Co-ordinators / Chairperson	I/C / Passport No.	Contact No.	Signature & Date
1.						
2.						
3.						
4.						
5.						
6.						

2. CLASSIFICATION OF PROJECT (Please circle one or more)

A. Project requiring animals to be sacrificed for the preparation of the whole animals or tissue specimens.

B. Procedure carried out under anaesthesia and the animals sacrificed without regaining consciousness.

C. Survival after an intervention, which causes minimal stress of short duration (e.g. venepuncture, brief restraint, and blood vessel cannulation under anaesthesia).

D. Survival after an intervention, which causes major or prolonged stress (e.g. major surgery, prolonged restraint, administration of toxic or painful substances and major behavioural modification).

E. Purely breeding projects.

F. Production of antisera.

G. Teaching purposes.

H. Fieldwork

I. Other procedures – please specify:

_____

3. ANIMALS REQUIRED

3.1 TABLE OF PROPOSED ANIMAL USAGE:

(**NOTE**: Ethical Clearance can only be given for work involving **LIVE VERTEBRATES** for a maximum period of three calendar years only.)

No.	*Scientific* and Common Name	Male (No.)	Female (No.)	Non-Specific Gender (No.)	Total (No.)
1.					
2.					
3.					
	Grand Total				

3.2 SOURCES OF ANIMALS:
(Address of Source / Supplier :)

3.3 LOCATION OF ANIMALS:
(Please indicate where the animals will be housed during the experimental period)

3.4 ENVIRONMENTAL ENRICHMENT:
(Please indicate type(s) of environmental enrichment (special / specific) to be used)

3.5 CARE OF ANIMALS:
(State the name and contact address of the persons responsible for the daily care of animals (including after office hours, weekends and public holidays))

3.6 PERMITS REQUIRED:
(If protected native species, provide details of appropriate permits held)

Holder :
Issuing Agency :
Date of Issue :
Serial No. :
Period of Validity :

3.7 JUSTIFICATION:
(Please explain the basis for selection of the species and justification for the number of animals to be used.)

NOTE: Minimum number of animals to be used to achieve the objectives of the project.

4. EXPERIMENTAL METHODS

4.1 Procedures to be carried out on the animals: (Please circle)

(a) Surgery: YES / NO
(If YES, answer 4.2 and 4.3)

(b) Anaesthesia: YES / NO
(If YES, answer 4.4 and 4.5)

(c) Other: YES / NO
(If YES, answer 4.6 and 4.7)

4.2 State surgical procedures to be carried out on the animals:

4.3 Name the person(s) having experience in performing the procedures:

4.4 Anaesthetic to be used:

Name :
Dose :
Route of Administration :
Duration :
Clinical signs to ensure anaesthesia are adequate:

4.5 Neuromuscular Blocking Agent to be used: YES / NO

If YES,

Agent: Dose:

Route of Administration: Duration:

Justification for use of neuromuscular blocking agent:

4.6 Outline the procedure:

4.7 Name the person(s) having experience in performing the procedure:

4.8 Supervision during experimentation:
(Detail the extent and method of supervision of animals during experimentation, including methods to be used for assessing and preventing pain and distress).

4.9 Post-procedural care:
(Detailed arrangements made by the investigators for immediate and continuing post-operative and / or post-procedural care, including details of restraint, housing and analgesics to be used).

4.10 Post-procedural survival time for the animals: (hours / days / months / years)

5. COMPLETION OF PROJECT

5.1 Animals to be euthanized: YES / NO

If YES,

(i) state the method to be used:

(ii) name of the person performing euthanasia:

(iii) method of disposal of euthanized animals:

(iv) If animals are not euthanized, state what happen to them:

6. HAZARDOUS MATERIALS

Does the project involved exposure of live animals to any of the following:

6.1 Ionising Radiation: YES / NO

If YES, Agent:

6.2 Carcinogen / Teratogen: YES / NO

If YES, Agent:

6.3 Pathogenic Organisms: YES / NO

If YES, Agent:

6.4 Other: YES / NO

Please give details.

If YES to any above;

Please indicate the health risks to human and / or animals involved in the project:

7. GENETIC MATERIALS

7.1 Will you be isolating the DNA? YES / NO

7.2 Will you be inserting DNA into live animals? YES / NO

8. DECLARATION BY PRINCIPAL INVESTIGATOR / COORDINATOR / CHAIRPERSON:

I hereby declare that I and / or co-investigators / co-coordinators / vice chairperson have the appropriate qualifications and experience to perform the procedures described in this project. I am familiar with the provisions of the UMS rules and regulation in animals for the Care and Use of Animals for Scientific Purposes; and accept responsibility for the conduct of the experimental procedures detailed above; in accordance with the requirement of the rules and regulation laid down by Animal Ethics Committee UMS.

I further declare that the procedures described in this project do not constitute unnecessary repetition of work previously carried out by other research workers or myself, and that each person engaged in this project has been adequately instructed in, and is competent to perform, procedures that they are to carry out. If they are not already skilled in the procedures, I will be responsible for seeing that they obtain the necessary training in advance, so that each procedure on an animal will be carried out in the most appropriate manner.

_____ _____

Signature: Principal Investigator Date

Assesment and Certification for Approval of a Research Project Involving the Use of Animals, and Approval as an Investigator for the Project

Name of Applicant :

F/P/I/U :

Title of Project :

AEC File No :

*** *For secretariat use only.*

NO	SECTION	COMMENTS	RECOMMENDATION
1.0	Proposal		
2.0	Classification of Project		
3.0	Animal Required		
4.0	Experimental Methods		
5.0	Completion of Project		
6.0	Hazardous Materials		
7.0	Genetic Material		

ANY OTHER COMMENTS

CERTIFICATION OF THE AEC (Chairperson / Authorised Representative)

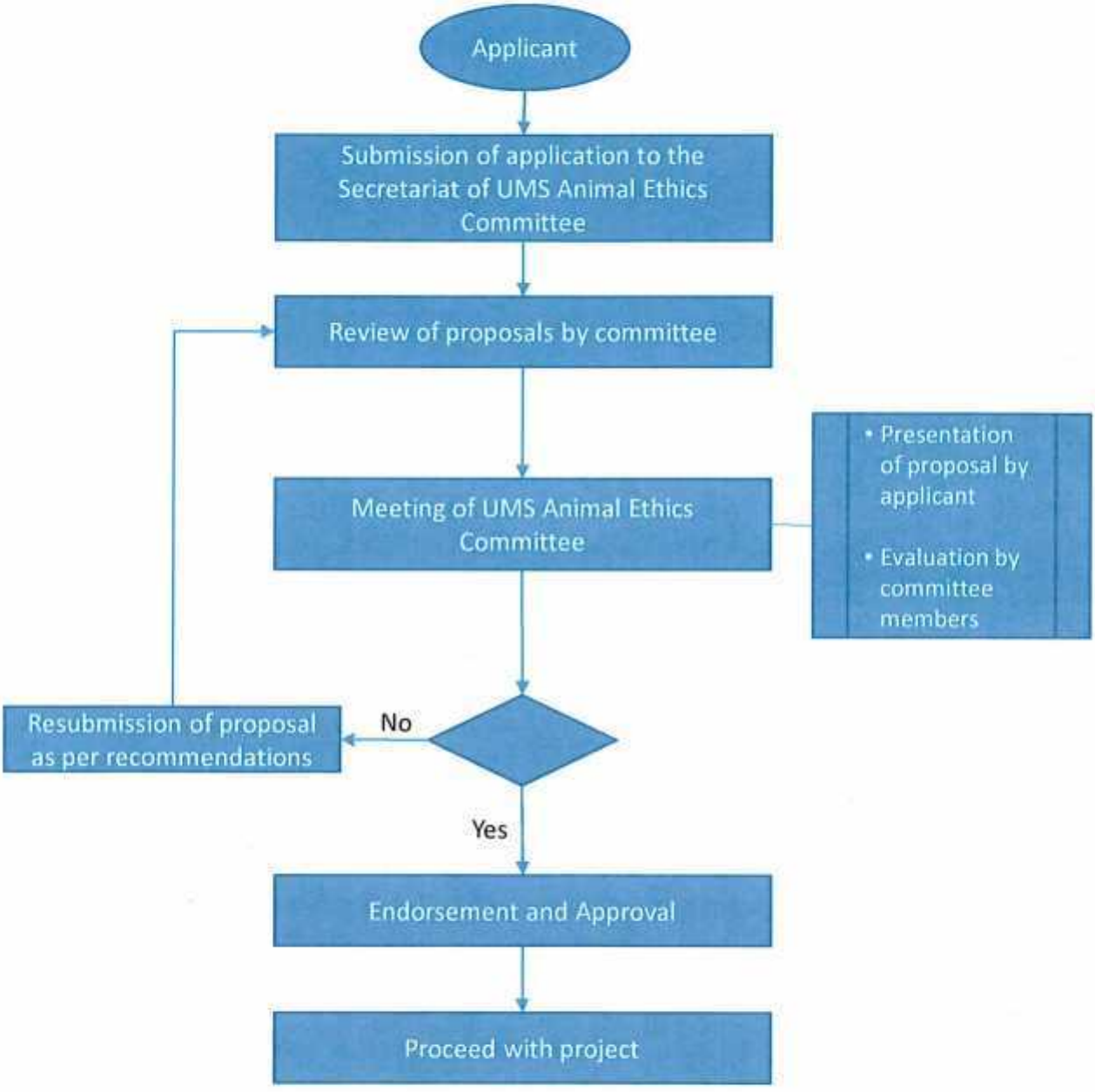
Name :

Signature : _____

Date :

CARTA ALIR PERMOHONAN KELULUSAN JAWATANKUASA ETIKA HAIWAN

FLOW CHART FOR THE APPLICATION AND APPROVAL OF A RESEARCH PROJECT INVOLVING THE USE OF ANIMALS AND APPROVAL AS AN INVESTIGATOR FOR THE PROJECT



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Ruj : UMS/PPI1.3.2/800-1/2/3

Tarikh : 27 Julai 2015

SENARAI EDARAN SEPERTIMANA DI LAMPIRAN

YBhg. Dato' / Prof. / Dr. / Tuan / Puan,

PEKELILING TIMBALAN NAIB CANSELOR (PENYELIDIKAN & INOVASI) BIL 2/2015:
- ***RESEARCHER'S GUIDELINES ON CODE OF PRACTICE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES***

Dengan hormat, perkara di atas adalah dirujuk.

Untuk makluman YBhg. Dato' / Prof. / Dr. / Tuan / Puan, Pekeliling Timbalan Naib Canselor (Penyelidikan & Inovasi) Bil 2/2015: *Researcher's Guidelines On Code Of Practice For The Care And Use Of Animals For Scientific Purposes* telah dikeluarkan pada 27 Julai 2015 dan boleh dicapai melalui laman web Pusat Penyelidikan & Inovasi di url http://www.ums.edu.my/ppi .

Sehubungan itu, mohon kiranya YBhg. Dato' / Prof. / Dr. / Tuan / Puan dapat memanjangkan makluman ini kepada semua kakitangan akademik di Fakulti/ Institut/ Unit masing-masing.

Segala perhatian dan kerjasama dari pihak YBhg. Dato' / Prof. / Dr. / Tuan / Puan dalam perkara ini amatlah dihargai dan didahului dengan ucapan terima kasih.

Sekian.

"BERTEKAD CEMERLANG"

Yang Ikhlas,

NURHANI SUGIANTO
Penolong Pendaftar Kanan
b.p Timbalan Naib Canselor (Penyelidikan & Inovasi)

S.K YBhg. Datuk Naib Canselor
Timbalan Naib Canselor (Akademik & Antarabangsa)
Timbalan Naib Canselor (Penyelidikan & Inovasi)
Timbalan Naib Canselor (Hal Ehwal Pelajar & Alumni)
Pemangku Pendaftar
Pengarah, Pusat Penyelidikan & Inovasi
Timbalan Pengarah PPI (Penyelidikan / Instrumentasi / Inovasi)
Seksyen Maklumat & Korporat PPI – Muat naik di web PPI dan *Announcement* : Laman Rasmi UMS
Fail