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# **Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka**

Forum of Ethics Review Committees of Sri Lanka  
Ethics Review Committee, Faculty of Medicine, University of Colombo  
2009

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## **GUIDELINES FOR ETHICS REVIEW OF RESEARCH PROPOSALS INVOLVING ANIMALS IN SRI LANKA**

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# **Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka**

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2009

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## Introduction

There has been a close relationship between animals and human beings for a long time. Animals have been used for food, transport and companionship. Animals have also been used in research throughout the evolution of science. The discovery of anaesthetics and Darwin's publication of *The Origin of Species*, showing the biological similarities between man and animal, contributed to the increase in animal experimentation.

There is an expectation in the science community and society generally that the use of animals in research should occur within a framework of legislative controls and strict codes of conduct that minimise the impact on the animals involved.

A seminal work, *The Principles of Humane Experimental Technique* by Bill Russell and Rex Burch, was published as long ago as 1959<sup>1</sup>. They defined the basis of humane procedure of animal experimentation to be the three Rs – Replace, Reduce and Refine.

- Replace means doing non-animal experiments wherever possible.
- Reduce means keeping the number of animals used to the minimum.
- Refine means designing experiments in such a way as to keep suffering to a minimum and to establish and use the most humane end-point, which should not normally mean the death of the animal.

Marshall Hall set out similar principles as long ago as 1831 when he outlined five principles which should govern experiments using animals<sup>2</sup>:

- An experiment should never be performed if the necessary information could be obtained by observations.
- No experiment should be performed without a clearly defined and achievable objective.
- Scientists should be well-informed about the work of their predecessors and peers in order to avoid unnecessary repetition of an experiment.
- Justifiable experiments should be carried out with the least possible infliction of suffering.
- Every experiment should be performed under circumstances that would provide the clearest possible results, thereby diminishing the need for repetition of experiments.

Wesley Robb, theologian and philosopher, once said, "Since humans are the only agents of morality on the earth, they have a moral obligation to treat animals humanely." What all this means, in the real world, is that animals will continue to be used for experimentation and that systems must be in place to ensure that this is done with compassion. There is general duty of care obligations to meet the physical, health and behavioural needs of animals used for research and to alleviate pain. The ability of an animal to cope with the environment and exert control over its life is crucial to animal welfare.

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Baumans<sup>3</sup> contends “The increasing demand for high standard animal models together with a critical view on the use of animals led to the development of Laboratory Animal Science in the 1950s, a field that can be defined as a multidisciplinary branch of science, contributing to the quality of animal experiments and to the welfare of laboratory animals. The increased interest in and concern about animal welfare issues led to legislative regulations in many countries and the establishment of animal ethics committees”.

Research involving animals should not commence unless such research has been reviewed and approved by an appropriate Ethics Review Committee (ERC) or Animal Ethics Committees (AEC). These Guidelines for Ethics Review of Research Proposals Involving Animals of Sri Lanka were produced to serve as guidance to ERCs/AECs to promote in Sri Lanka the use of standard operating procedures by researchers and ethics review committees that review research proposals involving animals, their tissues and data. These Guidelines lay the foundation for enhancing the quality of research, aims to ensure the safety, care and wellbeing of animals used in research and to safeguard such animals from inhumane treatment. They apply to any research involving animals, including research on live animals, or animal products or parts (i.e. tissues, cells, organs, embryonated eggs, secretions, etc.).

#### *References*

1. Russell, B. and Burch, Rex. 1959. *The Principles of Humane Experimental Technique*. Methuen
2. Marshall Hall (1790 - 1857) was an English physician and physiologist.
3. Baumans V. Use of Animals in Experimental Research: An Ethical Dilemma? *Gene Therapy*. 2004 Oct; 11 Suppl 1:S64-6.

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## Background

The National Bioethics Committee (NBC) of the National Science Foundation became aware in 2003 of the lack of legislation and nationally applicable codes of practice to ensure the humane treatment of animals used in research. A search for available material turned up only one institutional guideline: that of the Medical Research Institute's guide for researchers, section 10 titled *Ethical obligations when using laboratory animals*. The NBC recommended to universities and research institutes that Animal Ethics Committees be set up to promote and safeguard the humane treatment of animals used in research.

In the year 2005 the University Grants Commission (UGC), through the Director, Council for Agricultural Research Policy (CARP) requested the Vice-Chancellor of the University of Peradeniya to establish animal ethics committees. Such a committee was set up in the Faculty of Veterinary Medicine and Animal Science of the University of Peradeniya in 2007. Being mindful of the fact that animals are used in research not only by veterinarians but also by scientists in many disciplines such as zoologists, medical doctors, biochemists, pharmacologists, etc. it was felt that a comprehensive guideline that addressed the special circumstances, requirements and needs of these various researchers was needed.

This document, *Guidelines for ethics review of research proposals involving animals in Sri Lanka*, fulfils that void. It is worded in a fashion that makes its contents equally applicable for use by Animal Ethics Committees that deal only with research on animals as well as Ethics Review Committees that deal with research on human participants as a rule and some research using animals. It goes without saying that although the document is formatted for use by committees reviewing research proposals, the subject matter gives guidance on ethical conduct of research and the treatment of animal subjects to researchers themselves. The final outcome is the result of input by medical doctors and veterinarians experienced in reviewing research proposals, research scientists in other fields and lay persons in the field of animal welfare. The project was co-ordinated and carried out by the Ethics Review Committee of the Faculty of Medicine, University of Colombo.

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## **1. Ethics Review Committee (ERC)/Animal Ethics Committee (AEC)**

- 1.1. It is desirable that ERCs/AECs that review research involving animals consists of at least one veterinarian and a representative from an animal welfare organization and/or a member of public known for interest in animal welfare.
- 1.2.
  - a. It is the duty of the committee to ensure that research procedure(s) carried out on animals are appropriate and humane prior to granting approval.
  - b. The ERC/AEC has the rights 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.

## **2. Investigator(s) /Researcher(s)/ Scientists**

- 2.1.
  - a. The research team headed by a principal investigator may include a veterinarian, other scientists, research assistants, healthcare professionals, students, technicians and other personnel depending of the nature of the study.
  - b. Investigator(s) must be suitably trained in using animals for research purposes. Each member of the research team must be suitably qualified to fulfill the tasks of their job description including knowledge of applicable ethical guidelines. The requirement of a veterinarian can be dispensed for observational studies or in the opinion of the ERC/AEC such non inclusion is justified.
  - c. The members of the research team shall have the competence in the following:
    - i. ability to differentiate normal and abnormal physical and behavioral patterns of animals to be used in the research and during the research.
    - ii. awareness of potential risks/hazards to animals, humans (research team), community and the environment, that could arise as a consequence of the study
  - d. The welfare of animals must be a primary consideration of the research team and researchers must monitor and document the animal welfare (including maintenance of psychological well-being of the research animals) throughout

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the course of an investigation to ensure continued justification for the research.

- 2.2. a. It is the responsibility of the principal investigator to ensure that all members of the research team are aware of the relevant ethical guidelines and that their role and responsibilities in the research team are consistent with their competence, training and experience in research involving animals.
- b. The principal investigator is responsible for the conditions under which animals are kept during and after research even when the animals are being housed in an animal house.

### **3. Study design**

- 3.1. Any research involving animals should not be approved, unless the scientific purpose of the research including objective(s), rationale and design of the study are clearly justified (based on documentation of literature reviews, prior observations and approved laboratory and animal studies) on the basis that it would advance knowledge for the welfare of humans and /or animals and has adequate potential significance to justify the use of animals.
- 3.2. No study should be granted ethics approval unless the following are clearly justified:
  - a. The use of animals: Why is it that the research cannot be carried out with non animal alternatives?
  - b. The animal species used: Why is it necessary to use this particular species of animal?
  - c. The number of animals required: Is the lowest number required used?
- 3.3. The animal house/facility where this research is to be conducted should have facilities to provide
  - a. for the optimum welfare of the research animals.
  - b. good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research.
- 3.4. No study should be approved where there is a strong reason to believe that death or disabling injury may occur to animals unless the scientific benefits are incontrovertibly justified.

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#### 4. Experimental procedure - pain and discomfort

- 4.1. The research team personnel must treat the animals with kindness, respect and great care, understanding that the animals have sufficient organization to have their own basic drives, desires, and intentions and by this research we interfere with their effort to fulfill their destinies.
- 4.2. The ERCs/AECs must pay attention to the following when granting ethics clearance.
  - a. The study must be conducted in a manner which would avoid discomfort, pain, illness and trauma to animals. If this is unavoidable, the discomfort and pain must be minimized with the assumption that procedures that would produce pain in humans will also do so in other animals. Therefore alternative methodological and procedural techniques, which avoid or minimize illness, pain, trauma and discomfort have to be considered always.
  - b. Procedures which cause pain, stress, privation or death should be used only when an acceptable alternative procedure is unavailable.
  - c. Procedures involving more than momentary pain or slight aversive stimulation, which can not be relieved by medication or other acceptable methods, can be undertaken only when the objectives of the research cannot be achieved by any other method. These will be performed with appropriate pain management (including sedation, analgesia or anaesthesia - relevant to the species, etc.) compatible with the goal of the research.
  - d. Research studies which require prolonged aversive conditions or produce tissue damage or metabolic or psychological disturbances are strongly discouraged. These include prolonged exposure to extreme environmental conditions, experimentally induced prey killing, or infliction of physical trauma or tissue damage, etc.
  - e. When conducting a study, which is intentionally designed to examine aversive conditions with greater justification, the parameters of stimulation of pain should be optimized to minimise pain, without affecting the objective(s) of the research.
- 4.3. If a researcher detects signs of pain on experimental animals, which were not anticipated, he/she should immediately inform the ERC/AEC for necessary guidance.

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## 5. Surgery and anaesthesia

- 5.1. Any surgical procedures on and anaesthetization of large animals should be conducted only by a veterinarian. Approval may be given for others who are scientifically qualified and trained to do so, under the direct supervision of an attending veterinarian.
- 5.2. Multiple surgical procedures on the same animals are strongly discouraged. However, approval may be given with valid scientific justification considering the nature of the research, the nature of the surgery and the wellbeing of the animal.
- 5.3. Description of pre-surgical planning and evaluation procedures (including the individual responsibilities of the members of the surgical team according to their level of competence), surgical technique(s) and equipment to be used have to be incorporated in the proposal. Proper aseptic methods must be used.
- 5.4. Special considerations regarding anaesthetic agents.
  - a. Best suited anaesthetic methods should be selected appropriate to the species, clinical and humane aspects and research needs.
  - b. Procedures involving the use of paralytic agents without reduction in pain sensation should be avoided as far as possible.
  - c. Use of muscle relaxants or paralytics alone during surgery, without general anaesthesia, is unacceptable and is to be avoided.
  - d. Studies of pain on animals paralyzed with a neuromuscular blocking agent cannot be carried out without a general anaesthetic or an appropriate surgical procedure that eliminate sensory awareness.
- 5.5. When the surgical procedure is likely to cause greater discomfort beyond the provided analgesia/anaesthesia, and unless there is a specific justification not to do so, animals should be maintained under general anaesthesia during the whole surgical procedure.
- 5.6. Proper postoperative monitoring and care, in addition to food and housing, analgesics and antibiotics should be provided (if necessary) to animals in order to minimize discomfort and pain and to prevent infection and other undesirable consequences.

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## **6. Animal house/facility and Research environment**

- 6.1. A structurally well designed animal house/facility in keeping with current international standards should be available to ensure welfare of animals and of the research team and to ensure good quality research.
- 6.2. Animals have to be provided with adequate quantity of palatable, uncontaminated and nutritionally balanced food and uncontaminated drinking water to provide for their daily requirements and in keeping with research goals. In addition attention should be paid to providing sufficient number of containers for food and water to the animal house/facility and on their filling, refilling and cleaning and their arrangement within the animal house/facility taking into consideration the eating habits of the animals.
- 6.3. The food for all animals (unless it is required and ethical approval obtained) should be free from medicines, antibiotics, etc. and should be given according to a time table.
- 6.4. The animal house/facility must contain sufficient space, ventilation, proper instrumentation and mechanisms for noise management to ensure that animals are provided with humane care and healthy conditions during the research, and may have the service of a veterinarian.
- 6.5. The animal house/facility has to be cleaned regularly to maintain animal and human hygiene.
- 6.6. Records of the animal house/facility should be maintained to ensure that it has been inspected by an officer designated by the authorities under who the animal house/facility is maintained, on a regular basis. These records must be available to members of the ERC/AEC on request.

## **7. Acquisition of animals – law and rights**

- 7.1. All animals, which are not bred in the same animal house / animal facility, must be acquired lawfully. Sourcing and identification of animals must be transparent. Stray or feral animals or animals from shelters or pounds may not be used only with justification and ERC/AEC approval.
- 7.2. During the course of research involving animals, the person in charge (if applicable) of an animal has the liberty to bring the experiment to an end at any point if he/she believes that continuation of the experiment is harmful.

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- 7.3. The use of wild animals for research purpose needs justification and permission from the Department of Wildlife Conservation.
  - 7.4. Animals to be captured from the wild should be trapped in a humane manner.
  - 7.5. The retention and use of animals shall in every case in compliance with laws that are in effect at that time.

## **8. Post research procedures**

- 8.1. The research should be terminated when,
  - a. the goal is reached or
  - b. continuation will result in injury or suffering to the animals.
- 8.2. When the use of an animal is no longer required by an experimental protocol or procedure alternative uses of the animals should be considered. Such uses should be compatible with the welfare of the animal.
- 8.3. If death occurs, the carcass has to be disposed in an acceptable way, approved by the ERC/AEC, considering relevant legislation, health issues, environmental, and aesthetic concerns.
- 8.4. Animals caught from the wild that do not carry substantial risk to themselves and to the ecosystem may be released at the point of capture based on the recommendation of the Department of Wildlife Conservation.
- 8.5. Animals bred and reared in the laboratory should not be released.

## **9. Transportation of animals**

- 9.1. Acquired animals should be transported in a humane way by providing sufficient food, water, ventilation, space and facilities to prevent unnecessary discomfort and pain to the animals, according to the species, breed, caging/housing needs, mode of transport and climatic conditions, etc.
- 9.2. Other factors to be considered
  - a. Optimize transit time to include or to ensure rest for animals

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- b. Health certificate should be obtained at the point of transportation and destination (if healthy animals are used)
  - c. Quarantine procedures and Convention on International Trade in Endangered Species of Wildlife Fauna and Flora (CITES) must be strictly adhered to if animals are brought into the country.
  - d. Newly received animals must be allowed time to stabilize and acclimatize.
  - e. Certificate of transportation should be obtained from relevant authorities.

## **10. Euthanasia**

- 10.1. If the study requires the death of an animal or painful or stressful outcome or irreparable injury is anticipated at the conclusion of the research the most humane, reliable and safe euthanasia method (appropriate for the species to ensure immediate death) consistent with the study must be used.
- 10.2. Euthanasia must be carried out quickly and painlessly in an environment, in which the animal is free from fear and anxiety, under the supervision of an attending veterinarian where appropriate.
- 10.3. Any animal that is subjected to procedures in which the animal is anaesthetized and made insensitive to pain throughout the experiment must be euthanised before regaining consciousness.
- 10.4. Any animal observed to be in a state of severe distress or chronic pain that cannot be relieved should be euthanised immediately.
- 10.5. No large animal shall be discarded until its clinical death is confirmed by a veterinarian.
- 10.6. Euthanasia should be performed in a separate location in the animal house/facility.

## **11. Field Research**

- 11.1. Any field research should not disturb human or animal populations, sensitive ecosystems and normal interactions between populations in the community. Every effort should be made to minimize potential harmful effects of the study on the populations and on other plant and animal species in the area.

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- 11.2. Research conducted in populated areas should be done with respect for the property and privacy of the inhabitants of the area.

## **12. Animals used for routine diagnostic work and vaccine production**

- 12.1. A certificate of ethics conformity should be obtained from an ERC/AEC by all laboratories and organisations with respect to the use and treatment of animals used by them for routine diagnostic work or vaccine production; such certificates should be renewed annually.
- 12.2. Such laboratories and organisations should follow the standards of animal care contained in this document as well as any specific directives given by the ERC/AEC as a condition upon which the certificate is issued.

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## Annex A: Definitions and Terminology

- **“Acclimatization”** is the process of an organism adjusting to chronic change in its environment, often involving temperature, moisture, food, often relating to seasonal climate changes.
- **“Anaesthetic agents”** are drugs that causes temporary loss of bodily sensations.
- **“Analgesia”** is absence of the sense of pain without loss of consciousness.
- **“Anaesthesia”** is loss of bodily sensation with or without loss of consciousness or a method of preventing sensation.
- **“Animal”** means organisms which have a true nucleus (eukaryotic), are multicellular, and heterotrophic (do not make their own food), which also have nervous and muscle tissue, body symmetry, and identifiable body parts (eg. eyes, legs, antennae, a digestive system).
- **“Animal Facility”** means the places where animals are kept including yards, paddocks, tanks, ponds and buildings.
- **“Animal Welfare”** means the protection of the health and well-being of animals. It is the animal’s quality of life based on an assessment of an animal’s physical and psychological state as an indication of how the animal is coping with the ongoing situation as well as a judgment about how the animal feels.
- **“Animal welfare organization”** means an organization deals on the protection of the health and well-being of animals.
- **“Antibiotics”** are substances derived from a microorganism that is able to inhibit or kill another microorganism. A term used to describe a range of drugs which are used to treat conditions involving bacteria.
- **“Aseptic conditions”** means sterile conditions, with no unwanted organisms present.
- **“CITES”** means Convention on International Trade in Endangered Species of Wild Fauna and Flora. It is an international agreement between governments, drafted as a result of a resolution adopted in 1973 at a meeting of members of the International Union for Conservation of Nature (IUCN). Its aim is to ensure that international trade in specimens

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of wild animals and plants does not threaten their survival and it accords varying degrees of protection to more than 33,000 species of animals and plants.

- **“Community”** is a group of animals belonging to the same species living in a particular local area at a particular time.
- **“Death as an end-point”** is when the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects. That is, where the investigator or teacher will not intervene to kill the animal humanely before death occurs in the course of a scientific activity.
- **“Death”** means the permanent end of all life functions in an organism or part of an organism.
- **“Discomfort”** is an uncomfortable feeling of mental painfulness or distress.
- **“Distress”** is the state of an animal, that has been unable to adapt completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.
- **“Ecosystem”** is a natural unit consisting of all plants, animals, micro-organisms (biotic factors) and their interactions in a certain area functioning together with all of the non-living physical (abiotic) factors of the environment.
- **“Environment”** is the area in which something exists or lives
- **“Ethics”** is the framework in which actions can be considered as good or bad, right or wrong.
- **“Euthanasia”** is the practice of ending a life in a painless manner.
- **“Feral animal”** is an animal that has escaped from domestication and returned, partly or wholly, to its wild state.
- **“Hazard”** is a source of danger; a possibility of incurring loss or misfortune.
- **“Illness”** means impairment of normal physiological function affecting part or all of an organism.

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- **"Inhabitants"** are the creatures live s or reside in a particular place.
  - **"Investigator"** in animal research is any person who uses animals for scientific purposes.
  - **"Laboratory"** is a workplace used for experiments in natural science as well as for scientific research or medical diagnosis.
  - **"Manifestations"** are the symptoms or observable conditions which are seen as a result of some disease.
  - **"Medicines"** means a substance which specifically promotes healing when ingested or administered in some way.
  - **"Monitoring"** in animal research is the act of observing which is undertaken to assess the wellbeing of animals that are used and cared for, and to assess the adequacy of standards of animal care and use.
  - **"Muscle relaxants"** are drugs which affect skeletal muscle function and decrease muscle tone.
  - **"Noise"** is the auditory experience of sound that lacks musical quality.
  - **"Pain"** Is a somatic sensation of acute discomfort, a symptom of some physical hurt or disorder or a symptom of mental / emotional distress.
  - **"Palatable"** means acceptability to the mind or feelings.
  - **"Paralysis"** is the complete loss of muscle function for one or more muscle groups. Paralysis can cause loss of feeling or loss of mobility in the affected area.
  - **"Paralytic agents"** are drugs that cause paralysis.
  - **"Person in charge of an animal"** means a person who a) owns or has a lease, license or other proprietary right to or over the animal; or b) has custody of the animal lawfully or otherwise.
  - **"Population"** is a group of organisms of the same species inhabiting a given area.
  - **"Privation"** is a state of extreme poverty.

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- **“Project”** is a scientific activity or activities that form a discrete piece of work. A project cannot commence until it has been approved by an ERC/AEC.
  - **“Proposal”** is a written description of the intended study attached to the application for approval to carry out a project submitted for consideration by an Ethics Committee.
  - **“Rehabilitation”** of wildlife is the process of removing from the wild and caring for injured, orphaned, or sick wild animals with the goal of providing food, housing and medical care and returning them to the wild after treatment.
  - **“Research”** in relation to an animal means an experiment, procedure, test or study in which an animal is used and includes subjecting an animal to surgical, medical, psychological, biological, chemical or physical treatment.
  - **“Risk”** to an animal or a human means a potential negative impact / a form of danger.
  - **“Scientific purposes”** are all those purposes which aim to acquire, develop or demonstrate knowledge or techniques in any area of science including teaching, field trials, environmental studies, research, diagnosis, product testing, and the production of biological products.
  - **“Sedation”** is a state of reduced excitement or anxiety that is induced by the administration of a sedative agent.
  - **“Sedative agent”** is a drug that reduces excitability and calms a person.
  - **“Species”** is a group of organisms distinct from all other groups of organisms that are capable of reproduction and producing fertile offspring. This is the basic unit of plant and animal classification.
  - **“Stabilization”** make stable and keep from fluctuating or put into equilibrium.
  - **“Stray animal”** is an animal having no home or having wandered away from home.
  - **“Stress”** is a state of mental or emotional strain or suspense.
  - **“Teaching”** is developing, imparting or demonstrating knowledge or techniques in any area of science.

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- **“Transit time”** is the estimated time in days or weeks that your move will take from door to door.
  - **“Trauma”** is a physical injury or wound caused by an external force of violence, which may cause death or permanent disability. Trauma is also used to describe severe emotional or psychological shock or distress.
  - **“Vaccine”** is an immunogen consisting of a suspension of weakened or dead pathogenic cells injected in order to stimulate the production of antibodies.
  - **“Veterinarian”** means a Veterinarian registered under the Veterinarians and Practitioners Act No. 46 of 1956 and includes a Veterinary Practitioner.
  - **“Welfare”** includes the health, safety and well-being of an animal or human.
  - **“Well-being”** means a contented state of being happy and healthy and prosperous.
  - **“Wildlife”** is free-living animals of native, non-indigenous or feral species including captive-bred animals and those captured from free-living populations.

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## Annex B: References

The following documents were consulted in preparing these guidelines:

1. Ethical Guidelines for the Care and Use of Animals in Health Research in Nepal: Nepal Health Research Council (NHRC).
2. Ethical obligation when using laboratory Animals: Medical Research Institute, Ministry of Health, Sri Lanka.
3. Mappes TA, Zembaty JS. Beastly conduct: Ethical Issues in Animal Experimentation: Caplan AL. *Biomedical Ethics*. 1991; 4: 246-254
4. Guidelines for Ethical Conduct in the Care and Use of Animals developed by the American Psychological Association (APA)
5. Report of the Law commission on the draft Animal welfare bill, Sri Lanka
6. NUREMBERG CODE: Reprinted from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.* Washington, D.C.: U.S. Government Printing Office, 1949  
(<http://ohsr.od.nih.gov/guidelines/nuremberg.html>).
7. World Medical Association Declaration of Helsinki.  
<http://www.wma.net/e/policy/b3.htm>.

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## **Annex C: Participants and Contributors**

The first draft of these guidelines was developed by Dr. Vajira H. W. Dissanayake, Dr. Mangala Gunathilake, Dr. T. Chenthuran and Ms. Madubashini Jayamanne and presented to participants at the workshop on “Developing National Guidelines for Protection of Animal Participants in Research” held on 11 September 2008 at the Faculty of Medicine, University of Colombo. The list of participants at this workshop is as follows:

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Mr. N. S. B. M. Atapattu – Head / Department of Animal Science

***Faculty of Medicine, University of Ruhuna***

Prof. Chitra Pathirana – Senior Lecturer, Chairperson / Ethics Review Committee

***Faculty of Medical Sciences, University of Sri Jayewardenepura***

Dr. Neluka Fernando – Senior Lecturer and Head / Department of Microbiology

Dr. (Mrs.) Thusharie Sugandhika Suresh – Senior Lecturer in Biochemistry

***Department of Biological Sciences, Rajarata University of Sri Lanka***

Dr. Manoj Sanjeeva Fernando – Lecturer in Biological Sciences

***Faculty of Veterinary Medicine and Animal Science, University of Peradeniya***

Prof. P. Abeynayake – Dean/ Faculty of Veterinary Medicine and Animal Science

Dr. A. Arulkanthan – Lecturer in Veterinary Pathobiology

Dr. H. B. S. Ariyaratne – Head, Department of Basic Veterinary Sciences

Dr. Ashoka Dangolla – Senior Lecturer in Veterinary Clinical Studies; Chairperson, Ethics Committee on Research

Dr. D. D. N. de Silva – Senior Lecturer in Veterinary Clinical Sciences

Dr. Madhavi Hathurusinghe – Head, Department of Veterinary Public Health & Pharmacology

Dr. R. S. Kalupahana – Lecturer in Veterinary Medicine and Animal Science

Dr. J. M. K. J. K. Premaratne – Senior Lecturer in Veterinary Public Health & Pharmacology

Prof. Indira Silva – Professor in Veterinary Clinical Sciences, Head / Department of Veterinary Clinical Sciences

***Faculty of Medicine, University of Peradeniya***

Prof. R. Sivakanesan – Professor and Head, Department of Biochemistry

Dr. J.G. Shirani Ranasinghe – Senior Lecturer in Biochemistry, Faculty of Medicine, University of Peradeniya.

***Faculty of Agriculture, University of Peradeniya***

Dr. A. R. S. B. Athauda – Senior Lecturer in Animal Science

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***Faculty of Dental Sciences, University of Peradeniya***

Dr. Ranjith Pallegama – Senior Lecturer in Basic Sciences / Secretary, Ethics Review Committee

***Postgraduate Institute of Agriculture, University of Peradeniya***

Dr. Thusith Samarakone – Senior Lecturer

***Faculty of Medicine, University of Jaffna***

Dr. (Mrs) K. Muruganathan – Senior Lecturer, Faculty of Medicine, University of Jaffna

Dr. (Mrs). S. Pancharajah – Head / Siddha Medicine, Member- Ethics Review Committee

Dr. (Mrs). K. Soundararajan – Senior Lecturer, Siddha Medicine Unit

***Faculty of Science, University of Jaffna***

Ms. Nitiyagowry Rajan – Senior Lecturer, Department of Zoology

***Uwa Wellassa University***

Dr. S. C. Jayamanne – Dean / Science and Technology

***University of Wayamba***

Dr. Gamika Prathapasinghe – Lecturer in Livestock and Avian Science

Dr. S. S. E. Ranawana – Senior Lecturer in Livestock and Avian Science

***Open University of Sri Lanka***

Dr. I. Kumudu Rajapaksha – Senior Lecturer in Zoology

***Eastern University of Sri Lanka***

Dr. N. Varnakulendran – Head / Siddha Medicine Unit

Dr. P. Vinobaba – Senior Lecturer in Zoology

***Veterinary Research Institute***

Dr. J. K. H. Ubeyratne – Veterinary Research Officer, Division of Animal Breeding

Dr. (Mrs.) N. D. Senasinghe – Veterinary Research Officer, Division of Parasitology

Dr. Roshan Priyantha – Veterinary Research Officer, Department of Bacteriology

***Faculty of Medicine, University of Kelaniya***

Dr. Chrishantha Abeysena – Senior Lecturer in Community Medicine and Member, Ethics Review Committee

Dr. Rezvi Hassan – Senior Lecturer

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***Department of Animal Production and Health***

Dr. A. D. N. Chandrasiri - Additional Director General

***Gampaha Wickramarachchi Ayurveda Institute***

Dr. W. A. L. Chandrasiri – Director

***Institute of Fundamental Studies***

Dr. D. N. Magana-Arachchi - Research Assistant

***Department of Health Services***

Dr. P. A. L. Harischandra – Director Veterinary Services

***Department of National Zoological Gardens***

Dr. Chandani Ganga Wijesinghe – Veterinary Surgeon

***National Science Foundation***

Dr. Sachie Panawala – Research Officer

***Ministry of Plan Implementation***

Ms. Lalani S. Perera – Additional Secretary -Administration, Ministry of Plan Implementation

***Institute of Biotechnology, Molecular Biology and Biochemistry, University of Colombo***

Dr. Shiroma Handunnetti – Senior Lecturer

***Animal Welfare Groups***

Ms. Sagarica Rajakarunanayake - President, Sathva Mithra (*Friends of Animals*) - Sri Lanka

Ms. Chula Arsakularatne - Trustee, Lucy Trust for Ornamental Animals

Ms. Anoma Akmeemana - Member, Animal Welfare Trust

Ms. Champa Fernando – Member, Kandy Association for Community Protection through Animal Welfare (KACPAW)

Ms. Hemantha Jayathilake – President, Animal Welfare Protection Association

Ms. Yasmin Samarawickrame – Secretary, Animal Welfare Protection Association

Ms. Shiona Weerasekera – Committee Member, Animal Welfare & Protection Association Sri Lanka, Colombo.

***Journalists***

Ms. Kumudini Hettiarachchi – Deputy Editor, Sunday Times

Mr. Feizal Samath – Journalist, Sunday Times

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### **Lawyers**

Ms. Rathsara Gunasekara - Aparentist, Julius and Creasy Ltd  
Ms. Avanthi Perera - State Counsel, Attorney Generals Department  
Mr. Senaka Weeraratna LL.B. (Ceylon), LL.M. (Monash) - Attorney - at –Law, Former  
Consultant to the Sri Lanka Law Commission on Animal Welfare Legislation.

At the conclusion of the workshop an invitation was extended to all those present to submit responses to the draft guidelines. Written comments were received from the following persons:

Prof. Hemantha Senanayake  
Dr. Malik Fernando  
Dr. S.L. Pathirana  
Prof. R. Lal Jayakody  
Mrs. D. N. de Silva  
Dr. P. V. Randeniya  
Dr. Naazima Kamardeen  
Mr. N. S. B. M. Atapattu  
Prof. Chitra Pathirana  
Dr. Thusith Samarakone  
Ms. Nitiyagowry Rajan  
Dr. S. S. E. Ranawana  
Dr. J. K. H. Ubeyratne  
Dr. (Mrs.) N. D. Senasinghe  
Dr. Chrishantha Abeysena  
Ms. Sagarica Rajakarunanayake  
Ms. Champa Fernando  
Dr. Shamini Jayasekara – Research Officer, Medical Research Institute  
Dr. Nishadi Wijerathne – Lecturer in Behavioural Science Stream

These responses were discussed modifications made to the draft guidelines at a follow up workshop held at the Faculty of Medicine, University of Colombo on 15 December 2008 attended by the following persons.

Prof. Hemantha Senanayake  
Dr. Mangala Gunathileke  
Dr. S.L. Pathirana  
Dr. Thusith Samarakone  
Dr. (Mrs.) N. D. Senasinghe  
Ms. Sagarica Rajakarunanayake  
Ms. Champa Fernando  
Ms. N. M. M. Jayamanne

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The second draft of the guidelines was reviewed at a special meeting of the Ethics Review Committee of the Faculty of Medicine, University of Colombo on 4 March 2009 attended by the following ERC members.

Prof. Hemantha Senanayake  
Dr. Vajira H. W. Dissanayake  
Dr. Mangala Gunathileke  
Dr. Enoka Corea  
Dr. Malik Fernando  
Ms. N. M. M. Jayamanne

The application and evaluation forms were designed by Dr. Mangala Gunathilake.

The final document was edited and formatted by Dr. Vajira H. W. Dissanayake on 1 May 2009

## ANNEX D: APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS - PART I

for official use

Application No:								Date Received:			/			/		
Reviewed By:								ERC Meeting Date:			/			/		
Decision:								Date Informed:			/			/		

**1. Title of 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.*

**2.1. Principal Investigator/Supervisor:**

Title: Mr.  Ms.  Dr.  Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Signature

**2.2. Co-Investigator 1:**

Title: Mr.  Ms.  Dr.  Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Signature

**2.3. Co-Investigator 2:**

Title: Mr.  Ms.  Dr.  Prof.

Name:

Qualifications:

Designation:

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Place of Work:   
Address:   
Contact Nos:   
Email Address:   
Signature

**2.4. Co-Investigator 3:**

Title: Mr.  Ms.  Dr.  Prof.   
Name:   
Qualifications:   
Designation:   
Place of Work:   
Address:   
Contact Nos:   
Email Address:   
Signature

**2.5. Co-Investigator 4:**

Title: Mr.  Ms.  Dr.  Prof.   
Name:   
Qualifications:   
Designation:   
Place of Work:   
Address:   
Contact Nos:   
Email Address:   
Signature

**3. Proposed starting and ending dates: \* ‡**

Start Date:  End Date:

*\* From initial recruitment of animals until completion of data collection.*

*‡ Retrospective approval will not be given for projects already started or completed.*

**4. Has ethics review for this study been requested earlier from this committee or another similar committee?**

Yes  No

If yes,

\*Where?

\*When?

\*Result:

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# APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS - PART II

*for official use*

Application No:

## 1. Title of Project

## 2. Funding

Name and Address of Funding Source(s)

Amount

<input type="text"/>	<input type="text"/>
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## 3. A brief summary of the research proposal in simple language (maximum 500 words)

## 4. Scientific importance and validity of the study

4.1. What is the scientific importance of your study in relation to improving health care of animals/humans and/or knowledge on the subject?

4.2. Is your study an original one or a replication of a previous study?

Original

Replication

If it is a replication study please justify.

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

Yes

No

If YES, what is the name of the committee?

4.4. Do the investigators have basic knowledge and competence to conduct this study and to differentiate normal and abnormal behaviour of animals?

Yes

No

If NO, please indicate how investigators are going to acquire knowledge and skills?

4.5. How will the results of the study be disseminated?

4.6. Is the use of animals necessary to obtain required information?

Yes

No

4.7. Why the research cannot be carried out with non-animal alternatives?

4.8. What is the species of animals used and the reason for selecting the said animal model?

4.9. Have you obtained permission from relevant authorities to use the said animal species for your research?

Yes

No

If YES, please state the authority. If NO, when and from where will you obtain permission?

---

4.10. What is the source of animals and the arrangements that you have made to ensure constant supply of animals?

4.11. Is it necessary to transport animals from another place to the site where the research is carried out?

Yes  No

If YES, what are the arrangements that you have made to transport animals with optimum care?

4.12. What is the total number of animals used in the study and how did you calculate the sample size?

4.13. Are the facilities available at the animal house/facility adequate to conduct this study?

Yes  No

4.14. Are the facilities adequate to provide optimum welfare to animals?

Yes  No

4.15. Who is responsible for maintaining the welfare diary during the study?

4.16. What are the housing conditions available at the site?

Single/group housing	<input type="checkbox"/>	Temperature	<input type="checkbox"/>	Humidity	<input type="checkbox"/>
Type & size of cages	<input type="checkbox"/>	No. of animals per cage	<input type="checkbox"/>	Bedding materials	<input type="checkbox"/>
Light – dark regime	<input type="checkbox"/>	Ventilation	<input type="checkbox"/>		

4.10. Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research?

Yes  No

4.11. What is the type and source of food given to animals?

4.12. What are the arrangements made for feeding and for providing water?

**Humane end points**

4.13. Are there any humane end points that would be expected during the study?

Yes  No

If YES, give details.

4.20. If you observe an animal suffering severely, will you take necessary steps to euthanise the animal to prevent further suffering?

Yes  No

4.14. What is the method used to euthanise the animal? If a drug is used give details.

4.15. Who is responsible for euthanising the animal?

---

**Experimental end points**

4.16. What is the method/mode of disposal of used animals after research?

4.17. Are you euthanising the animals at the end of the study?

Yes  No

4.18. What is the method used to euthanise the animal? If a drug is used give details.

4.19. Who is responsible for euthanising the animal?

**5. Assessment of Risks/Benefits**

5.1. Are there any risks (physical, psychological) to animals during the study?

Yes  No

If YES, identify them and state how you plan to prevent or minimize these risks?

5.2. Are there any benefits to the animals used in the study?

Yes  No

If YES, identify them.

5.3. Are there any risks to research team by conducting this study?

Yes  No

If yes identify them and state how you would overcome these risks.

5.4. Justify the potential benefits to animals/humans against risks.

5.5. Is standard therapy, e.g. for therapeutic studies on sick animals, going to be withheld from the animals recruited for the study?

Yes  No  Not applicable

If YES, justify.

5.6. Is veterinary support for the animals adequate?

Yes  No  Not applicable

If NO, explain.

5.7. What is the procedure for dealing with adverse events?

5.8. Is there any procedure for reporting adverse events?

Yes  No  Not applicable

If YES Give details.

If No Explain.

**6. Respect for the dignity of the animals and owners of animals**

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6.1. Do you ensure that the animals are handled with care and compassion?

6.2. Do you ensure that you take adequate measures to reduce suffering of animals during the research?

**Informed consent**

6.3. Write briefly your procedure for obtaining informed consent from the owners of animals use for the research.

6.4. Who will obtain consent?

6.5. Is it written or verbal consent?

Written  Verbal  Not Applicable

If written please include consent form with translations. If verbal, please state in simple words (in Sinhala / Tamil / English) in a separate sheet what information you would convey to the participants and state below how consent would be documented

6.6. How will you ensure that the owner is adequately informed? Please include information sheets with translations.

6.7. How will you ensure your information is understood by the owners and queries answered?

6.8. Would the owners have difficulty in understanding the information due to illiteracy?

Yes  No

If YES, detail the arrangements that you would make to obtain consent from such owners.

6.9. Are you offering any financial or other incentives/ rewards/ compensation for giving consent for the use of their animals?

Yes  No

If YES please list them and state why they do not constitute undue inducement for granting consent?

(All incentives to be provided to owners must be approved by the ERC).

6.10. How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?

6.11. Are the animals of the owners consented under your care?

Yes  No

If YES how you would ensure they would not feel obliged to give consent in order to receive better veterinary care for their animals.

6.12. Will you obtain fresh informed consent if the procedures are changed during the research?

Yes  No  Not Applicable

**Confidentiality**

6.13. How will data/samples be obtained?

6.14. How long will data/samples be kept?

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6.15. Are you collecting the minimum information/samples required to fulfill the study objectives?

Yes  No

6.16. Who will have access to the personal data of the owners and animals?

6.17. How will you safeguard the privacy of the owners?

6.18. What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?

6.19. If you are planning to store data/samples for future study, will you obtain appropriate consent?

Yes  No

**Rights of the owners of animals**

6.20. How will you ensure the owners unconditional right to withdraw their animals from the research at any time?

6.21. Outline the procedures you will provide for the owners to ask questions and register complaints on behalf of their animals.

6.22. Who will be the contact person for the owners?

6.23. Is there provision for owners to receive information that is relevant to participation of their animals?

Yes  No  Not Applicable

If YES/NO Explain.

6.24. Is there provision for the owners to be informed of results of clinical research? Explain.

6.25. Is there provision to make the study product if any available to the owners following the research?

Yes  No  Not Applicable

If YES/NO Explain.

**7. Fair selection of animals**

7.1. What is your study population?

7.2. Justify your choice of study population.

7.3. Is the selection of animals (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitable distributed?

Yes  No  Not Applicable

If YES/NO Explain.

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7.4. How is the initial contact of owners and recruitment of animals to be conducted?

7.5. Is the research conducted on a vulnerable group of animals?

Yes  No

If YES please fill up section 9.

7.6. Is the research an externally sponsored research?

Yes  No

If YES please fill up section 10.

7.7. Is your research involves community animals?

Yes  No

If YES please fill up section 11.

7.8. Is your research a clinical trial?

Yes  No

If YES please fill up section 12.

## 8. Responsibilities of the researcher

8.1. What are the responsibilities of the researcher for provision of veterinary services to animals use in the study?

8.2. What are the provisions for continuation of care after the research is over?

8.3. Have you followed any applicable legal regulations or other guidelines?

Yes  No  Not Applicable

If YES, provide details.

If NO Explain.

8.4. Please declare any conflicts of interest including payments received by you or co-researchers and other rewards (Please list them and state how you would prevent them from influencing the conduct of the study).

8.5. Do you see any other ethical / legal/ social/ financial issues in your study? (Please list them and state how you would prevent them from influencing conduct of the study).

8.6. I do not wish the following reviewers/ ERC members to review my application.

8.7. I am willing to provide 6 monthly reports of my research to the Ethics Committee.

Yes  No  Not Applicable

## 9. Vulnerable groups (stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.)

9.1. What is the justification for the using the vulnerable group instead of the general animal population of the same species?

9.2. What is the procedure for obtaining consent of the owners of the vulnerable group of animals?

9.3. What is the procedure for withdrawal from research due to refusal of owners of the

---

vulnerable group of animals?

9.4. Are you providing adequate veterinary support? Explain.

9.5. Will the benefits of research be made reasonably available to this group of animal population? Explain.

**10. Externally sponsored research**

10.1. Has the research project been approved by an ERC in the sponsoring country?

Yes  No

If YES, please attach documentary evidence. If NO, give reasons.

10.2. Why is the research carried out in Sri Lanka and not in the sponsoring country?

10.3. What is the relevance of this study to Sri Lanka?

10.4. What are the post research benefits to Sri Lanka such as capacity building etc?

10.5. Are you adhering to any specific laws/ regulations/ guidelines of Sri Lanka and the sponsoring country/countries applicable to the study?

Yes  No  Not applicable

If YES, give details.

If No Explain.

10.6. Have you taken into account cultural and social customs, practices, and taboos in Sri Lanka when designing your study?

Yes  No  Not Applicable

If YES/NO Explain.

10.7. Are the animals used in the study receiving the best current treatment as part of the protocol?

Yes  No  Not Applicable

If NOT, explain why?

10.8. What is the ancillary care provided (treatment that is not part of the protocol)?

10.9. What are the provisions for continuity of care?

10.10. How will the rights to intellectual property be shared?

10.11. Are any of the data or biological samples to be transferred overseas?

Yes  No

If YES, describe the fate of the data or biological samples at the conclusion of the study.

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10.12. How will the results of research be conveyed to relevant authorities in Sri Lanka?

**11. Community animals based research**

11.1. State the impact and relevance of the research on the community animals in which it is to be carried out.

11.2. State the steps taken to recruit community animals for the research.

11.3. If the intervention is shown to be beneficial will the sponsor continue to provide it to animals after conclusion of the study?

If YES/NO explain.

11.4. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the animals of the same species?

Yes  No  Not Applicable

If YES/NO Explain how?

11.5. Will there any contribution of the research towards improvement of health/welfare of concerned community group of animals? Explain.

11.6. How will the results of the research be made available to the relevant authorities to do necessary improvements of health/welfare of concerned community group of animals?

**12. Clinical trials**

12.1. What phase clinical trial is being conducted?

12.2. Is it a multicentre trial?

Yes  No

If YES Give details.

12.3. Is the clinical trial registered with a clinical trial registry?

Yes  No

If YES name it.

12.4. Have adequate animal toxicity and teratogenicity trials been carried out?

Yes  No

12.5. What is the justification for using a control arm?

12.6. Does the control group receive the standard therapy?

Yes  No  Not Applicable

12.7. Are all animals treated equally?

Yes  No  Not Applicable

If NOT Explain.

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12.8. What is the procedure for dealing with adverse events?

12.9. What is the procedure for reporting adverse events?

Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?

Yes  No

12.10. What are the criteria for termination of the trial?

12.11. Is there provision for insurance of the animals used in the trial? Explain.

Yes  No



## Appendix E: Ethics Review Evaluation Form

for official use

Application No:

	Yes	No	NA	Comments
<b>1. Scientific importance and validity of the study</b>				
1.1. Will the study lead to improvements in health care of animals/humans and/or knowledge on the subject				
1.2. If the study is a replication of a previous study, is it justified?				
1.3. Has the research protocol been approved by a competent body?				
1.4. Are the investigators qualifications, competence and experience appropriate to conduct this study?				
1.5. Is there provision for dissemination of results of the research?				
1.6. Should the study be referred to a technical expert, policy maker or statistical expert? If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person.				
1.7. Are the objectives stated clearly?				
1.8. Is the study design appropriate in relation to the objectives?				
1.9. Is the study designed using accepted principles, methods and practices?				
1.10. Is there a plausible data analysis plan?				
1.11. Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of animals?				
1.12. If use of animals necessary to obtain required information, is it justified?				
1.13. If the research cannot be carried out with non-animal alternatives, is it justified?				
1.14. Is the reason for selecting the specified animal model justified?				
1.15. Have the researchers obtained permission from relevant authorities to use the said animal species for their research?				
1.16. Have the researchers arranged facilities for animals if transportation of animals are necessary from another place to the site where the research is carried out?				
1.17. Are the facilities available at the animal house/facility adequate to conduct this study?				
1.18. Are the facilities adequate to provide optimum welfare to animals?				
1.19. Is the person responsible for maintaining the welfare				

diary during the study indicated?				
1.20. Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research?				
1.21. Is the type and source of food given to animals mentioned?				
1.22. Are the arrangements made for feeding and for providing water?				
<b>Humane end points</b>				
1.23. Are the humane end points that would be expected during the study mentioned?				
1.24. Are the steps taken to minimize suffering/euthanising the animals mentioned?				
<b>Experimental end points</b>				
1.25. Is the method/mode of disposal of used animals after research mentioned?				
<b>2. Assessment of Risks/Benefits</b>				
2.1. Are the risks (physical, psychological) to animals during the study mentioned?				
2.2. Are there any benefits to the animals used in the study?				
2.3. Are the researchers qualifications, competence, and experience suitable to ensure safe conduct of the study?				
2.4. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits of the research for animals/humans adequately?				
<b>3. Respect for the dignity of the animals and owners of animals</b>				
3.1. Have the researchers taken adequate measures for the welfare of animals and to reduce suffering of animals during the research?				
<b>Informed consent</b>				
3.2. Is the process for obtaining informed consent of owners appropriate and adequately explained?				
3.3. Do you approve the financial or other incentives/ rewards/ compensation offered for giving consent for the use of their animals?				
3.4. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
3.5. Will the fresh informed consent be obtained if the procedures are changed during the research?				
<b>Confidentiality</b>				
3.6. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
3.7. Is the privacy of the owners safeguarded?				
3.8. Are data/sample storage and disposal procedure in				

relation to ensuring confidentiality and security of personal information adequate?				
<b>Rights of the owners of animals</b>				
3.9. Is the owner's unconditional right to withdraw their animals from the research at any time safeguarded?				
3.10. Is there provision to make the study product if any available to the owners following the research?				
<b>4. Fair selection of animals</b>				
4.1. Has the study population been determined primarily, based on the scientific goals of the study?				
4.2. Is the research conducted on a vulnerable group of animals?				
4.3. Is the research an externally sponsored research?				
4.4. Is the research involves community animals?				
4.5. Is the research a clinical trial?				
<b>5. Responsibilities of the researcher</b>				
5.1. Is the veterinary care to be provided to animals during and after the research adequate?				
5.2. What are the provisions for continuation of care after the research is over?				
5.3. Has the researcher followed any applicable legal regulations or other guidelines?				
5.4. Has the researcher obtained permission from the relevant authorities?				
5.5. Are there any conflicts of interest including payments and other rewards				
5.6. Are there any ethical / legal/ social/ financial issues in the study?				
<b>6. Vulnerable groups (stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.)</b>				
6.1. Is the use of vulnerable group instead of the general animal population of the same species, justified?				
6.2. Is the procedure for obtaining consent of the owners of the vulnerable group of animals adequate?				
<b>7. Externally sponsored research</b>				
7.1. Is there a local collaborator?				
7.2. Has the research project been approved by a ERC in the sponsoring country?				
7.3. Is the research relevant to Sri Lanka?				
7.4. Is the justification for post research benefits to Sri Lanka such as capacity building etc adequate?				
7.5. Are relevant local laws/ regulations/ guidelines of each country adhered to?				
7.6. If the data or biological samples to be transferred overseas are there adequate provision to safeguard the				

interests of the owner's of animals and protects intellectual property rights?				
7.7. How will the results of research be conveyed to relevant authorities in Sri Lanka?				
<b>8. Community animals based research</b>				
8.1. Is the impact and relevance of the research on the community animals in which it is to be carried out acceptable?				
8.2. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the animals of the same species?				
8.3. Will there any contribution of the research towards improvement of health/welfare of concerned community group of animals?				
8.4. Are the results of the research being made available to the relevant authorities to do necessary improvements of health/welfare of concerned community group of animals?				
<b>9. Clinical trials</b>				
9.1. If it is a multicentre trial, are all centres following the same protocol?				
9.2. Is the clinical trial registered with a clinical trial registry?				
9.3. Have adequate animal toxicity and teratogenicity trials been carried out?				
9.4. Is there a sufficient justification for using a control arm?				
9.5. Does the control group receive the standard therapy?				
9.6. Are all animals treated equally?				
9.7. Is the procedure for dealing with adverse events adequate?				
9.8. Is the procedure for reporting adverse events adequate?				
9.9. Are the criteria for termination of the trial detailed?				
9.10. Is there provision for insurance of the animals used in the trial?				

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**Final Assessment:**

	Pass	Concerns
Collaborative partnership	<input type="checkbox"/>	
Scientific value	<input type="checkbox"/>	
Scientific Validity	<input type="checkbox"/>	
Fair Selection of animals	<input type="checkbox"/>	
Favourable Risk / Benefit ratio	<input type="checkbox"/>	
Informed Consent of owners	<input type="checkbox"/>	
Respect for animals enrolled for the study	<input type="checkbox"/>	

*Additional Comments:*

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*Recommendation: Approve*  *Reject*

*Conditional Approval (Please state the conditions)*

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*Name of the Reviewer:* .....

*Signature:* .....

*Date:* .....