CODE OF CARE AND RESPONSIBILITY IN THE USE OF ANIMALS IN RESEARCH

INFORMATION NOTE

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With an increase in Research and Development (R&D) activities within universities, as well as public and private organisations, it is important to ensure that high standards are maintained. Although general guidelines are adequate in terms of providing an outline of the required standards, specific guidelines are needed to address in more detail the various aspects of experimental research involving the use of animals.

In this context, recognising the urgent need for institutions to have appropriate, satisfactory and recently reviewed guidelines, the Mauritius Research Council (MRC) has initiated work on the preparation of a set of guidelines named *Code of Care and Responsibility in the use of Animals in Research*. The aim is to set out guidelines that can address the current requirements of local institutions and set the standard for future work, while retaining sufficient flexibility to allow adaptation as new technology emerges.

The Council is of the view that scientific practice in Mauritius should be in accord with international guidelines as far as possible. The guidelines being proposed by the MRC, have been adapted from the *Australian Code of Practice for the Care and use of Animals for Scientific Purposes* (National Health and Medical Research Council, Australia, 1997) and the *Responsibility in the use of Animals in Medical Research* (Medical Research Council, UK, 1993), and are offered as a source of information to ensure that a proper research framework can be adopted by various institutions engaging in Research and Development.

It is expected that in the future, the MRC will only support research work involving the use of animals on the basis that researchers comply with legal provisions, any related codes of conduct or guidance, and the specific conditions of licences issued.

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1. INTRODUCTION

This Code is intended to provide guidance to medical researchers using animals or animal products in their research, and to members of Animal Ethics Committees who would be involved in reviewing applications for support. The guidance covers:

- the diversity of research involving animals;
- the ethical issues that arise; and
- the principles and procedures to be adopted by research institutions.

This guidance is additional to the legal requirements imposed by the Prevention of Cruelty to Animals Act (1982).[1]

2. DIVERSITY OF RESEARCH INVOLVING ANIMALS

Research involving animal experimentation is usually conducted with the objective, ultimately, of reducing human and animal disease and suffering. There is considerable diversity in such research ranging from the use of protozoal parasites, through invertebrates to mammals, particularly mice and rats.

The procedures in which animals are used may vary:

- Animals can be conscious (e.g. vaccination or administration of drugs);
- Procedures may be conducted under full anaesthesia with subsequent recovery;
- Animals may be used for the supply of tissues for *in vitro* culture;
- Animals may be used for the supply of materials (such as antibodies, enzymes and blood products).

[1] For more details please refer to the Act.

3. ETHICAL CONSIDERATIONS

In using animals in research, all those involved should consider carefully the problems and concerns associated with:

- keeping animals in captivity;
- killing animals; and
- causing animals distress or pain, either during the research or husbandry.

Researchers must recognise that there are many different views on the above points. This *Code* recognises that research using animals may bring benefits to human and animal health that cannot be realised in any other way, and that such research must be regulated, in particular to minimise any distress or pain that may be caused.

4. DESIGN OF RESEARCH

The ultimate objective of health related research in Mauritius should be the maintenance and/or enhancement of human and/or animal health and welfare. All research should seek where possible to avoid the use of animals, and the researcher must put forward sound scientific reasons for their use explaining why no realistic alternative exists. All studies must take full account of the welfare of the animals.

- The objective of the research should be feasible and clearly defined. Decisions made on the use of animals in research is an integral part of good research and good laboratory practice.

- The species with the most appropriate physiology for the work should be used. Wherever possible the 'simplest' organism possible should be used.

- Only a minimum number of animals should be used in an experiment, but the number must be sufficient to ensure significant statistical validity in the answers to the questions posed.

- The severity of procedures performed on animals must be the minimum possible. The experiment must be as short as possible, and analgesia/ anaesthesia should be used to minimise pain.

The use of animals in research must be fully justified. All animal experimentation should incorporate, as far as possible, a statement of principles concerning welfare and the effective implementation of the widely accepted three Rs relating to Refinement, Reduction and Replacement[2]. The three Rs have been defined as:

- **Refine** the experimental procedures to minimise suffering;
- **Reduce** the number of animals used; and
- **Replace** the use of animals (for example, by *in vitro* methods) where possible.
- **Design of research – the 3 Rs**

  The **replacement** alternatives can be:

  a) Living systems,

  b) Non-living systems, and

  c) Computer Simulations.

  Living systems

  Living systems including in vitro methods that utilise organ, tissue or cell culture techniques. Invertebrate animals, such as the fruit fly, have long been used in research and represent another type of living alternative to vertebrate animals. Finally, microorganisms and plants represent living alternatives for some types of research and testing. Further, if no invertebrate model is appropriate, the use of species lower on the phylogenetic scale may be considered a replacement alternative.

[2] Russell, W and Burch R. The principles of humane experimental technique (1992).

Non-living systems

Non-living systems include physical or mechanical systems and chemical techniques. Mechanical models may be used in the training of specific techniques and can replace living animals in some cases. Chemical techniques are the most widely used nonliving systems and include such useful systems as the enzyme linked immunosorbent assay (ELISA). Techniques that identify the presence of chemical reactions and enzymes, or simply analyze chemical structure, can all be useful in the prediction of toxicity without the use of animals.

Computer simulations

Computer simulations may replace some animal use and can be particularly useful when a question is well defined and there is existing data. Moreover, with the advent of the Ebene Cybercity and the Bioinformatics Institute, such replacement technique may prove to be fruitful.

5. ANIMAL EXPERIMENTATION LICENCES

Animal experimentation licences must cover the following:

- A personal licence should be held by an individual prior to performing any scientific work involving animals;
- An institutional licence is required for the institution/department/laboratory where the work is to be performed;
- A project licence should specify the programme of work where regulated procedures are to be carried out;
- Each licence allows only identified procedures on specified types of animals;
- Breeding establishments where rodents, rabbits, cats, dogs and primates are bred require a 'Breeding Establishment and Animal Supplier Licence';[3]

[3] If these are not available or licensed in Mauritius, action might be necessary.

- Licensees must be fully and appropriately trained.

5.1 LICENCE APPROVAL

Applications are normally approved for a period of 3 years if the following conditions are satisfied:

- Licensees must adhere to all provisions of the Prevention of Cruelty to animals Act (1982) and *Code of Care and Responsibility in the Use of Animals in Research*;

- Licensees must submit a satisfactory Annual Report including a Statistical Vivisection and Experimentation return for each calendar year; and

- No adverse occurrences have been reported on the licensee relating to animal use.

5.2 REQUIREMENTS FOR THE GRANTING OF A LICENCE FOR SPECIFIC ANIMAL RESEARCH

- Potential results are important enough to justify the use of animals;

- The research cannot be done by non-animal methods;

- A minimum number of animals will be used;

- Dogs, cats or primates are only used when other species are not suitable; the use of pregnant animals should be avoided as far as possible, especially in the case of domestic animals such as dogs and cats.

- Measures are in place to ensure that discomfort or suffering is kept to a minimum by appropriate use of anaesthetics or pain killers;

- The researchers and technicians conducting experimental procedures on animals must have the necessary training, skills and experience; and

- The research premises must have the necessary facilities[4] for the proper care of the animals.

6. ANIMAL ETHICS COMMITTEE (AEC)

Ideally, the AEC should consist of approximately ten members. As an example, an institution – based AEC include a separate person appointed to each of the following categories.

- A person with qualifications in veterinary science, with experience relevant to the institution or, in special circumstances, a person with qualifications and experience to provide comparable expertise;

- A person with substantial recent experience in animal experimentation;

- A person with demonstrable commitment to, and established experience, in furthering the welfare of animals, who is not employed by or otherwise involved in the care and use of animals for scientific purposes. The person should, where possible, be selected on the basis of membership of an animal welfare organisation;

- An independent person who does not currently or who has not in the past conducted scientific or teaching activities using animals, and who is not an employee of the institution;

- A person responsible for the daily care of animals within the institution.

The AEC may include additional members to ensure that it functions effectively. Importantly, the person who chairs the Committee should be a senior member of the scientific/academic community.

[4] These will need to be developed if not available.

6.1 ROLE OF THE ANIMALS ETHICS COMMITTEE

- The AEC must ensure that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals;

- The AEC must recommend to the institution any measure(s) needed to ensure that appropriate standards are maintained;

- AEC members should conduct inspections of all animal housing and laboratory facilities and maintain appropriate records to ensure compliance with the Prevention of Cruelty to animals Act (1982) *Code of Care and Responsibility in the Use of Animals in Research*;

- The AEC must examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals in scientific research or related activities. The Committee should only approve those studies for which animals are essential and which conform with the requirements of the *Code of Care and Responsibility in the Use of Animals in Research*, Prevention of Cruelty to animals Act (1982) while taking into account ethical and welfare aspects, as well as scientific value;

- AECs must ensure that any activity in breach with the *Code* or Prevention of Cruelty to animals Act (1982) ceases immediately and appropriate action is taken;

- The AEC must nominate a person on site where animals are used, to respond to emergencies. If possible, this person should be a member of the AEC;

- Large institutions with multiple sites of animal care must consider the appointment of an officer with veterinary or other appropriate qualifications. This person would be authorised by the AEC to ensure compliance with the *Code* and Prevention of Cruelty to animals Act (1982) and with the decisions of the AEC;

- In cases of emergency before an animal is treated or killed, all reasonable steps must be taken to consult with the Principal Investigator and the Chairperson of the AEC. Any such action must be reported promptly in writing to the Principal Investigator and the Chairperson of the AEC, including reasons for the actions taken;

- The AEC must examine and comment on all institutional plans and policies that may have a bearing on animal welfare; and

- The AEC must maintain a register of approved research projects, as well as keep a log of those projects that were rejected.

6.2 ASSESSING PROPOSALS

- Only those scientific or teaching activities that conform to the requirements of all the relevant sections of the *Code for the Care and Responsibility in the Use of Animals in Research* Prevention of Cruelty to animals Act (1982) will be approved;

- Proposals must be considered and approved **ONLY** at meetings of the AEC;

- Where possible, decisions on approval of proposals must be made without undue delay on the basis of consensus;

- The investigators and/or teachers must be informed of decisions in writing;

- Scientific or teaching activities involving the use of animals must not start until written approval from the AEC is given;

- Representations by an investigator(s) to members of the AEC regarding an application is unethical and will result in the rejection of the research proposal. Members of the AEC must report immediately any such representation to the Chairman.

7. USE OF ANIMALS

7.1 PERSONAL RESPONSIBILITY

In addition to the legal responsibilities, any person using animals in research whether for experimentation, testing or the provision of tissue, is responsible for ensuring that the animals are afforded the highest levels of welfare and protection. Those involved in the care and transportation of animals, as well as experimentation, should ensure that the facilities within which they are kept are of a high quality and that conditions of care and management are equally high.

7.2 CHOICE OF ANIMALS

- Stray pets must never be used in scientific procedures;
- Animals must be free from infections and diseases;
- Animals must come from known sources;
- All mice, rats, hamsters, guinea pigs, etc, should be obtained from designated breeders or suppliers;
- Dogs and cats may only be used if no other species is suitable;
- A project licence should not authorise the use of primates unless the AEC is satisfied that no other species is suitable;
- No chimpanzees or great apes may be used under any circumstances;
- Wild caught primates are banned from use unless an exceptional case is established;
- Researchers must give due consideration to the use of more than one species while carrying out toxicity tests (see Appendix 2).

7.3 NUMBER OF ANIMALS TO BE USED

- Standardisation between studies should be with regard to source, age, weight and health status of the animals so as to minimise experimental variables within and between studies;

- Expert advice may be required on a study-by-study basis to determine the appropriate number of animals;

- Justification for the approved number of animals should be provided.

7.4 REPEATED USE OF ANIMALS

- Individual animals must **NOT** be used in more than one study, either in the same or different projects without the approval of the AEC;

- However, re-use of animals may reduce the total number of animals used in a project, result in better experimental design, and also reduce distress or avoid pain to other animals;

- Studies involving the re-use of animals, and approved by the AEC must:
  - not cause the animals pain or distress;
  - be such that the second or subsequent study should produce little or no pain or biological stress to the animals (for example, modifying diet, taking a succession of blood samples, repeated non-invasive recording procedures); and
  - be such that the animals have fully recovered from the first study before further procedures are commenced.

7.5 SUPPLY OF ANIMALS

Animals must be obtained from a source approved by the AEC. All vertebrate animals must come from a registered breeder or supplier[5]. Breeding must be carefully regulated to meet research needs, with respect to number, uniformity and health. In particular, there must be no over breeding and no unnecessary culling and the quality of the animals must be high enough to allow them to be used in minimum quantities.

[5] If these are not available or are not of internationally acceptable standard, action may be necessary.

7.6 ACCOMMODATION AND TRANSPORT OF ANIMALS

Those in charge of animals, whether permanently or temporarily housed or in transit, should ensure that scrupulous husbandry is observed. Animals should be properly fed, watered and cleaned. They should have a suitable environment which is not subject to extremes of temperature, humidity or pollution. Animals should not be kept or transported in overcrowded conditions.

- Transportation can cause distress due to confinement, movement, noise and changes in the environment and personnel;

- The extent of any distress depends on the animal's health, its temperament, species, age, sex, the number of animals travelling together, the duration and mode of transport;

- The conditions and duration of the transport must ensure that the health and well-being of the animals are not unnecessarily compromised;

- Containers must be escape and tamper-proof, there must be adequate nesting and bedding facilities, and animals must be protected from sudden movements and extremes of climate;

- Food and water must be provided when necessary;

- Transport by air should be in accord with the appropriate regulations[1], and the domestic transport of livestock must be in accord with the relevant code of practice[2].

- Both suppliers and recipients of animals must ensure that the deliveries are satisfactory and that the animals are received by a responsible person.

- The condition of animals on acceptance or rejection should be noted by the responsible person in a log book.

[1] e.g. International Air Transport Association (IATA) regulations

7.7 ADMISSION OF NEW ANIMALS INTO HOLDING FACILITIES

- When new animals are admitted into the animals holding area, they should be quarantined and inspected by a qualified person;

- Their health should be evaluated, treatment started if required and their suitability for the proposed studies assessed;

- This period should allow the acclimatisation to the staff and holding facility;

- Animals that do not adapt satisfactorily to their new environment should not be kept, and where possible, returned to the supplier.

7.8 ANIMAL WELFARE AND HEALTH

- Animals should be given due respect and care by all who look after, handle or perform experiments on them. Their health should be maintained and monitored and any deterioration attended to immediately. Pain, including injury, physiological stress and significant discomfort, whether immediate or in the long term should be kept to a minimum at all times.

- Animals should be kept healthy before and, as far as in keeping with the aims of the research, during the experiment.

- Where recovery is planned, this should result in no lasting suffering to the animal. Where lasting pain, suffering or distress is likely to be caused, the animal should always be humanely and painlessly killed at the end of the experiment.

7.9 SURGERY

- Surgical procedures must be carried out under appropriate local or general anaesthesia. There should be continuous monitoring of depth of anaesthesia and of side-effects such as hypothermia, cardiovascular and respiratory depression;

- The choice and administration of anaesthetic, analgesic and tranquillising agents must be suitable for the species and appropriate for the purpose of the study;

- When more than one surgical procedure is to be performed, the animal must have recovered to good general health between each procedure. Every effort must be made to reduce the total number of procedures and the AEC must have been informed and approved of the need for more than one procedure;

- If an animal is not to recover from the surgery, it must be unconscious for the whole procedure, either by continuing the administration of the general anaesthetic or by inducing brain death;

- When the animal is to recover from the surgery, surgical procedures must conform to the accepted standards in human and veterinary practice. Analgesics and tranquillisers must be used when required and their use should parallel that in current medical and veterinary practice.

7.10 POST–OPERATIVE CARE

- Comfort of animals must be promoted throughout the post-operative period;

- Attention must be given to warmth, hygiene, fluid and food intake and control of infection. The use of analgesics and tranquillisers may be needed to minimise post-operative pain or distress;

- Care should be taken that when recovering from anaesthesia animals 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;

- Appropriate clinical reports must be kept, and must be accessible to all involved in the post-operative care of the animal;

- Carers must ensure that adequate monitoring, treatment and care of post-operative animals is provided. Investigators must be kept fully informed of the animals' condition during the recovery period;

- Any post-operative animal observed to be in a state of severe pain or distress that cannot be alleviated quickly must be killed humanely without delay;

- Regular observation of surgical wounds is essential to check the progress of healing. Any problems must be attended to immediately.

7.11 THE ANIMAL'S ENVIRONMENT

- Since most laboratory animals spend most of their time confined to pens and cages, investigators should ensure that conditions for holding and experimentation are of a high standard.

- Immediate housing, for instance, cages and the surrounding environment, should provide animals with spacious, high quality living space and contribute to the good general welfare and minimise stress. Species-specific considerations, together with behavioural requirements and environment enrichment need to be given due attention.

- Indoor or outdoor animal houses must be appropriate to the needs of the species;

- The environmental conditions must suit the behaviour and the biological needs of the animals, unless otherwise approved by the AEC for the purpose of the project;

- Air exchange, temperature, humidity, light and noise should be maintained within limits compatible with the good heath and well being of the animals.

7.12 FOOD AND WATER

- Animals must receive appropriate, uncontaminated and nutritionally adequate food according to the accepted requirements for the species;

- Drinking water should be constantly and reliably available and should be clean, fresh and uncontaminated;

- Variations to these requirements as part of the study design must receive prior AEC approval.

7.13 IDENTIFICATION OF ANIMALS

- The method of identification must be reliable and cause the least stress possible. This can be done by neckband, tattoo, individual tag, electronic numbering device, physical mark or by a label or marking attached to the cage of the animals;

  Cage cards should also include:
  a) Source of the animal,
  b) Strain or stock,
  c) Names and locations of responsible investigators,
  d) Pertinent dates, and
  e) Protocol number.

- The person in charge of the facility is responsible for ensuring that animals are identified before allocation to an approved project, after which time both the person in charge and the investigator are jointly responsible.

7.14 IMPLANTED DEVICES

- Skilled and specialised attention is required in the care of animals following an operation in which monitoring or sampling devices have been implanted, or a fistula created;

Waste disposal

A research animal facility generates a significant amount of waste that must be removed and disposed of on a regular, frequent basis.

Waste containers should be readily accessible throughout the facility and should be leak-proof and equipped with tight-fitting lids. Disposal methods must conform to national requirements.

Animal carcasses and tissues require a separate cold storage area and regularly scheduled removal. Hazardous waste, including carcasses of animals exposed to radioactive or biohazardous agents, must be adequately sterilised and/or contained prior to removal and disposal.

Pest control

The research animal facility is an active place, with frequent movement of personnel, animals, equipment, containers, and food and bedding, creating ideal conditions for the introduction of pests, including arthropods, birds and rodents.

A regularly scheduled, documented pest control and monitoring programme should be implemented, which effectively combines elimination of all entry and harbourage sites with good waste disposal and personnel training.

- Regular observation is essential to determine signs of distress, pain or infection, which must be treated immediately.

7.15 NEUROMUSCULAR PARALYSIS

- Neuromuscular blocking agents must not be used without adequate general anaesthesia or an appropriate surgical procedure, which eliminates sensory awareness;

- Immobilisation of an animal using a neuromuscular agent alone, is not acceptable.

7.16 ELECTRO-IMMOBILISATION

- Electro-immobilisation must not be used as an alternative to analgesia or anaesthesia;

- The AEC must carefully evaluate published evidence to assess whether electro-immobilisation is likely to cause distress in cases when it is used.

7.17 MODIFYING ANIMAL BEHAVIOUR

- Procedures used to modify an animal's behaviour or to induce it to perform specific tasks depend on motivating the animal;

- Inducement may be positive reinforcement but the inducement may be some form of biological stress. Researchers should ensure that this stress be as mild as possible;

- Severe water, food, social or sensory deprivation must never be used;

- Behaviour can be modified using procedures that involve no more than a physiological stress, for example, thirst within the range of the normal experience of the species.

7.18 BREEDING COLONIES

Breeding colonies may be of two types:

- colonies in which only the offspring are accessible to researchers; and

- specialist breeding colonies in which both the breeding animals and the offspring may be used for experimental work.

7.19 HANDLING AND RESTRAINING ANIMALS

- Handling of animals should be done by appropriately instructed and competent people using methods to avoid distress and injury;

- The use of restraint device(s) is(are) sometimes necessary for the welfare of the animals and the safety of the handler;

- Restraint devices must only be used to the minimum extent for the minimum period required to accomplish the purpose of the study, and should be appropriate for the animal;

- Tranquillisers or anaesthetics may help restraint but can prolong recovery from the procedure – the recovery of animals must be carefully monitored;

- Periods of prolonged restraint should be avoided. Where animals are in prolonged restraint, consideration must be given to their biological needs, including their behavioural requirements and they must be monitored regularly by a veterinarian or other qualified person not participating in the project. If any ill effects are shown, the animal must be removed from the restraint, or the method should be modified.

8. SCIENTIFIC ACTIVITIES INVOLVING HAZARDS TO HUMANS AND ANIMALS

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

- All staff must be aware of the hazards involved in working with any pathogen. Staff may require tests for confirming the absence of infection before, during and after the study;

- The AEC should make sure that advice of the institution's Biohazards Committee[3] has been sought and that appropriate measures for containment, disposal and decontamination have been established;

- Animals being administered infectious organisms should be quarantined as appropriate, taking into account risks to other animals and to people;

- The end-point of studies involving hazardous agents should conform to the requirements for toxicological studies (see Appendix 1);

- Precautions, security and emergency plans to contain hazardous agents must be appropriate to a 'worse-case' situation.

[3] Such a committee may need to be set up.

9. EXPERIMENTAL MANIPULATION OF ANIMALS' GENETIC MATERIAL

- All work involving the introduction of foreign DNA into mammalian cells or whole animals must be conducted in accord with the Genetics Committee[4] of the institution and the relevant Biohazards Committee;

- All proposals to manipulate the genetic material of animals, their germ cells or embryos must also be submitted to the AEC for approval;

- The manipulation of genetic material of animals has the potential to affect the welfare of their offspring adversely. Investigators must inform the AEC of known potential adverse effects on the well-being of the animals;

- The clinical status of animals in which the genetic material has been manipulated experimentally must be monitored for unusual or unexpected adverse effects. Investigators must report such effects to the AEC.

10. COMMUNICATION OF IMPROVEMENTS IN TECHNIQUES

- All researchers engaged in animal experimentation must ensure that any new procedure which reduces the number of animals needed for research, testing or diagnosis or the severity of procedures, is communicated to other researchers;

- Researchers should make a point of including in their published papers, information which is likely to be of help to others conducting similar experiments. The objective should be to record everyday practice and note pointers for best practice.

[4] This Committee may need to be set up, with an ability to liaise with the National Biosafety Committee.

11. COMPLETION OF PROJECTS

- On completion of the project, animals must be returned promptly to normal husbandry conditions;

- Where applicable, investigators should share with other investigators tissue from animals being killed.

12. FOETAL EXPERIMENTATION

- If foetal experimentation or surgery compromises the ability of the neonate to survive, it must be killed humanely before or immediately following birth unless such pain or distress can be relieved;

- Investigators must assume foetuses have the same requirements for anaesthesia and analgesia as adult animals of the same species, unless specific evidence to the contrary is provided;

- Consideration must be given to any special requirement of the foetus when performing surgery on the mother;

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

13. PRE-EUTHANASIA CONSIDERATIONS

- Sedatives given to the animals prior to euthanasia reduces anxiety and distress to both the animal and operator;

- Killing should be done in a quiet area, away from other animals;

- An autopsy must be performed on animals dying unexpectedly.

14. HUMANE END-POINTS

- Euthanasia is the method whereby the animal is killed gently and considered as an act of humane killing with the minimum of pain, fear and distress;

- Action has to be taken to end animal suffering in the following situations:
  - when the degree of suffering observed is not required by protocol and cannot be justified by the objective;
  - when the objective has been or cannot be realised; and
  - when the quality of data likely to be produced has been compromised.

- Reasons for humane killing:
  - to indicate the end of an experiment;
  - to harvest tissue required for research;
  - to alleviate unanticipated pain, distress and suffering; and
  - when the health status of the animal deteriorates and their welfare is compromised.

- The suffering of animals should be assessed by using parameters such as behaviour, appearance, food consumption, body weight changes, body temperature changes, physical examination, clinical observation and laboratory investigations (for example, haematology and serum biochemistry);

- End points should be described in meaningful terms, reflecting findings that can be recognised by those entrusted with the welfare of animals under experimentation;

- Observation schedules should be tailored to allow the early detection of end-points and there should be no delay between detection and implementation of those end-points;

- Animals must be checked at least once a day by a competent person;

- When deaths are encountered or where it is necessary to kill animals on welfare grounds, records should distinguish clearly between the two;

- All dead animals should be removed as soon as possible from their pens/cages, autopsied and the results reviewed to determine whether they add to scientific information or identify scope for refinement;

- If methods that do not cause instantaneous death are used, the aim should be to induce unconsciousness as quickly as possible by using a method that ensures that animals remain unconscious until they die;

- Studies must be scheduled so that animal welfare and scientific objectives are not compromised by inadequate resources of facilities and staff.

15. METHODS OF HUMANE KILLING

Methods of euthanasia for commonly used species							
Species	**CO_2/O_2 (70:30)**	**Anaesthetic overdose**	**Cervical dislocation**	**Double pithing**	**Freezing**	**Decapitation**	**Exsanguination and Captive Bolt**
Mice			Up to 500g	-	-	Foetuses & Neonates only	-
Rats			Up to 500g	-	-	Foetuses & Neonates only	-
Guinea Pigs			**NR**	-	-	-	-
Rabbits	<600 g only		Up to 1 kg otherwise **NR**	-	-	**NR**	-
Cats	**NR**		-	-	-	-	-
Dogs	**NR**		-	-	-	-	-
Amphibians	-		-		**NR**	In unconscious animals only	-
Fish	-		-	-	**NR**	-	-
Reptiles	-		-	-	**NR**	-	-
Birds	Birds up to 1.5 kg		Up to 3 kg otherwise **NR**	-	-	Foetuses & Neonates only	-
Sheep	-		-	-	-	-	
Pigs	-		-	-	-	-	
Ungulates	-	-	-	-	-	-	

(Recommended) **NR** (Not Recommended) **-** (Prohibited)

16. METHODS FOR HUMANE KILLING OF FOETAL, LARVAL AND EMBRYONIC FORMS

Method	Animals for which appropriate
Overdose of anaesthetic using a route and anaesthetic agent appropriate for the size, stage of development and species of animal.	All animals
Refrigeration, or disruption of membranes, or maceration in apparatus approved under appropriate slaughter legislation or exposure to CO_2 gas near 100 % concentration until they are dead.	Birds Reptiles
Cooling of foetuses followed by immersion in cold tissue fixative.	Mice, Rats and Rabbits

17. DISPOSAL OF CARCASSES

- Carcasses should be disposed of onsite where possible by incineration or through a macerator;

- Carcass disposal must comply with relevant clinical waste and incineration legislation[5].

- Infected, toxic or radioactive carcasses should be disposed of in such a manner so as to prevent a hazard;

- The material for disposal should comply with existing controls and all other forms of local protective regulations[6] under the guidance of the safety officer;

- Death must be confirmed before carcass disposal. Personnel must be adequately trained to recognise and confirm that death has occurred;

- Carcasses must be double wrapped and frozen, until disposal by standard procedures can be effected;

- Animal services[7] may coordinate disposal processes.

[5] Such legislation may need to be finalised.
[6] These regulations may need to be finalised.
[7] These services may need to be set up.

18. AUTOPSY

- An autopsy should be performed when animals die unexpectedly.

19. MANAGEMENT AND STAFF

19.1 PERSON IN CHARGE

- Animal acquisition, breeding and holding facilities must be supervised by personnel with appropriate veterinary or animal care qualifications and experience;

- The person in charge should be responsible for the management of the day-to-day care of the animals in holding and breeding facilities, and for supervising the work of other staff. He/she should act as liaison between the investigator and facility staff;

- He/she should ensure that there is reliable monitoring of the well-being of all animals by the staff and should be attentive to signs of pain, distress and illness specific to each species housed;

- He/she should ensure that ill or injured animals which are not assigned to approved projects are treated promptly, and the cause of death investigated for animals dying unexpectedly;

- He/she should contribute to the development and maintenance of the institution's animal care policies and procedures;

- He/she must make sure that staff are provided with appropriate protective clothing, maintain high standards of personal hygiene, do not eat, drink or smoke in animal areas, and have had all required vaccinations;

- He/she must document procedures used in holding and breeding facilities;

- These procedures should cover:

  - the requirements of the species held;
  - the studies being conducted;
  - health and safety of staff;
  - the transport, quarantine and disposal of animals;
  - routine husbandry, prevention, diagnosis and treatment of disease.

  Importantly, these should also be known by all staff involved in the care and use of the animals and should be reviewed regularly.

- The person in charge must keep adequate records of:

  - the source, care, allocation, movement between locations, use and disposal of all animals and any diseases developed;
  - the fertility, fecundity, morbidity and mortality in breeding colonies, in order to monitor the management of the colonies and to assist detection of the origin and spread of disease;
  - the health status, genetic constitution and the physical environment of the animals when required.

- He/she must make the maintained records available to the investigators;

- He/she must inform the investigators of any changes to the conditions under which the animals are held and that may affect the results of the studies.

19.2 STAFF

- There is a need for well-trained and committed staff to ensure that high standards of animal care are maintained;

- Institutions must encourage and promote formal training in animal science or technology. Personnel working with animals in a holding facility should be instructed appropriately in the care and maintenance of those animals, how they may affect the animals' well-being and how their actions may affect the outcome of scientific activities;

- Personnel should be instructed on how to recognise any early stage changes in animal behaviour, performance and appearance;

- New staff should be appropriately instructed in their duties and in institutional policy;

- All personnel expected to kill animals should be properly trained and competent;

- Animal care staff should engage in appropriate continuing education.

The health and safety of individuals working in animal care and use represent an area of institutional concern requiring commitment from the institution. The emphasis of such a programme is the prevention of illness and injury, and must also include provisions for early diagnosis and treatment when necessary.

Elements of an Occupational Health and Safety Programme:

a) Administrative procedures,
b) Facility design and operation,
c) Risk assessment,
d) Exposure control,
e) Education and training,
f) Occupational healthcare services,
g) Personal protective equipment,
h) Equipment performance,
i) Information management,
j) Emergency procedures, and
k) Programme evaluation.

A wide range of personnel (animal care staff, students, investigators, etc) should be provided with the opportunity to participate in the Occupational Health and Safety Programme, addressing amongst others:

a) Hazards posed by the animals and materials used,

b) Exposure intensity, duration, and frequency,

c) Susceptibility of personnel, and

d) History of occupational illness and injury in the workplace.

There should be ethical requirements to inform individuals of health risks that affect them and appropriate precautions to be taken. The objectives can be reached if employees are trained to understand the hazards associated with their work area and job duties.

Training should include information about:

a) Zoonoses,

b) Chemical safety,

c) Microbiological and physical hazards,

d) Hazards associated with experimental procedures,

e) Handling of waste materials and,

f) Personal hygiene.

Agricultural Research

Farm animals are used in a variety of research contexts, including:

a) Vaccine trials,

b) Studies of basic biological processes,

c) Studies of pharmacokinetics and organ transplantation, and

d) Studies of nutritional, breeding and management methods to increase the supply and quality of food and fibre.

Unlike typical laboratory animals, farm animals used for research and teaching may be housed in many different kinds of environments, ranging from traditional laboratory environments to enclosed or extensive farm settings. Consequently, standards for the evaluation of research, teaching, and testing using farm animals may need to be specified.

BIBLIOGRAPHY

1. National Health and Medical Research Council (NHMRC), Australia. Australian code of practice for the care and use of animals for scientific purposes, 6th edition,1997.
   Online at: www.health.gov.au/nhmrc/research/awc/code.htm

2. Home Office. Animals (Scientific Procedures) Act 1986, Guidance on the Conduct of Regulatory Toxicology and Safety Evaluation Studies. Home Office, HM Government, UK, June 2003.
   Online at: www.homeoffice.gov.uk/docs2/regtoxicologydraftrevision4_03.html

3. House of Lords Select Committee on Animals in Scientific Procedures. The United Kingdom Parliament. Session 2001 – 2002, Volume I – Report, July 2002.
   Online at: www.parliament.the-stationery-office.co.uk/pa/ld/ldanimal.htm

4. Mauritius Society for Prevention of Cruelty to Animals (MSPCA). Policies on Animal Welfare, 1984.

5. Medical Research Council. Responsibility in the Use of Animals in Medical Research. Medical Research Council, London, UK, July 1993.
   Online at: www.mrc.ac.uk/pdf-animals_ethics_booklet_1993.pdf

6. Universities Federation for Animal Welfare (UFAW). The Principles of Humane Experimental Technique. Russell, WMS and Burch, RL (1959). Reprinted by UFAW, Methuen, London, UK 1992 (ISBN 0 900 767 78 2).

7. World Medical Association. World Medical Association Statement on Animal Use in Biomedical Research.
   Online at: www.wma.net/e/policy/17_u_e.html

APPENDIX 1

TOXICOLOGICAL STUDIES

(a) Explanatory Note

- These involve investigations of the safety of agents or naturally occurring toxins for use in human beings, animals, the household or the environment. These studies should be performed by persons with appropriate training in toxicology or pharmacology.

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

    - In particular, *in-vitro* methods should be used as an initial screening test wherever possible.

- End points of such studies should be as early as is compatible with reliable assessment of toxicity and minimise the extent of pain and distress.

- Investigators must **NOT** allow experimental/evaluation activities to reach painful or lingering deaths of animals unless no other experimental end point is feasible and the goals of the study are prevention, alleviation, treatment or cure of a life-threatening disease or situation in human beings or animals.

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

(b) Choice of testing method

- When more than one method exists for a particular toxicity test or safety evaluation, then the method of choice should be the one that uses animals of the lowest degree of neurophysiological sensitivity, causing the least amount of pain, suffering, distress or lasting harm and requires the least number of animals.

- The Organisation for Economic Co-operation and Development (OECD) recognises 4 tests methods for acute oral toxicity:

  (1) acute oral toxicity method;
  (2) fixed dose procedure;
  (3) acute toxic class method; and
  (4) up/down method.

- Acute toxic class method and the up/down method cause less animal suffering and/or require fewer number of animals than the Lethal Dose 50 (LD50) test and therefore, should be the methods of choice.

(c) Dose selection and administration of substance being tested

(i) Acute studies:

- Single dose should be the norm in acute toxicity tests. Justification for the use of repeat dose should be given;

- LD50 has been largely replaced by more humane tests. Its use in the future will be hard to justify;

- Death is rare even if set as the end point.

(ii) Repeat dose studies :

- The top dose should be selected such that the scientific objective is achieved without seriously affecting the well-being of experimental animals;

- Dose selection and dosing schedules should be based on previously obtained toxico-kinetic data of the administered compound.

(d) Routes of administration

- Reasons for route of administration should be provided;

- The route of administration should be the same as the intended or expected exposure to the test material. For example, if the test material is to have a dermal application, its route of administration to the animal should be through the skin;

- Selected route should be the one causing the least pain, suffering or distress to the test animals.

(e) Sampling of body fluids

- Haematological and biochemical parameters must be monitored;
- Time points for collecting body fluids should be based on relevant data from previously obtained preliminary investigations;
- Sampling should be kept to a minimum;
- Sampling should not cause undue physiological stress to experimental animals;
- When samples of body fluids are required over a period of study, consideration should be given as to whether samples should be taken from all dosed animals, or whether sampling representative subgroups would be enough;
- If sampling involves restraint of animals, the duration of restraint must be kept to the shortest time possible;
- Blood samples can be taken from a variety of routes, but the method should be the least stressful to the animal and consistent with the scientific aim of study.

APPENDIX 2

SPECIES SELECTION

This section relates largely to the requirements of Drug Regulatory Authorities[11] but may be of value as guidance to researchers in other studies requiring the use of laboratory animals.

- Animals subjected to regulated procedures have to be of the lowest neurophysiological sensitivity so as to meet the stated objective;

- Species should be sensitive to designated toxicity tests. Metabolism and background data on the species to be used should be available;

- Practical considerations like animal size, availability and length of gestation should be taken into account;

- Medicines regulatory systems allow judgement to be exercised when selecting an appropriate non-rodent species;

- The most appropriate species for regulatory assessment should be chosen on scientific grounds;

- Specific justification is required for the use of cats, dogs, non-human primates and endangered species;

- The number of animals used in regulatory and safety evaluation studies of medicines prior to marketing must be sufficient to allow meaningful interpretation of data generated.

[11] Currently there is no Drug Regulatory Authority in Mauritius.

APPENDIX 3

NAME OF INSTITUTION

ANIMAL ETHICS COMMITTEE

APPLICATION FOR APPROVAL TO USE ANIMALS OR ANIMAL TISSUES

This application, if approved, will be included in the Animal Ethics Committee (AEC) Register and will, therefore, be a public document. Any commercial or patentable information should be sent separately and marked 'commercial-in-confidence'. ***Application to be typewritten*.**

PROJECT TITLE:

PRINCIPAL INVESTIGATOR (licensed): **POSITION AT INSTITUTION** **CONTACT TELEPHONE**

SCHOOL(S)/DEPARTMENT

PROPOSED DURATION OF PROJECT: **From:** **To:**

(The AEC requires investigators to submit a new application when a project has had approval for three years.)

ANIMAL ETHICS COMMITTEE OFFICE USE ONLY

Date Application received:	

AEC Register number:

Project category	Species	Number of Animals

Comments:

Period of approval	**From**		**To**	
Signed Chairman AEC				
Date:				
Date approval notified (Department/Principal Investigator):				

DETAILS OF PROJECT/EXPERIMENT

1. SOURCE OF FUNDS

2. LAY DESCRIPTION

What are the scientific or educational aims of the proposed work. Please state the significance of the work and its relation to previous studies. Justify the project in terms of potential value of the experiment in obtaining or establishing significant information relevant to the understanding of humans or animals, maintenance and improvement of human or animal health and welfare, improvement of animal management or production, or achievement of educational objectives. (Attach additional papers if necessary.)

3. Give a clear, step-by-step description of the proposed work. Include full details of the following where relevant; agents and dose rates to be used, surgical and other procedures proposed, monitoring procedures in place particularly where anaesthesia, analgesia or tranquillising agents are to be used, the duration and end point of the experiment, and the fate of the animal following the experiment. (Attach additional pages if necessary).

4. SUMMARY OF ANIMAL USE

4.1	Please state reasons why animals are necessary for the project and why techniques which do not use animals have been rejected as unsuitable.

4.2 Details of animals and source

Species	Special features*	Total Number of animals	Numbers requested for this year	Source: Department bred or other. Please specify

* For example, transgenic, disease bred, Mauritian native or imported into Mauritius and thereby requiring quarantine certification.

4.3	Is the acquisition, holding, or use of the experimental animal (e.g. protected native or imported) subject to any permit, law or regulation of Mauritius?	**Yes**	**No**
	If YES, specify permit and attach copy of relevant approval/		
4.4	Please justify species chosen		
4.5	Please justify total number of animals requested in terms of the experimental design. It is expected that projects are designed to minimise animal numbers.		
4.6 a)	Location and care of animals during experiments Where will animals be located during experimental period? (If locations of experimental manipulation and housing differ please indicate.)		
b)	Have arrangements been made for acquisition and housing of the animals		
4.7	What experience and training do the investigators have in working with the species requested?		

5.	OTHER ETHICAL CONSIDERATIONS		
5.1	Is this a repetition of a previously performed experiment? If YES, please justify *(attach)* repetition.	**Yes**	**No**
5.2	Have any of the animals proposed for this experiment been used for previous experiments? If so, please justify *(attach)* their use in this project.	**Yes**	**No**
5.3	Are neuromuscular and similar blocking agents to be used? If YES, please include *(attach)* details of procedures proposed to ensure that pain will be blocked by appropriate anaesthesia and analgesia.	**Yes**	**No**
5.4	Does this project involve experimental studies on unanaesthetised animals which may cause pain or distress and where analgesia will not be used? If YES, please include *(attach)* planned end point for the experiment, the reasons and justification for its choice, and measures to be taken to minimise pain and distress.	**Yes**	**No**
5.5	Does this project pose any health risks to other animals or staff? If YES, please elaborate and give *(attach)* details of measures taken to minimise risks.	**Yes**	**No**
5.6	Do any features of this proposal raise special ethical considerations? If YES, please elaborate *(attach)* on each	**Yes**	**No**

6. EXPERIMENTER'S ASSESSMENT OF PROJECT CATEGORY

Please tick below which of the following categories best describe the project for which approval is being sought. It may fall into two or more categories and these should be indicated.

Category 1

☐ 1.1 No experimentation on living animals (i.e. animals are killed painlessly for biochemical analysis, or *in vitro*, cell tissue or organ studies).

☐ 1.2 Experiments under anaesthesia, without recovery (i.e. animals are fully anaesthetised for the duration of the experiment, and are killed at its conclusion without recovery from anaesthesia).

Category 2

☐ 2.1 No anaesthesia, minor procedures used (e.g. injections, blood sampling, antibody raising, minor dietary manipulations).

Category 3

☐ 3.1 Minor post-operative sequelae (e.g. following biopsies or cannulations).

☐ 3.2 Significant post-operative sequelae.

Category 4

☐ 4.1 Studies on the biology of pain or on the responses to physical stresses (e.g. heat, cold, burning, ionizing radiation), in unanaesthetised animals.

☐ 4.2 Studies on unanaesthetised animals of the toxic actions of drugs or other chemical agents or of infectious agents.

☐ 4.3 Studies involving experimental induction of abnormal foetal growth.

☐ 4.4 Continuing or recurrent experimentation on individual animals that lasts for more than three months.

☐ 4.5 Experiments involving the restriction of food or water intake, or other major dietary intervention.

☐ 4.6 Studies on mutant strains of animals prone to serious disease (e.g. stroke-prone rats)

☐ 4.7 Laboratory studies designed to produce substantial and overt changes in behaviour by physical or chemical means.

Category 5

☐ 5.1 Observational study only.

Category 6

☐ 6.1 Other experimentation not covered above. Please specify.

7. Research Personnel

Please list below the names and qualifications of all research personnel other than the Principal Investigator e.g. research students, research assistants) who will be involved in this project.

INVESTIGATORS' DECLARATION (to be signed by each principal investigator)

I hereby declare that I have the appropriate qualifications, experience and training to perform the procedures described in this project and that I consider all other personnel listed in this application have appropriate qualifications and experience for their role in the project. I, the undersigned, have read the *Prevention of Cruelty to Animals Act 1982* and the *Code of Care and Responsibility in the Use of Animals in Research*, and accept responsibility for the conduct of the experimental procedures detailed above, in accordance with the principles contained in the *Code* and any other conditions laid down by NAME OF INSTITUTION Animal Ethics Committee (AEC).

Principal Investigator(s) Signature(s):	**Date:**	**Academic Qualifications**

Head of Institution's Declaration

I acknowledge that it is my responsibility to ensure that members of staff engaged in animal experimentation comply with the conditions laid down by

- *Name of Institution* Animal Ethics Committee,
- the *Prevention of Cruelty to Animals Act 1982*, and
- *Code of Care and Responsibility in the Use of Animals in Research.*

I certify that the animals required for this project can be provided, housed and maintained at a standard consistent with the requirements of the Animal Ethics Committee and the *Code* and that approval of this project will not compromise the conditions under which other animals in the Institute/Department are held.

Head of Institution's signature:		**Date:**	

NAME OF INSTITUTION

ANIMAL ETHICS COMMITTEE

ANNUAL REPORT ON APPROVED PROJECT

An annual report must be submitted for **ALL** projects, whether continuing or not. If you wish to continue the project, the annual report will be the basis on which continuation is approved. **Note that a new application must be submitted for any project continuing beyond three years.** ***Report to be typewritten*****.**

PROJECT TITLE:

Principal Investigators (licensed)	Position at Institution	Contact Telephone	Unit/ Department

AEC register number: | | | | | | |

Do you wish to renew approval for this project **YES/NO**

NAME OF INSTITUTION ANIMAL ETHICS COMMITTEE USE ONLY

AEC register number: | | | | | | | Date report received**:**

Forwarded to AEC for Renewal/Final Report Chairman AEC:

Date:

ANIMAL ETHICS COMMITTEE USE ONLY

Date report received**:**

Animals approved	
Species	Numbers

Comments:
Project renewed to

Chairman AEC:
Date:

Date approval notified (AEC/Head of Institution/Principal Investigator):

A. REPORT

1.1 How many animals have you used in this project in the last calendar year?

			FATE OF ALL ANIMALS USED		
Species	Number approved	Number used	Euthanased	Survive (no further experimental use)	Survive (continuing experimental use)

1.2 Does this differ, in number, species or source, from your estimate for this period? YES/NO

If **YES**, explain how and why (attach additional pages if necessary).

1.3 Were any difficulties encountered during the course of the experiments that affected the welfare of the experimental animals? Such difficulties could include experimental design or technique, untoward reactions, illness of animals or problems with housing or staff.

YES/NO

If **YES**, please provide details (attach additional pages if necessary).

…….
Signature

…….
Date

B. RENEWAL REQUEST

2.1 Animals requested for use in the coming year

Species	Special features required (if any)*	Numbers requested	Source: (please specify)

** For example, specific strain or age, transgenic, Mauritian native, animals requiring quarantine certification.*

2.2 Are you applying to use new species or significantly greater numbers of animals than last year? YES/NO

If **YES**, explain why. (Attach additional pages if necessary).

2.3 Do you wish to make any significant changes to approved experimental procedures? YES/NO

If **YES**, give full details of proposed procedures and explanation of change. (Attach additional pages if necessary.)

2.4 Did the original application require a Permit for the acquisition, holding, or use of experimental animal(s)?

YES/NO

If **YES**, please attach copy of relevant Permit(s) to cover proposed continuation of project.

3. Other Research Personnel

Please list below the names and qualifications of all research personnel other than the Principal Investigator (e.g. research students, research assistants) who will be involved in this project.

4. Investigators' Declaration (to be signed by each principal investigator)

I hereby declare that

(a) I have the appropriate qualifications, experience and training to perform the procedures described in this project and that I consider all other personnel listed in this application have appropriate qualifications and experience for their role in the project;

(b) I have read the *Prevention of Cruelty to Animals Act 1982* and the *Code of Care and Responsibility in the Use of Animals in Research*, and accept responsibility for the conduct of the experimental procedures of this project, in accordance with the principles contained in the C*ode* and any other conditions laid down by the Name of Institution Animal Ethics Committee (AEC);

(c) the Animal House Manager had been made aware of the requirements of this project.

Principal Investigators' Signatures	Date	Academic Qualifications

5. Head of Institution's Declaration

I acknowledge that it is my responsibility to ensure that members of staff engaged in animal experimentation comply with the conditions laid down by:

(a) the Name of Institution Animal Ethics Committee,
(b) the *Prevention of Cruelty to Animals Act 1982* and
(c) the *Code of Care and Responsibility in the Use of Animals in Research.*

I certify that the animals required for this project can be provided, housed and maintained at a standard consistent with the requirements of the Animal Ethics Committee, the *Code* and that approval of this project will not compromise the conditions under which other animals in the Name of Institution are held.

Head of Institution **Name:** _____

Signature: _____

Date: _____