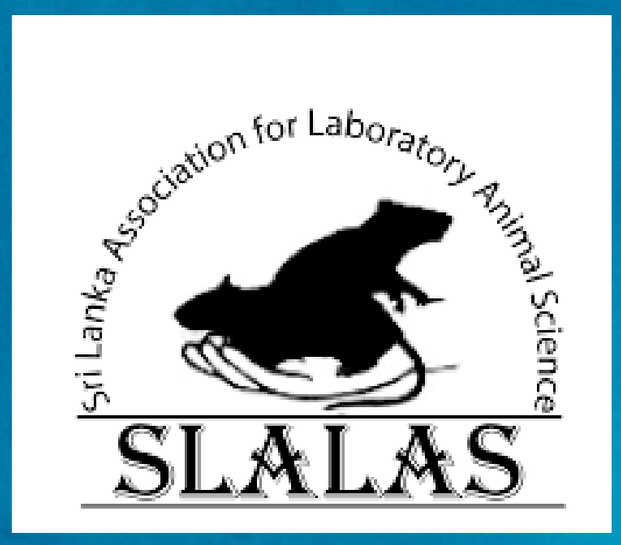
GUIDELINES FOR THE CARE AND USE OF ANIMALS IN LABORATORY-BASED RESEARCH



SRI LANKA ASSOCIATION FOR LABORATORY ANIMAL SCIENCE

https://doi.org/10.61943/slalas.1020231_i

GUIDELINES FOR THE CARE AND USE OF ANIMALS IN LABORATORY-BASED RESEARCH

SRI LANKA ASSOCIATION FOR LABORATORY ANIMAL SCIENCE (SLALAS)

Guidelines for the Care and Use of Animals in Laboratory-based Research

Publisher
Sri Lanka Association for Laboratory Animal Science (SLALAS)

Guidelines for the Care and Use of Animals in Laboratory-Based Research

eISBN: 978-624-5640-05-8
1st Edition
October 2023

GUIDELINES FOR THE CARE AND USE OF ANIMALS IN LABORATORY-BASED RESEARCH

Resource Contribution

Professor Mangala Gunatilake (University of Colombo)
Dr. Mayuri Thammitiyagodage (Medical Research Institute)
Dr. Tharanga Thoradeniya (University of Colombo)
Dr. Inoka Sandanayake (National Science Foundation)
Dr. Chamini Kanatiwela de Silva (Clinical Trials Unit, University of Kelaniya)
Dr. Ureshani Karunarathna (University of Sri Jayewardenepura)

Supportive team

Dr. Samantha Iddamaldeniya (Veterinary Research Institute)
Dr. Kalpani Ratnayake (CINEC Campus)
Dr. Varuni Gunatilake (University of Sri Jayewardenepura)
Dr. Krishanthi Premarathne (Wayamba University of Sri Lanka)
Dr. Saroja Weerakoon (University of Colombo)

Publisher
SRI LANKA ASSOCIATION FOR LABORATORY ANIMAL SCIENCE (SLALAS)
slalasci@gmail.com

Table of Contents

1.0 Introduction

Biomedical research using animals has been practised for several millennia. The results of these experiments have led to many advances in science and medicine. However, the use of laboratory animals has always been controversial because of concerns over the welfare of these animals.

The guiding principle of animal experimentation is the 3Rs concept (Replacement, Reduction and Refinement) described by William Russell and Rex Burch in 1959. The 3Rs concept has helped to inspire and guide humane progress in experimental techniques for the past 60 years.

In recent years, concerns on the welfare of animals have resulted in various new legislations and guidelines in many countries. However, in Sri Lanka, the existing legislation, the '*Prevention of Cruelty to Animals Ordinance of 1907',* is outdated and does not address the ethics and welfare of animals used in research. The proposed '*Animal Welfare Bill*', which addresses the prevention of cruelty to all animals, including laboratory animals, is yet to be enacted by the Parliament of Sri Lanka.

In 2009, the 'Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka' were published by the Ethics Review Committee (ERC) of the Faculty of Medicine, University of Colombo and the Forum of Ethics Review Committees of Sri Lanka. Since then, this document was used by ERCs' when reviewing protocols, as well as by researchers when conducting animal experiments.

The need for a comprehensive set of guidelines for conducting research using animals was identified at the Fifth Annual Scientific Sessions of the Sri Lanka Association for Laboratory Animal Science (SLALAS) in 2018. Subsequently, the Working Committee on Bioethics of the National Science Foundation requested SLALAS to prepare consensus guidelines for the use of animals in research. Thus, the first draft of this document was discussed at the Sixth Annual Scientific Sessions of SLALAS in 2019. Then this was revised and finalised through discussions at subsequent meetings.

The resulting document, the '*Guidelines for the Care and Use of Animals in Laboratory-based Research',* details the responsibilities of the research team, the Animal Ethics Review Committees (AERC) and the institutions. These guidelines are expected to ensure the humane use of animals in Sri Lanka for the advancement of science through high quality research.

2.0 Purpose of the Guidelines

2.1 Purpose

The primary goal of this set of guidelines is to facilitate high-quality research and promote optimum animal welfare in Sri Lanka. This will guide researchers/academics in Animal Ethics Review Committees (AERC) and funding agencies when developing/ carrying out/ reviewing research protocols involving animals.

The guidelines mainly focus on the care and use of animals in laboratory-based research purposes in Sri Lanka. It is also applicable for the care and use of animals for other purposes such as disease diagnosis, testing, education and training. The guidelines address using *laboratory-bred* and other vertebrate and invertebrate animals *housed under laboratory conditions* (e.g. wild-caught toque monkeys) and vertebrate embryonated eggs used for research testing, diagnostics and educational purposes. However, this does not address livestock and other animals used for research, testing, diagnostic and educational purposes housed under *domestic or natural settings*.

This set of guidelines includes sections such as composition, responsibilities, qualifications and experience of the research team, experimental protocol design and conduct, animal facility, acquisition of animals, and AERC. In addition, the minimum required standards and best practices are highlighted under relevant sub-sections in this set of guidelines.

2.2 Scope and Objectives

This document is developed to:

1. provide guidelines to emphasise the responsibilities of personnel and institutions carrying out research, testing, diagnostics and educational activities involving animals.

2. ensure that the use of animals in research, testing, diagnostics and education is justified and humane.

3. ensure welfare of the animals by assuring physical and psychological comfort, avoiding pain or distress and assuring good health.

4. ensure the use of appropriate species and number of animals while maintaining necessary standards (microbiological and genetic).

5. minimize the number of animals used in research, testing, diagnostics and education, and encourage the use of alternative methods to replace animals to promote the 3Rs concept (Replacement, Reduction and Refinement).

3.0 Research Team and Responsibilities

The welfare of animals must be a primary consideration of the research team, animal facility and the institution/(s). Therefore, animal welfare (including maintenance of physiological and psychological well-being of the research animals) must be monitored and documented throughout the procedure.

It is the responsibility of the principal investigator and the research team to adhere to post-experimental procedures included in the protocol (for euthanasia or rehabilitation) to ensure minimum pain and discomfort to the animal.

On completion of the research, it is the responsibility of the research team to appropriately report the research findings by adhering to international guidelines to maximise published information and minimise unnecessary animal use.

3.1 Qualifications and Experience of the research team (Investigator(s) /Researcher(s)/ Scientist(s))

i. The research team headed by a principal investigator must include a veterinarian with adequate experience in laboratory animal science and/or in the relevant field as required for the research protocol. The team may include a scientist having educational qualifications in laboratory animal science recognised by the University Grants Commission (UGC), Sri Lanka. The other members of the research team may include scientists, research assistants, healthcare professionals, students, technicians and other personnel depending on the nature of the study.

ii. All personnel involved with the care and use of animals must be qualified and trained in basic principles of laboratory animal science to ensure research quality and animal welfare. Each research team member must be suitably qualified to fulfill the tasks identified in the research protocol, including knowledge of applicable ethical guidelines.

iii. The members of the research team directly involved with the care and use of animals, shall have:
    a. Ability to differentiate normal and abnormal physical and behavioral patterns of animals to be used in the research.

b. Awareness of potential risks/hazards to animals, humans (research team), community, and the environment could arise as a consequence of the use of animals.
c. Other specific skills are relevant to the research project.

3.2 Obtaining Approval of Animal Ethics Review Committee AERC)

i. Ethical issues should be considered early in the planning process and written approval for the protocol must be obtained from an AERC (Refer section 6) before the start of the project while adhering to the necessary elements pointed out in this set of guidelines. Moreover, the investigators must satisfy the AERC of their competence to conduct the techniques involving animals as described in the protocol.

ii. Other necessary permissions (e.g. permission from the Department of Wildlife Conservation) as required must be obtained before commencement of the procedure.

iii. Investigators should inform the AERC;
   a. any deviations from the approved protocol
   b. when each project is completed or discontinued

iv. Investigators should comply with the requirements and guidelines stipulated by the respective AERC.

3.3 Designing Experimental Protocols

3.3.1 General Considerations

i. The 3Rs concept (Replacement, Reduction and Refinement) should be applied at all stages of animal experimentations/ procedures.

ii. When designing the study, the research team should ensure that respect for animals underpins all procedures.

iii. Animals should be used only when alternative methods are not available to achieve the proposed objective/s. If animal use is a must, the scientific purpose of the research (including objective/s, rationale and design of the study) should be significant and justified.

iv. Research involving animals should be undertaken with reasonable expectations and a clear scientific purpose. In addition, there should be

due consideration for human and animal health and the advancement of knowledge and, should provide significant information that benefits health and/or welfare of humans and/or animals.

v. Harm–benefit analysis must be carried out to assess whether the suffering, pain and distress caused to the animals is justified by the ultimate benefits to humans, animals and/or the environment.

vi. In toxicity testing, suitable non-animal tests or *in vitro* methods should be used for initial screening before testing on animals.

vii. The availability of appropriate conditions to house the animals should be ensured when designing experiments.

viii. At the end of the planning process, the investigator/s must re-check the protocol to ensure that the 3Rs are being optimally covered.

3.3.2 Selection of An Animal Model

The selected animal species should be best suited for the purpose of the procedure. The biological nature of the animals; behavioural characteristics, genetic constitution, and cognitive development should be considered to ensure that the choice of species is appropriate. The scientific validity of animal models of human diseases depends on how closely a given model resembles a particular disease.

3.3.3 Determination of Number of Animals

i. Only the minimum number of animals must be used. An unnecessarily large or small number of animals will waste animals and resources. The number of animals to be used in the procedure should be calculated using a scientifically acceptable statistical method.
e.g. Power calculation to determine sample size

ii. The number of animals used for toxicity testing should be in accordance with the relevant guidelines; Organization for Economic Cooperation and Development (OECD)/ World Health Organization (WHO)/ Food and Drug Administration (FDA), etc.

3.3.4 Avoiding pain and discomfort

The experiment must be designed to avoid pain and discomfort to the animals. If this is not possible, pain, distress and discomfort should be minimised considering the following:

i. most appropriate and humane experimental procedures should be chosen.

ii. personnel involved in animal care and use should be competent in species-specific identification of pain and distress and other relevant technical skills.

iii. experimental procedures should be planned to be conducted over the shortest possible time according to the relevant guidelines without compromising the quality of research.

iv. when pain is anticipated, appropriate pre-emptive analgesia, anaesthesia or sedation must be used in accordance with current veterinary/laboratory animal science practices.

v. appropriate anaesthetic, analgesic and tranquilising agents must be selected depending on the species and the experimental procedure.

vi. when unanaesthetised animals are subjected to stimuli to produce pain, such as in research on pain mechanisms and relief of pain, the stimuli should not exceed the pain threshold of humans.

vii. adequate monitoring of animals should be carried out to ensure prompt alleviation of pain, distress or discomfort.

viii. a plan to manage potential adverse effects of all procedures must be laid down in the protocol
e.g. increase the frequency of monitoring, consulting a veterinarian, identifying humane endpoints (Refer section 3.3.5).

ix. most appropriate and humane experimental endpoints should be developed to minimise pain and distress.

x. most appropriate method should be used for euthanasia (Refer section 3.4.5.4).

3.3.5 Endpoints

i. Different endpoints (experimental, scientific and humane) should be clearly defined in the protocol.

ii. Death as an experimental endpoint is generally unacceptable.

iii. Endpoints are -specific, objective, measurable, unambiguous and should be identified and agreed upon by the research team before starting an experiment.

iv. During a procedure, if pain management methods cannot alleviate animal suffering, it should be recognised as a humane endpoint and the animal should be euthanised.

3.4 Conducting Experimental Protocols

3.4.1 Handling and restraining animals

i. Appropriate handling will minimize stress and injury to the animal as well as to the researcher.

ii. Animals should be handled only after obtaining adequate training.

iii. When necessary, restraint devices should be used minimally, considering the welfare of the animal and the safety of the handler. Prolonged periods of restraint should be avoided.

iv. If any negative impacts are detected, the animal should be removed from the restraint or the method should be modified to minimise the impact.

3.4.2 Pain and Discomfort

3.4.2.1 General considerations to minimise pain, discomfort and distress

i. The research team personnel must treat the animals with kindness, respect and great care.

ii. Evaluation of pain, discomfort and distress in animals is sometimes difficult. Therefore, the investigators must assume that animals experience pain in a manner similar to humans, unless the contrary is established.

iii. Measures should be taken to avoid pain and discomfort to the animals at all times.

3.4.2.2 Monitoring of pain and distress

i. Investigators should be knowledgeable to recognise any deviation from normal behaviour and identify species-specific signs of pain, discomfort, and distress.

ii. Research animals must be regularly monitored to identify pain and its severity using validated tools.
e.g. Grimace scales (NC3Rs).

iii. Investigators should appropriately record the observations in animal welfare monitoring sheets (welfare diaries) which should be available at the institutional animal facility and made available to all involved in the care of animals. For example, variations in body weight, water intake, and grooming behaviour etc. can be recorded as needed.

iv. If unexpected pain is observed during a procedure, measures should be taken to minimise the pain with minimal interference to the experimental procedure. If pain cannot be alleviated, animal suffering should be ended by applying humane endpoints.

3.4.3 Experimental Protocols with Special Procedures

When conducting animal experiments that include special procedures and the above mentioned, study specific considerations should be followed to ensure the welfare and well-being of animals. Some examples are given below.

i. When withholding or severe food or water restriction is a part of the experimental protocol, it should not produce any continuing detrimental effect on the animals. This should be ensured by monitoring fluid balance and/or body weight.

ii. Experimental protocols involving pathogenic microbes, radioactive compounds, corrosive substances, toxins, allergens, carcinogens, etc., which cause hazards to humans, other animals or the environment, must be explained to the fullest extent possible to all personnel involved. Such experiments should be carried out in accordance with relevant institutional guidelines. Appropriate measures should be established for containment, disposal and decontamination with the advice of the institution's biological safety committee or an equivalent committee.

3.4.4 Surgery and Anaesthesia

3.4.4.1 Pre-operative

When the surgical procedures are included in the experimental protocol, attention should be given to the following;

i. Pre-experimental practice on cadavers is mandatory to familiarise with anatomical landmarks that will streamline the surgical procedures. This will minimise the quantity of anaesthetic required, operative time and tissue damage.

ii. Pre-identify the potential problems pertaining to surgery /anaesthesia that may cause risks to the animal at the experimental design stage. Be prepared to promptly manage such problems.

iii. Recruit most fit animals for the purpose through a clinical examination.

iv. Implement a pre-designed pain management plan.

v. Ensure pre-surgical fasting to minimize anaesthetic complications.

vi. Ensure therapeutic levels of pre-emptive antibiotics during the surgical procedure if applicable only.

3.4.4.2 Surgery

i. Surgery should be carried out under appropriate local or general anaesthesia and, performed by adequately trained personnel under the guidance and supervision of experts in animal surgery and anaesthesia.

ii. Suitable/appropriate equipment to perform anaesthesia and surgery should be available.

iii. Animal must be unconscious (pain free) throughout the procedure.

iv. Appropriate aseptic techniques; surgical field, sterile instruments, sterile surgical gloves, gowns, caps, and face masks should be used.

v. Depth of anaesthesia should be closely monitored throughout the procedure to avoid hypothermia and cardiovascular and respiratory depression.

vi. All tissues should be handled with care to minimize tissue damage and bleeding.

vii. If the animal is not intended to recover from the surgery, make sure the animal is unconscious throughout the procedure. This may be performed by an overdose of general anaesthesia.

3.4.4.3 Post-operative

i. Post-operative pain, discomfort and distress should be minimized by using analgesics and tranquillisers.

ii. Ensure warmth, hygiene, fluid and food intake, and control of infection of the animal during the post-operative period.

iii. Animals that are recovering from anaesthesia should be housed individually to prevent injury.

iv. Clinical records (observations, drugs, fluids or other treatments) should be appropriately maintained and made available to all involved in the care of animals.

3.4.5 Completion of Projects

3.4.5.1 General considerations

i. When the procedure is completed, animals must be returned to normal husbandry conditions/euthanised/returned to natural habitat if appropriate and permitted.

ii. Tissue from animals being euthanised, should be shared with other investigators for scientific purposes where possible.

3.4.5.3 Rehabilitation and Returning to Natural Habitats

After completion of the project, animals may be rehabilitated if a qualified person gives the assurance that there is no possibility of any hazard to humans, animals or the environment.
Wild-caught animals may be returned to their natural habitats in consultation with the Department of Wildlife Conservation.

3.4.5.4 Euthanasia

i. A reliable, appropriate procedure that is compatible with the aims of the experiment should be used to euthanise the animal.

This should produce rapid loss of consciousness with minimal pain, discomfort and distress until death occurs.

ii. Death should be established before appropriately disposing of the carcass.

3.4.5.5 Autopsy

When animals die unexpectedly or are euthanised due to unforeseen complications, variables that may compromise the remaining research animals should be promptly and adequately identified. Hence, an autopsy on such animals should be performed by a well-qualified and experienced person.

4.0 Facilities

4.1 Animal Facility

Facilities include the buildings, tanks, yards or paddocks in which animals are housed.

The design and management of facilities will depend on the type of animals to be housed and the experimental procedures to be undertaken. The overall condition and management of facilities should permit effective maintenance and servicing and be compatible with maintaining good health and welfare of animals.

i. Institutions that use animals for scientific purposes (research, testing, diagnostics and educational purposes) should ensure adequate numbers of appropriately trained and skilled personnel to care for the animals.

ii. The animal facility should be established according to the guidelines provided by the Regulatory Authority as stipulated in the proposed animal welfare bill of Sri Lanka.

iii. The institution should appoint a veterinarian having qualifications and training in laboratory animal science as the in charge of the facility and he/she should ensure that all personnel working at the facility are properly trained.

iv. The animal facility should have capacities to provide optimum welfare to the animals with adequate financial support, facilities and human resources. Appropriate post-experimental procedure (rehabilitation or euthanasia) should be carried out upon cessation of experiments.

4.2 Animal Accommodation (pens, cages and containers)

Animal accommodation should be designed, constructed and managed to meet species-specific needs and to ensure the comfort and well-being of the animals and to minimise experimental variables.

The following factors should be considered:

i. Adequate space and proper design ensuring species-specific behavioral requirements.

ii. Standard macro-environmental conditions ensuring species-specific requirements (lighting, temperature, air quality, appropriate day/night cycles etc.).

iii. Standard micro environmental conditions ensuring species-specific requirements (enrichment, nesting material for pregnant animals etc.).

iv. Comfortable, absorbent, dust-free, non-palatable, non-toxic, sterilisable bedding or litter.

v. Ready access to species-specific standard feed and water.

vi. Clean cages/pens/enclosers and other accessories (e.g. enrichment materials, water bottles, cage cards).

vii. Easy access for proper observation of animals.

viii. Provision of single housing when and if necessary. e.g. during recovery from surgery or collection of samples. During such instances minimise the impact of social isolation of an animal.

4.3 Management of the Facility

4.3.1 Head of the Facility

i. The process of animal acquisition and the management of breeding and holding facilities should be supervised by persons with appropriate veterinary and laboratory animal science qualifications as well as experience with the species involved.

ii. The head of the facility should ensure supply of healthy animals for research and diagnostic purposes, be responsible for management of day-to-day care of the animals in facilities and supervision of the work of other personnel in the facility.

iii. The institution's animal care procedures should be maintained by the head of the facility and be available as Standard Operating Procedures (SOPs) approved by the relevant authority. He/she should contribute to the development of the institution's animal care and welfare assurance policies.

iv. The head of the facility should act as the link between investigators and facility personnel and the management of the facility. Any changes

to the conditions under which animals are held that may affect the research should be informed to the investigators and any adverse incidents should be communicated to the AERC by him/her.

The head of the facility should ensure regular assessment of the well-being of animals by being familiar with the signs of pain, distress and illness specific to each species. The primary responsibility for ensuring adequate monitoring of the well-being of animals assigned to an experimental protocol lies with the research team in liaison with the animal facility personnel.

v. In the case of an unexpected death of an animal, the head of the facility is responsible in carrying out postmortem investigations.

vi. The head of the facility should ensure high standards of personal hygiene by providing appropriate protective equipment and instructions to maintain them.

vii. The head of the facility should maintain adequate records of:

   a. the source, allocation, movement between locations, care, use and disposal of all animals, and of any diseases developed,

   b. the fertility, fecundity, morbidity and mortality in animal breeding groups and colonies,

   c. microbiological monitoring reports and postmortem records in order to assist detection of the origin and spread of disease, and

   d. the health status, genetic constitution and the physical environment (equipment and facility).

viii. These records must be made available to the authorized monitoring bodies for inspection.

4.3.2 Personnel

i. A sufficient number of well-trained and committed staff should be available to ensure high standards of animal welfare and care. Institutions should encourage and promote formal training of animal facility staff in laboratory animal science.

ii. Personnel in the facility should be appropriately instructed of their duties and be familiar with institutional procedures and policies.

iii. Personnel in the facility should be appropriately trained to care and maintain the animals and they should be made aware of how their actions may affect the animals' welfare and the outcomes of procedures.

iv. They should be trained in early identification of changes in animal behaviour, performance and appearance.

v. Personnel should be informed of potential hazards (allergies) and zoonotic diseases that might be contracted to humans through animals or to animals through humans. Precautions such as immunization (e.g. against tetanus and other zoonoses) and regular health checks should be recommended for all personnel handling animals.

4.4 Husbandry Procedures

Species-specific routine husbandry procedures must be performed by experienced and trained personnel.

4.4.1 Food and Water

i. Clean, fresh, uncontaminated and nutritionally adequate feed according to standard requirements for the species should be provided. The feed should be in sufficient quantity and of appropriate composition to maintain normal growth and normal weight of animals and to provide for requirements such as in pregnancy or lactation.

ii. Uneaten perishable food should be removed promptly unless contrary to the needs of the species.

iii. Changes to dietary regimes should be a gradual process.

iv. Sufficient trough space or feeding points should be provided to animals when they are fed in groups, to avoid undue competition for food, especially if feed is restricted. Feeding space is determined by the size and number of animals that must eat at one time.

v. Clean, fresh and uncontaminated drinking water should be constantly and readily available.

4.4.2 Identification of Animals

Individuals or groups of animals should be identified by a reliable and least stress method which is appropriate for the species and the procedure. Identification methods include neck-band, individual tag, physical mark, or a label or marking attached to the cage, container, pen or yard.

4.4.3 Disposal of Animal Carcasses and Waste

Appropriate provision must be made for prompt and sanitary disposal of animal carcasses and waste material in accordance with the authorised standards methods.

5.0 Acquisition of Animals

5.1 Obtaining Animals

5.1.1 From a Breeding Facility

Animals should be obtained from breeding and supply facilities that maintain conditions suitable for specific animal species as approved by the Regulatory Authority stipulated in the proposed Animal Welfare Bill of Sri Lanka.

5.1.2 From Natural Habitats

i. The Department of Wildlife Conservation (National policy on Wild life Conservation, 2000) must be consulted and necessary permissions obtained when wild animal species are required to be captured and reared under laboratory conditions for research.

ii. Animals should be taken from natural habitats only when that particular species is not bred in captivity.

iii. Suitable species-specific techniques and strategies, and skilled personnel should be employed to minimise pain, discomfort and distress during capture. After capture, appropriate and safe cages/pens should be used to avoid trauma.

iv. Capture-induced trauma if any should be treated immediately and animals must be frequently observed and monitored for signs of pain, discomfort and distress following capture.

5.1.3 From Other Countries

Recommendation must be obtained from the Director General, Department of Animal Production and Health for the importation of live animals and samples obtained from animals (e.g. Lyophilized serum). The import license are issued by the Sri Lanka Customs.

5.2 Transport of Animals

Movement, noise and confinement may lead to distress in animals while transporting.

i. Animals should be transported under species appropriate conditions.

ii. The distress and its extent depend on the species, age, sex, temperament, health, the duration that food or water is deprived of, the mode of transport, the number travelling together and the social relationships of the animals, environmental conditions (temperature and humidity) and sudden movements.

iii. Food and water should be provided whenever necessary.

iv. It is the responsibility of both the suppliers and recipients to ensure satisfactory delivery procedures.

5.3. Admission of New Animals into Holding Areas

When new animals are being admitted into animal holding areas, they should be quarantined and inspected by a qualified person (a veterinary surgeon having adequate experience on the particular animal species). Their health should be evaluated, treatment instigated if required, and their suitability for the proposed procedures should also be assessed. This period should also allow their acclimatization to the holding facility and personnel.

These new animals must be housed physically separated from other animals and in general no experimental manipulations are permitted while animals are held in quarantine. Animals which do not adapt satisfactorily to their new environment should not be kept and appropriately disposed (e.g. wild caught animals returned to their natural habitat. Refer section 3.4.5).

6.0 Animal Ethics Review Committee (AERC)

Ethics approval is a mandatory requirement whenever research, testing, diagnostics, educational and training activities involve animals.

6.1 Composition of AERC

i. AERCs that review research proposals involving animals should be approved by a recognized authority in Sri Lanka as stipulated in the proposed Animal Welfare Bill.

ii. AERC should consist of at least one veterinarian having expertise in laboratory animal science, and a representative from an animal welfare organization and/or a member of public known for interest in animal welfare.

iii. The AERC will comprise of at least five persons, including a separate person from each of the following categories:

Category A: a person with qualifications in veterinary science, who is registered as a veterinary surgeon with the Sri Lanka Veterinary Council, having expertise in laboratory animal science.

Category B: a suitably qualified person with substantial experience in the care and use of animals for scientific purposes and/or with commitment to furthering the welfare of animals.

Category C: a suitably qualified person with substantial experience in the care and use of animals for scientific purposes and/or with commitment to furthering the welfare of animals, who is not employed by the institution.

Category D: a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities and not fitting into any other category.

The AERC may also invite suitable persons, as agreed by the committee, to advise the committee, at their discretion.

6.2 Responsibilities and Duties

i. Activities of the AERC should be transparent, unbiased and members should have ethical conduct.

ii. It is the duty of the committee to ensure that all procedure(s) carried out on animals are appropriate and humane prior to granting approval.

iii. The AERC has the right to monitor any project that it has approved (including field visits without prior notice) and revoke the approval given previously if the committee finds that the study is not being carried out ethically and according to the terms and conditions agreed upon.

iv. AERC should communicate with the head of the facility on any adverse incidents.

7.0 Abbreviations

AERC: Animal Ethics Review Committee

FDA: Food and Drug Administration

NC3Rs: National Centre for the replacement, refinement and reduction of animals in research

OECD: Organization for Economic Cooperation and Development

SOPs: Standard Operating Procedures

UGC: University Grants Commission

WHO: World Health Organization

8.0 Definitions

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: "Animal means any living being that includes domestic animal, farm animal, animal in captivity, wild animal, companion animal, aquatic animal, stray animal and food animal."

Animal Welfare: The physical and mental state of an animal in relation to the conditions in which it lives and dies

Distress: Acute or chronic response of an animal caused by stimuli that produce observable biological stress as shown by abnormal physiological or behavioural responses.

Embryonated egg: An egg in the last half of incubation.

Endangered species: The Red Data book published by the International Union for Conservation of Nature (IUCN) defines threatened species as "A taxon is endangered when the best available evidence indicates that it is facing a very high risk of extinction in the wild".

Euthanasia: The humane termination of life.

Experiment: Any test or trial for a scientific purpose, including any activity to test a hypothesis or demonstrate a known fact.

Fetus: An unborn mammal in the last half of gestation.

Investigator: A person approved by an ERC/AERC to be responsible for the conduct of an approved project/experimental protocol involving animals.

Humane endpoints: the point at which pain or distress in an experimental animal is prevented, terminated, or relieved.

Pain: An awareness of acute or chronic discomfort, occurring in varying degrees of severity, and resulting from injury, disease, or emotional distress as evidenced by biological or behavioural changes or both.

Tranquillisers: Drugs which are used to treat anxiety or produce sedation.


Sri Lanka Association for Laboratory Animal Science
SLALAS

9.0 References

Canadian Council for Animal Care
www.ccac.ca/en/alternatives/index.html

Food and Drug Administration (FDA) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/

Forum of Ethics Review Committees of Sri Lanka, Ethics Review committee, Faculty of Medicine, University of Colombo (2009) Guideline for ethics review of Research proposals involving animals in Sri Lanka. http://fercsl.lk/resources/guidelines-reports/

NC3Rs, National Centre for Replacement, Refinement and Reduction of Animals in Research, UK www.nc3rs.org.uk.

Nepal Health Research Council (2005) Ethical guidelines for the care and use of animals in health research in Nepal. http://nhrc.gov.np/publication-category/guidelines/

New Zealand Government, (2010) Good Practice Guide for the use of animals in research, testing and teaching
https://www.massey.ac.nz/massey/fms/Animal%20Ethics/Documents/Good%20Practice%20Guide1.pdf?D96727FC0960E485212099075174 0013

The Organisation for Economic Co-operation and Development (OECD), Guidelines for Toxicity Testing
https://www.oecd.org/about/publishing/

World Health Organization. Regional Office for the Western Pacific. (1993). Research guidelines for evaluating the safety and efficacy of herbal medicines. Manila: WHO Regional Office for the Western Pacific. https://apps.who.int/iris/handle/10665/207008

World Organisation for Animal Health (OIE) (2021). – Animal welfare, Section 7. In Terrestrial Animal Health Code, 21st Ed. OIE, Paris. https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=titre_1.7.htm

10. Appendices

Appendix I

APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS (PART I) – BASIC INFORMATION

For official use

Application No:		Date received:	
Revised By:		ERC Meeting Date:	
Decision:		Date Informed:	

1. Title of the Project:

2. Investigators:

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

Title, name, Designation and Affiliation of Investigators	Role	Signature

A short curriculum vitae of all the investigators should be attached to application.

3. Contact Details of the Principal Investigator

Address	
Telephone numbers	
Fax number	
Email Address	

4. Funding:

Name and Address of Funding Source (s):	Amount:

5. Proposed starting and ending dates[*#] and Study Setting:

Date of ☐ commencement

Date of completion ☐

Study Setting	

[*]From initial recruitment of animals until completion of all data collection.
[#]Retrospective approval will **not** be given for projects already started or completed.

6. Has ethics approval for this study been requested earlier from …… or another similar committee?

Yes ☐ No ☐

If yes, provide details (Names of committees and outcome of the review)

Please note that for studies sponsored by foreign funding agencies or sponsors, ethics review and approval is required from the country of the funding agency or the sponsor.

7. Scientific review

Has research proposal been subjected to scientific review by any other committee?

Yes ☐ No ☐

If yes, provide details (Names of committees and outcome of the review)

Appendix II

APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS (PART II)

For official use

Application No:	

8. Title of the Project:

9. Name of the Principal Investigator:

10. List of documents submitted for review:

Title of the Document	Version	Date

11. Protocol check list:

Please indicate the following.

4.1 Summary of the protocol	**Yes**	**No**	**Protocol section number**	**Reviewer checked**
Provided a summary with a maximum of 500 words indicating objectives, selected animal model/s, methodology and expected outcomes				

Reviewers' comments:

4.2 Scientific importance and validity of the study	**Yes**	**No**	**Protocol section number**	**Reviewer checked**
Details of collaborations if the planned study is a collaborative study				
Adequacy of knowledge and skills of the researcher/research team to conduct the study				

Type of study – Original or replication; if a replication reason for the replication				
Application of 3Rs – Any studies relevant to the project performed previously with Replacement models and the outcome				
Justification for planning the study with an animal model				
Benefits and/ or contribution to advancement of science compared to harm inflicted on animals				
Details such as species, strain, age, weight, gender of the selected animal model				
Justification for selecting the stated animal model with scientific evidence				
Source of selected animal model				
Obtained permission from relevant authorities to acquire the stated animal model				
Determination of sample size required for the project				
Arrangements for continuous supply of animals required for the project				
Arrangement of facilities to transport animals to the place where the study is conducted				
Plan for the dissemination of study outcomes				

Reviewers' comments:

4.3 Availability of facilities	**Yes**	**No**	**Protocol section number**	**Reviewer checked**
Place where the animal study is conducted				
Availability of adequate facilities for optimum welfare of the animals: Type of housing; single or group housing type and size of the cage number of animals per cage type of bedding material used temperature, humidity, ventilation and light/dark regime type and source of food arrangements for feeding and water supply				

Reviewers' comments:

a. Experimental procedure and assessment of harm vs benefits	Yes	No	Protocol section number	Reviewer checked
Described in detail				
Comparison of harm (any physical, psychological) inflicted on animals vs benefits				
Any risks for the members of the research team and animal facility staff				
Measures taken to reduce/minimize these harms to humans				
Mentioning a refinement procedure if unexpected outcome (pain and suffering) is noticed in animals due to the procedure				
Adequacy of veterinary care for animals				
Deviation of standard therapy for animals during the experimental procedure				
Availability of facilities for post-experimental care				
Procedure for reporting adverse events/outcomes				
Details of the surgical procedure				
Anaesthesia: Drug, dose, route of injection				
Availability of facilities for post-surgical care				

Reviewers' comments:

4.5 Endpoints	Yes	No	Protocol section number	Reviewer checked
Clear identification of different endpoints in the protocol: Experimental Scientific Humane				
Method of removal of animals at the end of the experiment or once the scientific objectives are achieved; euthanized/rehabilitated/reused/released as pets/released for dissections/released to the wild/released to the community				
If animals are euthanized; Who is responsible for euthanizing the animal/s Method of euthanasia If drugs are used; name of the drug, dose, route of injection Method of carcass disposal				
If animals are rehabilitated; Who is responsible for rehabilitation and their welfare				
If animals are reused;				

Until such time who is responsible for animal welfare				
If animals are released as pets/ or for dissections Until such release who is responsible for animal welfare				
Adherence to Department of wildlife regulations if wild animals are released to the wild at the completion of the study				
Possibility of having any humane endpoints in the study				
Plan for identification of humane endpoints specific to the study Frequency of observation of animals Observers Scales used to quantify observations -physiological, biochemical, behavioural, grimace scales etc.				
Decision for minimizing animal suffering; if euthanasia is mentioned Who is responsible for euthanizing the animal/s Method of euthanasia If drugs are used; name of the drug, dose, route of injection Method of carcass disposal				

Reviewers' comments:
