

**ETHICAL GUIDELINES
FOR THE
CARE AND USE OF ANIMALS
IN HEALTH RESEARCH
IN NEPAL**

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FOREWORD

Nepal Health Research Council (NHRC), an apical body in health research in Nepal was established in 1991 with the objective of "promoting scientific study and quality health research in Nepal". We all know that animal experimentation was the foremost step before initiating the human experimentation; therefore, use of animals in the human health research plays a vital role in the enhancement of scientific knowledge and basic research. Keeping this made us to realize to develop the ethical guideline for the care and use of animals in health research in Nepal. The proposed guideline has to ensure that the research conducted in animals should be rational and follow international norms and standards.

Since NHRC act 1991 and byelaws has entitled the council to publish and disseminate such type of guideline to make health research more scientific and justifiable. Accordingly in the present context of Nepal, the use of animals in health research is becoming an essential component of research, therefore meticulous care and scientific use of animal in health research is the demand of time. NHRC has taken special initiative and exhaustive effort involving experts from different disciplines at several occasions and workshops to formulate this guideline in proper shape and order.

The major objective of the ethical guideline is to provide proper moral directives for the researcher and institutions involved in the use of animals in health research. NHRC wishes to ensure the good care of all animals used in health research on the basis of international norms and values. This ethical guideline will help in motivating and facilitating the researchers and the institutions in the area of the use of animals in health research.

I am especially thankful to Task Force Committee members - Mr. Bhupendra Bahadur Thapa, Dr. Rebati Man Shrestha, Mr. Kailash Prasad Subedi, Mr. Suman Ghimire, Dr. Bhoj Raj Joshi, Mr. Rishi Raj Bhandari and Dr. Shanker Pratap Singh for their tremendous effort and special initiation in the preparation of this ethical guideline. I wish to express my sincere thanks to Dr. Anil Kumar Mishra, Fr. Joesph L. Thaler, Mr. Dhan Prasad Sharma Poudel, Dr. Rajendra Kumar BC, Ms. Pearl Banmali, for their outstanding contribution in making this guideline in good shape. I would like to thank Fr. Jim Donnelly *for* proof reading the guideline and all the editors including the participants of the consultative meeting. .

It is our sincere hope that the present guideline will serve as a useful document for all the researchers and the institutions involved in use of animals in health research.

Dr. Sachey Kumar Pahari
Chairman
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PREFACE

Use of animals is an important aspect of health research, which is the tool for acquiring knowledge for the benefit of suffering people as well as maintaining good health. Large number of animals is being used for health research, and these animals have the feeling of pain and suffering as human being. So, unnecessary exposure to pain and improper handling of the experimental animals should be avoided.

It is human to treat the animals in humanly manner. Official pharmacopoeia prescribes the same quality of medicine to animals as for humans. This shows that we should treat animals in the similar manner as we treat human beings.

The use of animals for research in medicine is decreasing and effort is being made to replace animal experiment by other laboratory experiments. However it is not possible in all instances so we have to use animals. When it is extremely necessary to use animals, there should be a general guideline to treat them in proper manner. Care should be taken to subject the animals to as less pain as possible and if killing is necessary it should be done subjecting to less pain.

Research using animal is a wide field, and it is not possible to cover all aspects of animal use for experiment in one guideline. Nepal Health Research Council is established for improving public health by means of appropriate health research activities. The council issues guidelines in various areas to conduct research in proper manner. This "Ethical Guidelines for the Use of Animals in Health Research in Nepal" is targeted for the areas of public health and academic institutions where animals are used. There are other organizations using animals for other purposes. For them too, this guideline is useful, and it can serve as reference document.

This guideline clearly specifies the conditions when the animals can be used for research, what are the conditions to be observed and what are the technical requirements for such experiment. However, it does not try to give details of process involved, because it varies from experiment to experiment and institute to institute. Such guidelines have to be prepared by the institute for their own use.

The guideline is also focused on the use of animals in the teaching institutions. Though used in less number, many institutes use animals for the academic purposes. In such cases there is no formal approval of the research project, but the care, of the animal should be as per the guidelines. In many instances, we may use the, wild animals. Their use should not disturb the wild population, their habitat should not adversely affect the human population.

We hope that this guideline will be very helpful for the research community. I

The Executive Board of the Council is the main body to administer the provision of NHRC Act. The council may constitute other subcommittees for supporting and administering its responsibilities. So, there is Ethical Review Board for the Care and Use

of Animals (ERBA) to recommend, research proposals where the use of animal is required and monitor during research.

'This guideline is the first one of its kind in Nepal. We believe that it will be useful for the proper use of animals as well as for the development of the internal working procedures for the research organizations/institutes. It will also be useful for the use of appropriate animal, which will help in producing reliable results. We expect the best use of this guideline from the health researchers and academic community. Any suggestions for the improvement of this document are most welcome.

Mr. BhiIpendraBahadur Thapa, Director, DDA
Dr. Shanker Prasap Singh, Member-Secretary, NHRC

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SECTION A

Ethical Guidelines for the Care and Use of Animals in Health Research in Nepal

Introduction

An Act of Parliament created the Nepal Health Research Council (NHRC) in 1991 with the specific purpose of “promoting scientific study and quality health research in Nepal”. NHRC shares and expresses a deep concern for the welfare and the humane treatment of animals in health research and educational instruction. It has long been established that animals play a significant role in advancing health science. Animal experimentation has provided knowledge on the understanding of human beings and has provided models for training and other scientific knowledge.

NHRC recognizes that animal research is essential to the further development of scientific knowledge; while at the same time it realizes that ethical guidelines are necessary for the care and use of animals in human health research to indicate what qualifications and required knowledge the researcher must have while at the same time address what should be done to the animals before, during and after the research period. NHRC obliges all those involved in the use of animals in health research to ensure that the research conducted is rational, unavoidable and that no unnecessary pain or injury is inflicted on the research animals and that the best possible environment is maintained.

NHRC wishes to secure the good care of all animals used in human health research. These ethical guidelines are formulated to motivate and facilitate researchers and institutions/organizations in the area of the use of animal in health research in Nepal and to encourage all researchers to exercise humane care and treatment to animals during any research.

Proper care, use and humane treatment of animals used in health research, testing and education require scientific and professional judgment based on knowledge of the needs of the animals and the special requirements of the research, testing, and educational programs.

These guidelines are established as per the Nepal Health Research Council Act, 1991, Section 10. Therefore Nepal Health Research Council has framed the following ethical guidelines for the care and use of animals in health research in Nepal.

Objectives of the Ethical Guidelines

1. To provide guidelines and to emphasize the responsibilities of persons and institutions involved in health research involving animals.
2. To ensure that the use of animals in health research is justified and humane.

3. To ensure that the welfare of animals is always considered.
4. To ensure care, housing, anti-cruelty and maintenance of research animals.
5. To provide guidelines for the necessary steps to be taken to assure physical comfort, to avoid pain or distress and to assure the good health of all research animals.
6. To provide guidelines for the accepted sources of animal acquisition.
7. To minimize the number of animals used in health research.
8. To assure the appropriate species, quality, and number of animals in health research.
9. To promote the development and use of techniques. which replace animals for research.
10. To ensure that all those involved in the use of animals in health research be appropriately qualified, act humanely and be protected.
11. To minimize the discomfort, distress, and pain in connection with sound research.
12. To ensure the appropriate use of sedation, analgesia, anesthesia and euthanasia.
13. To provide guidelines for the ethical use of animals in educational settings.
14. To provide a list of HMG Rules and Regulations that applies to the use of animals in health research. To ensure animal welfare as per the rules and regulations of HMG.

1. The Scientist/Researcher/Investigator

- 1.1 The *researcher should be qualified* to undertake the research involving animals. He/she must be able to make informed decisions and is able to give reasoned arguments for the values and appropriateness of the objectives of the research involving animals.
- 1.2 Prior to undertaking the research, the *researcher has a responsibility* to be sufficiently knowledgeable to comply with all ethical guidelines.
- 1.3 The *researcher should ensure* that all personnel involved in the research using animals are familiar with these guidelines.
- 1.4 Animal use procedures *must conform to* HMG regulations regarding personnel, supervision, record keeping, and veterinary care.
- 1.5 The *researcher should have knowledge* about the behavioral characteristics of the animal subjects so as to be aware of normal, species-specific behaviors and unusual behaviors that could forewarn the researcher of potential health problems.

- 1.6 The *researcher should ensure that all individuals who use animals* under his/her supervision receive explicit instruction in experimental methods and in the care, maintenance, and handling of the species being studied. Responsibilities and activities of all individuals dealing with animals should be consistent with their respective competencies, training and experience in either the laboratory or the field setting.
- 1.7 The researcher should be *familiar with the current literature* and the current status of matters relevant to the research.
- 1.8 The researcher should be *aware of potential risks* to the animals, society, environment and the researcher.
- 1.9 If a researcher has *doubts about the depth of his/her knowledge* in research that involves severe pain, stress or privation he/she is obligated to consult with informed colleagues and/or the ERB of NHRC and seek their advice.
- 1.10 The researcher *should ensure that all individuals* under his/her supervision have the training and competence needed to carry out their responsibilities required for the research.

2. Animal Facility-Research Staff

- 2.1 *Personnel at risk* should be provided with clearly defined procedures for conducting their duties and should understand the hazards involved in animal research and should be proficient in implementing the required safeguards.
- 2.2 *Personnel should be trained* regarding zoonoses, chemical safety, microbiologic and physical hazards (including those related to radiation and allergies), unusual conditions or agents that might be part of experimental procedures (including the use of genetically engineered animals and the use of human tissue in immuno-compromised animals), handling of waste materials, personal hygiene and other considerations (e.g. precautions to be taken during personnel pregnancy, illness or decreased immuno-competence) as appropriate to the risk imposed by their workplace.
- 2.3 It is recognized that the *animal facility-research staff* is a critical component in the animal research management system.
- 2.4 The staff must be provided with *all required protective clothing* (masks, aprons, gloves, boots etc. as required).
- 2.5 *Facilities should be provided* such as lockers, washbasins and toilets, as required to maintain personal hygiene.
- 2.6 *Regular medical check-ups* should be provided for all staff. The staff should have all required vaccinations. Development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational-health physicians and nurses. Confidentiality and other medical and legal factors must be considered in the context of appropriate regulations.

- 2.7 *A health-history evaluation* before work assignment is advisable to assess potential risks for individual employees. Periodic medical evaluations are advisable for people in some risk categories. An appropriate immunization schedule should be adopted.
- 2.8 Clear procedures should be established for *reporting all accidents*, bites, scratches and allergic reactions. Nonhuman-primate diseases that are transmissible to humans can be serious hazards. Animal technicians, clinicians, investigators, predoctoral and postdoctoral trainees, research technicians, consultants, maintenance workers, security personnel, and others who have contact with nonhuman primates or have duties in nonhuman-primate housing areas should be routinely screened for diseases.
- 2.9 *Necessary training of the staff* should take place by a registered veterinarian at all levels that include handling techniques, cleaning of the facility, animal and personal hygiene, disinfection and sterilization. They should also be familiar with the normal activities of healthy and sick animals.
- 2.10 *Appropriate arrangements* should be made to decontaminate clothing exposed to potential hazards. Disposable gloves, masks, head covers, coats, coveralls and shoe covers might be desirable in some circumstances. Personnel should wash their hands and change clothing as often as necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility. Personnel should not be permitted to eat, drink, use tobacco products, or apply cosmetics in animal rooms.
- 2.11 Washing and showering facilities appropriate to the program should be available. Facilities, equipment, and procedures should also be designed, selected, and developed to provide for ergonomically sound operations that reduce the potential of physical injury to personnel (such as might be caused by the lifting of heavy equipment or animals and the use of repetitive movements). Safety equipment should be properly maintained and routinely calibrated.
- 2.12 Special safety equipment should be used in combination with appropriate management and safety practices. As a general rule, safety depends on trained personnel who rigorously follow safe practices. Institutions should have written policies governing experimentation with hazardous biologic, chemical, and physical agents.

3. Researcher's Responsibilities/Duties to the Animals

- 3.1 The researcher has the ultimate responsibility for all matters related to the welfare of the research animals. The researcher is responsible for the care of the animal. The researcher should make sure that he/she continually consults with an experienced veterinarian and care givers that include other veterinarians, livestock and wildlife specialists. Researchers should submit written proposals to the ERB that demonstrates an understanding of the ERB ethical guidelines and demonstrates that the research will comply with the ethical guidelines and

relevant HMG legislation. No animal should be used in human health research until written ethical approval is obtained.

- 3.2 The *researcher should either be qualified* or receive the assistance of a registered veterinarian for the care of animals to ensure the comfort, health and humane treatment of animals involved in health research are given appropriate consideration and care.
- 3.3 The *researcher accepts stewardship* for animals used in health research and respects their welfare.
- 3.4 The researcher demonstrates that *the research is justifiable* and based on documentation of literature reviews, prior observations, approved studies and when applicable, laboratory and animal studies.
- 3.5 In the use of animals, *the researcher will follow the ethical and regulatory guidelines* established at the institutional level by professional associations and by governmental authorities.
- 3.6 The researcher *will utilize, when appropriate*, inanimate materials and processes instead of animals.
- 3.7 If the use of an *animal species is scientifically necessary*, a lower animal species could be used without compromising the integrity of the research.
- 3.8 When *designing the research protocol*, the number of animals used should reflect the minimum necessary to yield valid answers to the research hypothesis.
- 3.9 The researcher will *take active measures* to use procedures that minimize both the incidence and severity of the pain and suffering experienced by animals.
- 3.10 In *non-survival research or surgery*, do not allow the animal to regain consciousness or experience any pain prior to euthanasia.
- 3.11 In *non-survival research or surgery* use a species-appropriate and effective method of euthanasia.
- 3.12 Procedures *subjecting animals to pain, stress, privation or death* should be used only when an acceptable alternative procedure is unavailable. Always the researcher must consider ways to minimize the trauma to the animal. At the same time the researcher has an ethical obligation to consider whether the research objectives could be met using broad alternatives not involving pain or discomfort.
- 3.13 Researchers should examine methodological and procedural techniques for the *purpose of minimizing discomfort, illness and pain to the animals*.

4. Justification for the Research

- 4.1 Research should be undertaken with *reasonable expectations and with a clear scientific purpose*. There should be due consideration for human and animal

health and the advancement of knowledge. There should be a reasonable expectation that the research will:

- 4.1.a *Increase knowledge* of the processes underlying the evolution, development, maintenance, structure, alteration, control or biological significance underlying behavior; or
 - 4.1.b Obtain/establish significant information relevant to the understanding of humans/animals, or
 - 4.1.c Determine the *replicability* of prior research; or
 - 4.1.d Increase *understanding of the species* under study; or
 - 4.1.e Provide *results that benefit* the health or welfare of humans or animals.
- 4.2 The scientific purpose of the research should be of *sufficient potential significance* to justify the use of animals. The researchers should act on the assumption that procedures that would produce pain in humans will also do so in animals.
- 4.3 The research must be scientifically valid and must use only the minimum number of animals necessary.
- 4.4 The *species chosen for study should be best suited* to answer the question(s) posed, taking into account their biological characteristics, including behavior, genetic constitution and nutritional, microbiological and general health status. The animals should be of appropriate species and quality and the minimum number used to obtain valid results. The researcher should always consider the possibility of using other species, non-animal alternatives or procedures that minimize the number of animals in research and should be familiar with the appropriate literature.
- 4.5 It is assured that the researchers and other personnel will *treat the animals with kindness* and will take proper care to avoid or minimize discomfort, distress and pain.
- 4.6 Procedures that may cause *more than momentary pain* or distress will be performed with appropriate sedation, analgesia or anesthesia in accordance with standard veterinary practice.
- 4.7 The research must be *designed to avoid pain or distress* to animals. If this is not possible, pain or distress must be minimized. An animal that develops signs of pain or distress not predicted in the proposal must have the pain or distress alleviated promptly. If severe pain cannot be alleviated promptly, the animal must be killed humanely. Alleviation of such pain or distress must take precedence over finishing a research.
- 4.8 *Pain management* appropriate to the species, the circumstances and the procedure must be provided.
- 4.9 The *best possible living conditions* will be provided to the animals used during the research. Qualified veterinarians will be consulted to advise and monitor this

situation. Animals must be transported, housed, fed, watered, handled and used under conditions that are appropriate to the care of the species. The overall welfare of the animals must be the primary consideration of the researcher.

- 4.10 *The researcher should monitor the research* and the animals' welfare throughout the course of an investigation to ensure continued justification for the research. The researcher has an obligation to treat all animals with respect and consider their welfare as an essential factor when planning and conducting the research.
- 4.11 The researcher and other animal handlers are *appropriately qualified* and have sufficient experience for conducting health research involving animals.
- 4.12 Ethical Review Board for Animals has approved the animal research proposal.

5. Care and Housing Facilities of Animals

- 5.1 *Proper housing and management* of animal facilities are essential to animals' well being, to the quality of research data and teaching or testing programs in which animals are used, and to the health and safety of personnel.
 - 5.1.a *A good management program* provides the environment, housing, and care that permit animals to grow, mature, reproduce and maintain good health, provides for their well being and minimizes variations that can affect research results. Specific operating practices depend on many factors that are peculiar to individual institutions and situations.
 - 5.1.b *The environment* in which animals are maintained should be appropriate to the species, its life history and its intended use. Animals should be housed with a goal of maximizing species-specific behaviors and minimizing stress-induced behaviors.
 - 5.1.c Many *factors should be considered in planning* for adequate and appropriate physical and social environment, housing, space and management. These include:
 - 5.1.c1 The species, strain, and breed of the animal and individual characteristics, such as sex, age, size, behavior, experiences, and health.
 - 5.1.c2 The ability of the animals to form social groups with similar species through sight, smells and possibly contact, whether the animals are maintained singly or in groups.
 - 5.1.c3 The design and construction of housing.
 - 5.1.c4 The availability or suitability of enrichments.
 - 5.1.c5 The project goals and experimental design (e.g., production, breeding, research, testing and teaching). The intensity of animal manipulation and invasiveness of the procedures conducted. The

presence of hazardous or disease-causing materials. The duration of the holding period.

5.1.c.6 Good animal management and human requirements and health protection often require separation of animal facilities from personnel areas, such as offices and conference rooms.

5.2 Laboratory animals are very sensitive to their living condition. Procedures *appropriate for a particular care and housing of animal species* may be inappropriate for others. Therefore specific guidelines are stipulated *regarding the care and housing of experimental animals*. The cage, pen or stall normally provides the limits of an animal's immediate environment.

Allowances should be made for the following:

- 5.2.a For normal *physiologic and behavioral* needs of the animals, including urination and defecation, maintenance of body temperature, normal movement and postural adjustments and where indicated, reproduction.
- 5.2.b For *specific social interaction* and development of hierarchies within or between enclosures. Consideration should be given to an animal's social needs. The social environment usually involves physical contact and communication among members of the same species although it can include non-contact communication among individuals through visual, auditory, and olfactory signals. Appropriate social interactions among similar species are essential for normal development in many species.
- 5.2.c For the animals to remain *clean and dry* (as consistent with the requirements of the species). Provisions should be made for sanitizing cages and equipment. Cage-washing equipment should be selected to match the types of cages and equipment used.
- 5.2.d For adequate ventilation and *proper management of noise* within the animal facility. Noise control should be considered in facility design and operation. Assessment of the potential effects of noise on an animal warrants consideration of the intensity, frequency, rapidity of onset, duration, and vibration potential of the sound and the hearing range, noise-exposure history, and sound-effect susceptibility of the species, stock, or strain. It should be noted that many species could hear frequencies of sound that are inaudible to humans. Because *changes in patterns of sound exposure* have different effects on different animals personnel should try to minimize the production of unnecessary noise. *Excessive and intermittent noise* can be minimized by training personnel in alternatives to practices that produce noise and by the use of cushioned casters and bumpers on carts, trucks and racks. Radios, alarms, and other sound generators should not be used in animal rooms unless they are parts of an approved protocol or an enrichment program.
- 5.2.e For the animals to access *food and water* and permit easy filling, refilling, changing, servicing and cleaning of food and water utensils.

Animals should be fed *palatable, non-contaminated and nutritionally adequate food* daily or according to their particular requirements unless the protocol in which they are being used requires otherwise.

- 5.2.e.1 *Managers* should be judicious in purchasing, transporting, storing, and handling food to minimize the introduction of diseases, parasites, potential disease vectors (e.g., insects and other vermin) and chemical contaminants into animal colonies.
- 5.2.e.2 *Purchasers* are encouraged to consider manufacturers' and suppliers' procedures and practices for protecting and ensuring diet quality (e.g., storage, vermin-control and handling procedures). Institutions should urge feed vendors to provide data from feed analysis for critical nutrients periodically. The user should know the date of manufacture and other factors that affect shelf life of food. Stale food or food transported and stored inappropriately can become deficient in nutrients. Careful attention should be paid to quantities received in each shipment and stock should be rotated so that the oldest food is used first.
- 5.2.e.3 Areas in which diets and diet ingredients are processed or stored should be kept clean and enclosed to prevent entry of pests.
- 5.2.e.4 *Contaminants in food* can have dramatic effects on biochemical and physiologic processes, even if the contaminants are present in concentrations too low to cause clinical signs of toxicity.
- 5.2.e.5 *Feeders* should be designed and placed to allow easy access to food and to minimize contamination with urine and feces.
- 5.2.e.6 There should be enough space and enough feeding points to *minimize competition for food* and ensure access to food for all animals.
- 5.2.e.7 *Food-storage* containers should be cleaned and sanitized regularly.
- 5.2.e.8 Animals should have access to *potable, uncontaminated drinking water* according to their particular requirements. Watering devices should be checked daily to ensure their proper maintenance, cleanliness and operation.
- 5.2.f *To secure an environment* that does not allow escape of or accidental entrapment of animals or their appendages between opposing surfaces or by structural openings.
- 5.2.g *To provide an environment* that is free of sharp edges or projections that could cause injury to the animals.

- 5.2.h *To provide observation* of the animals with minimal disturbance of the animal.
- 5.3 *Those familiar with the animal species* should be best qualify professionally to judge the appropriate measures necessary to maintain or improve the care and housing of the research animals. Issues related to space management should be considered that include:
- 5.3.a Animal housing, care, and sanitation.
 - 5.3.b Reception space, quarantine, and separation of animals.
 - 5.3.c Separation of species or isolation of individual projects when necessary.
 - 5.3.d Specialized laboratories or such activities as surgery, intensive care, necropsy, radiograph and preparation of special diets, experimental procedures, clinical treatment and diagnostic laboratory procedures.
 - 5.3.e Containment facilities for hazardous biologic or chemical agents.
 - 5.3.f Storage areas for food, bedding, pharmaceuticals, biologics and supplies.
 - 5.3.g Space for storing, washing and sterilizing all facility equipment and supplies.
 - 5.3.h Space for storing wastes/carcasses before removal.
 - 5.3.i Space for the training and education of staff as well as space for administrative and supervisory personnel.
 - 5.3.j Storage lockers, toilets, showers, sinks and break areas for personnel.
 - 5.3.k Security features appropriate for the facility.
- 5.4 *Qualified personnel should be consulted* for the proper animal care, reproduction and management policy for the care and housing of animals and their advice taken seriously while considering are search proposal involving animals.
- 5.5 *The building for housing* the experimental animal should be provided with measures to control any contamination in the building through human, material, rodents and wild animals.
- 5.6 *Visitors and working staff* should be allowed access to the animal area when necessary and under supervision.
- 5.7 *The facilities/ housing for animals are required* to be inspected twice a year by the Ethical Review Board (Committee).
- 5.8 *All procedures carried out on animals* are to be reviewed to ensure that the procedures are appropriate and humane.
- 5.9 *Animals are to be provided with humane care and healthy living conditions* during their stay in the facility. Researchers are encouraged to consider

enriching the environment of their laboratory animals and should keep abreast of literature on the well being and the enrichment for the animal species with which they work. Animals should have opportunities to exhibit species-typical activity patterns.

- 5.10 Animals used in health research should be *housed in a separate location away from public housing*. The animals will not be exposed to dust, smoke, noise, rodents, insects and birds.
- 5.11 The *cages for the animals* will be made of suitable material and should be a suitable size and should have adequate feeding, watering and movement arrangements. The cage should be made in such a manner as to avoid any injury to the animals. The bedding should be appropriate for the animal. *Animal bedding* is a controllable environmental factor that can influence experimental data and animal well-being. The veterinarian with investigators should select the most appropriate bedding material.
- 5.12 There shall be an *adequate environmental* setting for the animals including proper sanitation, temperature, light, humidity, sound and ventilation.
- 5.13 The entire *housing environment* for the animals should be monitored to check and record any infection in the facility. The staff should have a regular medical check up, and post-mortem of all dead animals is essential.
- 5.14 *Adequate veterinary care* must be provided, including access to all animals for evaluation of their health and well-being.
- 5.15 At times, *special facilities and safety equipment* are required to protect the animal-care and investigative staff, other occupants of the facility, the public, animals and the environment from exposure to hazardous biologic, chemical and physical agents used in animal experimentation. Facilities used for animal experimentation with hazardous agents should be separated from other animal housing and support areas, research and clinical laboratories and patient-care facilities and should be appropriately identified and access to them should be limited to authorized personnel. Such facilities should be designed and constructed to facilitate cleaning and maintenance and to avoid the risk of contamination to the environment.
- 5.16 *Sheltered or outdoor housing* such as barns, corrals, pastures and islands is a common primary housing method for some species. This housing must provide protection from extremes in temperature or other harsh weather conditions and must have adequate protective and escape mechanisms for submissive animals. Facilities should include windbreaks, shelters, shaded areas, areas with forced ventilation, heat-radiating structures or means of retreat to conditioned spaces, such as an indoor portion of a run. Shelters should have sufficient ventilation and be designed to prevent buildup of waste materials and excessive moisture. Construction materials should allow easy cleaning or replacement. Floors or ground-level surfaces of outdoor housing facilities can be covered with dirt,

absorbent bedding, sand, gravel, grass or similar material that can be removed or replaced.

- 5.17 Excessive buildup of *animal waste and stagnant water* should be avoided by, for example, using contoured or drained surfaces. Conventional, biologic and hazardous waste should be removed and disposed of regularly and safely. On-site incineration should comply with all HMG/local regulations. Adequate numbers of properly labeled waste receptacles should be strategically placed throughout the facility.
- 5.18 *An appropriate living environment* for all species of animals should be maintained.
- 5.19 Qualified personnel should care for animals every day, including *weekends and holidays*, both to safeguard their well-being and to satisfy research requirements. Emergency veterinary care should be available after work hours, on weekends, and on holidays. In the event of an emergency, the appropriate people should be able to be reached who are responsible for the animals. This can be facilitated by prominently posting emergency procedures, names or telephone numbers in animal facilities. Emergency procedures for handling special facilities or operations should be prominently posted. A disaster plan should be developed by the animal facility that takes into account both personnel and animals.
- 5.20 All *animals should be observed* for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs. As a rule, this should occur daily, but more-frequent observations might be warranted.
- 5.21 It is imperative that appropriate methods be in place for *disease surveillance and diagnosis*. Unexpected deaths and signs of illness, distress or other deviations in any animal should be reported promptly to ensure appropriate and timely delivery of veterinary medical care.
- 5.22 Animals that show signs of a *contagious disease* should be isolated from healthy animals in the colony.

6. Arrangements for Nutritious Feed for Animals

- 6.1 Every species of animal in research should be provided with *aproper/balanced feed*. A balanced diet should include proteins, carbohydrates, fats, minerals, vitamins, salt and water. A qualified person should recommend the diet.
- 6.2 Researchers should be *aware of the eating habit/behavior* of each animal used in the research.
- 6.3 While providing *a balanced feed* to the normal animals it should not be given food that could include medicines, drugs, hormone or antibiotic. Diet should be given according to a timetable and promote low cholesterol.

- 6.4 The feed used for the animals from production farms should be *quality feed*, and mention should be made of the manufacture date, chemical composition and date of expiration.
- 6.5 Only quality ingredients should be used in the animal feed that should be free from dust, moulds, fungi, mico-toxin and other contaminated material. Animal feed should be stored and handled carefully so as to avoid any contamination.
- 6.6 Each animal must get required quantity of feed, based on animal maintenance and production requirements.
- 6.7 Clean water should be made available to all animals at all times.

7. Acquisition of Animals

- 7.1 *Potential vendors* should be evaluated for the quality of animals to be supplied by them. A *registered veterinarian* should properly evaluate animals to be used in research.
 - 7.1.a *All animals must be acquired lawfully* and the receiving institution should make reasonable attempts to ensure that all transactions involving animal procurement are conducted in a lawful manner.
 - 7.1.b The *genetic and health status of the animals* should be available. Such animals can only provide reliable results. If the animal is to be imported, the importers must take prior permission from the Department of National Parks and Wildlife Conservation and the Department of Livestock Services (under Animal Health and Livestock Service Act 2055 (1999 AD) and rules 2057 (2001 AD)).
- 7.2 Animals not bred in a research facility are to be *acquired lawfully as per the prevailing laws*. A health certificate should be obtained from a registered veterinarian.
- 7.3 Researchers should make every effort to ensure that those responsible for *transporting the animals* to the facility provide adequate food, water, ventilation, space and impose no unnecessary stress on the animals.
- 7.4 *Wild animals for experimentation* shall be acquired as National Parks and Wildlife Conservation Act 2029 (1977AD) and the Wildlife Farming, Breeding and Research Policy 2059 (2002 AD), Convention on International Trade in Endangered Species of Wild Flora & Fauna (CITES), Animal Health and Livestock Service Act 2055 (1999 AD) and rules 2057 (2001 AD). (Quarantine)
- 7.5 *Endangered/threatened animal species* should only be used subject to national/international laws and permits and ethical concerns.

8. Transportation of Animals

- 8.1 The transportation of the animal from one facility/place to another is extremely important and must be taken with the utmost care. *A health certificate* for the animal should be obtained at the point of transportation origin and destination.
- 8.2 *Considering the animal*, the distance and seasonal/climatic conditions, the species of the animal and other relevant factors, attention must be given to: the mode of transportation, the container used, the number of animals in a cage, food/water during transit, protection during transit to avoid injury and stress.
- 8.3 *All transportation of animals* should be planned to minimize transit time and the risk of zoonoses, protect against environmental extremes, avoid overcrowding, provide food and water when indicated and protect against physical trauma. Some transportation-related stress is inevitable, but it can be minimized by attention to certain factors.
- 8.4 Each *shipment of animals should be inspected* for compliance with procurement specifications and signs of clinical disease and should be quarantined and stabilized according to procedures appropriate for the species and the circumstances.
- 8.5 *Coordination of ordering and receiving* with animal-care personnel is important to ensure that animals are received properly and that appropriate facilities are available for housing.
- 8.6 *Newly received animals* should be given a period for physiologic, psychological, and nutritional stabilization before their use. The length of time for stabilization will depend on the type and duration of animal transportation, the species involved, and the intended use of the animals.

9. Research Procedures

- 9.1 *Human consideration for the well-being of the animal* should be incorporated into the research design and conduct of all procedures involving animals, while keeping in mind the primary goal of experimental procedures - the acquisition of sound and replicable data.
- 9.2 *Animals must not be used in more than one study* either in the same or different projects, without the approval of the Ethical Review Board (Committee) If an animal is to be used in more than one study the Ethical Review Board (Committee) must be satisfied that:
 - 9.2.a None of the procedures cause the animal pain or distress.
 - 9.2.b The second and subsequent studies produce little or no pain or biological stress and that the animals have recovered fully from the first study before further procedures are carried out.
- 9.3 Behavioral studies that involve *no aversive stimulation* to, or overt sign of distress from, the animal are acceptable. These include observational and other non-invasive forms of data collection.

- 9.4 *Investigators engaged in research on pain* in animals should consider the following guidelines aimed at minimizing pain in the animals and when submitting a manuscript, state explicitly that they have been followed. The following guidelines are concerned with the importance of the investigation, the severity and the duration of the pain.
- 9.4.a It is essential that *competent personnel review* the intended experiments on pain in conscious animals beforehand. The investigator should be aware of the ethical need for the continuing justification of his investigations.
 - 9.4.b If possible the investigator should *try the pain stimulus on him/herself*; this principle applies for most non-invasive stimuli causing acute pain.
 - 9.4.c To make possible the evaluation of the levels of pain, the investigator should give *a careful assessment of the animal's deviation* from normal behavior. The outcome should be recorded in the final report.
 - 9.4.d In *research of acute or chronic pain in animals* measure should be taken to provide a reasonable assurance that the animals are exposed to the minimum of pain necessary for the purpose of the experiment.
 - 9.4.e An *animal presumably experiencing chronic pain* should be treated for relief or pain. The pain relief should not interfere with the aim of the investigation.
 - 9.4.f *Studies of pain in animals paralyzed* with a neuromuscular blocking agent should not be performed without a general anesthetic or an appropriate surgical procedure that eliminates sensory awareness.
 - 9.4.g The *duration of the research experiment must* be as short as possible and the number of animals involved kept to a minimum.
 - 9.4.h When *alternative behavioral procedures are available*, those that minimize discomfort to the animal should be used. When using aversive conditions, researchers should adjust the parameters of stimulation to levels that appear minimal, though compatible with the goals of the research. Researchers are encouraged to test painful stimuli on themselves, whenever reasonable.
 - 9.4.i Procedures in which the *animal is anesthetized and insensitive* to pain throughout the procedure and is euthanized before regaining consciousness are generally acceptable.
 - 9.4.j *Procedures involving more than momentary or slight aversive stimulation*, which is not relieved by medication or other acceptable methods, should be undertaken only when the objectives of the research cannot be achieved by other methods.
 - 9.4.k Experimental procedures that require *prolonged aversive conditions* or produce tissue damage or metabolic disturbances require greater

justification and surveillance. These include prolonged exposure to extreme environmental conditions, experimentally induced prey killing, or infliction of physical trauma or tissue damage. An animal observed to be in a state of severe distress or chronic pain that cannot be alleviated and is not essential to the purposes of the research should be euthanized immediately.

- 9.4.l Procedures that *use restraint must conform* to regulations and guidelines.
- 9.4.m Procedures involving the *use of paralytic agents* without reduction in pain sensation require particular prudence and humane concern. Use of muscle relaxants or paralytics alone during surgery, without general anesthesia, are unacceptable and should be avoided.
- 9.5 *Surgical procedures*, because of the invasive nature, require close supervision and attention to humane considerations.
 - 9.5.a It is important that all persons associated with the surgery have *appropriate training and skills* required for the proposed surgery.
 - 9.5.b Appropriate attention to *pre-surgical planning*, personnel training, aseptic and surgical technique, animal well-being, and animal physiologic status during all phases will enhance the outcome of surgery.
 - 9.5.c *Pre-surgical planning* should include input from all members of the surgical team, including the surgeon, anesthetist, veterinarian, surgical technicians, animal-care staff, and investigator. The surgical plan should identify personnel, their roles and training needs, and equipment and supplies required for the procedures planned the location and nature of the facilities in which the procedures will be conducted; and pre-operative animal-health assessment and post-operative care.
 - 9.5.d *All surgical procedures and anesthetization* should be conducted under the direct supervision of a licensed veterinary surgeon who is competent in the use of the procedures.
 - 9.5.e If the surgical procedure is *likely to cause greater discomfort* than that attending anesthetization, and unless there is specific justification for acting otherwise, animals should be maintained under anesthesia until the procedure is ended.
 - 9.5.f *Sound post-operative monitoring and care*, which may include the use of analgesics and antibiotics, should be provided to minimize discomfort and to prevent infection and other untoward consequences of the procedure.
 - 9.5.g *Animals cannot be subjected to successive surgical procedures* unless these are required by the nature of the research, the nature of the surgery, or for the well-being of the animal. Multiple surgeries on the same animal must receive special approval of the Ethical Review Board for Animals.

- 9.5.h When the use of *an animal is no longer required by an experimental protocol or procedure*, in order to minimize the number of animals used in research, alternative uses of the animals can be considered, which are compatible with the goals of research and the welfare of the animal. Care should be taken that such an action does not expose the animal to multiple surgeries. Necessary ethical approval must be secured from the concerned authorities.
- 9.6 *The return of wild-caught animals to the field* can carry substantial risks, both to the free-ranging animals and to the ecosystem. Animals reared in the laboratory cannot be released. Therefore such animals must be euthanized after the research is completed.
- 9.7 *Anesthesia*: The proper use of anesthetics and analgesics in research animals is an ethical and scientific imperative.
- 9.7.a *Anesthesia should* be used to control pain and distress during research/experimentation. The researcher should ensure that any research considered painful to the animal should be conducted under appropriate anesthesia appropriate to the animal. The anesthesia should be given for the full duration of the research.
- 9.7.b The selection of the *most appropriate anesthetic* should reflect professional judgment as to which one best meets clinical and humane requirements without compromising the scientific aspects of the research protocol.
- 9.8 *Euthanasia* is the act of killing animals by methods that induce rapid unconsciousness and death without pain or distress. Protocols should include criteria for initiating euthanasia. Euthanasia should be carried out in a manner that avoids animal distress.
- 9.8.a If at any stage during the research the researcher feels the research has to be abandoned or irreparable injury has been inflicted, the animal should be *euthanized by an approved method* of euthanasia.
- 9.8.b *Euthanasia should be performed* in a professional and compassionate manner by skilled personnel who are knowledgeable about the species of animal. Death should be confirmed by personnel who can recognize cessation of vital signs in the particular species.
- 9.8.c *When delegating euthanasia responsibilities*, supervisors should be aware of this as a potential problem for some employees or students.
- 9.9 The researcher must ensure that an animal is *clinically dead* before it is sent for disposal.

10. Field Research

- 10.1 *Field research*, because of its potential to damage sensitive ecosystems and ethnologies, *should be subject to the permission* of concerned authorities and local authorities and communities.
- 10.2 Researchers conducting field health research using animals should not *disturb their populations as far as possible*. Every effort should be made to minimize potential harmful effects of the study on the population and on other plant and animal species in the area.
- 10.3 *Research conducted in populated areas* should be conducted with respect for the property and privacy of the inhabitants of the area.
- 10.4 Particular *justification is required* for the study on endangered species.

11. Educational Use of Animals

- 11.1 *Laboratory exercises as well as classroom demonstrations* involving live animals can be valuable as instructional aids. Animals could also be used in science fairs and demonstrations as per animal ethical guidelines for such educational use.
- 11.2 Researchers/educators are encouraged to include instruction and discussion of the *ethics and values of animal research* in all courses that involve or discuss the use of animals.
- 11.3 Animals may be used for *educational purposes only after review* by an ethical committee appropriate to the institution.
- 11.4 Some procedures that can be justified for research purposes may not be justified for educational purposes. Consideration should be given to the *possibility of using non-animal alternatives*.
- 11.5 *Classroom demonstrations* involving animals should only be used when instructional objectives cannot be achieved through the use of videotapes, films or other methods.

12. Student Animal Research Projects

- 12.1 *Student health projects involving pain or distress* in animals should be undertaken judiciously and only when training objectives cannot be achieved in any other way.
- 12.2 *Qualified animal instructors* should always supervise student projects involving animals.
- 12.3 The student instructors must carefully consider and articulate the appropriateness of the research project and its procedures.

13. Termination of a Research

- 13.1 *Research should be terminated* whenever it becomes apparent to the researcher that the continuation of the research will result in injury or suffering to the animal that is incompatible with these guidelines.
- 13.2 The *killing or other disposition* of research animals must be accomplished in a humane manner.
- 13.3 *When euthanasia* appears to be the appropriate alternative, either as a requirement of the research or because it constitutes the most humane form of disposition of an animal at the conclusion of the research, the following guidelines apply:
- 13.3.a *Euthanasia* shall be accomplished *in a humane manner*, appropriate for the species, and in such a way as to ensure immediate death. *A registered veterinarian shall closely monitor the method of euthanasia.*
- 13.3.b *Euthanasia* should be *carried out* quickly and painlessly in an atmosphere free from fear and anxiety.
- 13.3.c There should be *minimum physiological and psychological disturbances.*
- 13.3.d *Euthanasia* should be carried out considering the purpose of the study and with minimal psychological effect on humans involved.
- 13.3.e There should be a *designated location* in an environment free from contamination for euthanasia.
- 13.3.f *The method used* should be proven, accepted, affordable, reliable and safe.
- 13.4 *Disposal of euthanized animals* should be accomplished in a manner that is in accord with all relevant legislation, consistent with health, environmental and aesthetic concerns. No animal shall be discarded until a registered veterinarian verifies its death.

14. Information Provided to the Ethical Review Board for Animal Research (ERBA) by Researchers

- 14.1 *The researcher should provide his/her professional qualifications/CV and stated research experience* as evidenced by research publications.
- 14.2 *Protocol Information* that includes addresses, title of the research, purpose of the research, expected result of the research, justification for and reasons why animals are required in the research, sponsor of the research, results of previous related research, study design, the descriptions of procedures to be performed and the provisions for managing adverse reactions, the institution of affiliation of the principal investigator and the institution(s) where the research is being conducted as well as other data required by the Ethical Review Board.

- 14.3 The ERBA should know if the researcher stands to gain financially in this animal research.
- 14.4 The *researcher must be able to explain* the rationale for both the research problem and its methodology to colleagues, peers, and the Ethical Review Board for Animals.
- 14.5 If necessary the *researcher must be able to defend* the research against the criticism that the suffering inflicted on the animal is necessary in view of the objectives of the research.

15. Record Keeping and Evaluation

- 15.1 It is understood that proper record keeping is extremely important for any animal used in health research. The record forms should be kept simple but complete.
- 15.2 All animals used in health research must be regularly monitored and up-to-date records kept.
- 15.3 Records of breeding and experimentation and deaths of all research animals are essential.
- 15.4 Receipts for feed and other items related to the animals should be kept and maintained.
- 15.5 Records of all the machinery and other implements used in the research should be maintained and monitored.
- 15.6 Monthly and annual reports of activities should be prepared and reviewed for monitoring and evaluation.
- 15.7 Records of all treatment provided to the animals.
- 15.8 Copy of the research protocol.

16. Procedure for Submitting the Proposal for Using Animals in Health Research

- 16.1 All research proposals should be submitted to NHRC/ERBA.
- 16.2 Sufficient information should be placed in the proposal to satisfy the ERB that the use of animals is justified.
- 16.3 Proposals should contain the following:
 - 16.3.a Project Title
 - 16.3.b The names and qualifications of the responsible investigators and all others directly involved.
 - 16.3.c An explanation of how these qualifications and experiences are appropriate to the research and to the animals used.

- 16.3.d A clear explanation of:
 - 16.3.d.1 The scientific or educational aims of the research.
 - 16.3.d.2 The expected benefits of the research.
 - 16.3.d.3 Rationale and purpose of the proposed use of animals.
- 16.3.e Justification of how the project will:
 - 16.3.e.1 Increase our understanding of humans and animals.
 - 16.3.e.2 Maintain or improve human or animal health and welfare
 - 16.3.e.3 Improve animal management or production.
 - 16.3.e.4 Achieve the ecological or educational objectives.
- 16.3.f Clearly *stated reasons as to why animals* are required for the research and, in particular, why techniques, which do not use animals, have been rejected as unsuitable. Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- 16.3.g Details on *what happens to the animals* from the time they are obtained until the time the project is completed. This should include:
 - 16.3.g.1 Experimental and other procedures, including dose and route of any substance administered.
 - 16.3.g.2 Surgical and related procedures, including doses of anesthetic, analgesic and tranquilizing agents and methods of monitoring their adequacy.
 - 16.3.g.3 Conditions of care, handling and housing of animals.
 - 16.3.g.4 Arrangements for the disposal of animals at the completion of the study, including methods of euthanasia if applicable.
- 16.3.h Justification of all aspects of animal use including *handling and housing*, which may impact on the welfare of the animal.
- 16.3.i Methods to *minimize distress/pain/discomfort* must be detailed.
- 16.3.j Details of how the *animals will be monitored* including:
 - 16.3.j.1 Methods and frequency of monitoring.
 - 16.3.j.2 Personnel involved in the monitoring.
 - 16.3.j.3 Details of who will be responsible for the management of emergencies.
- 16.3.k State the *numbers of animals required and provide justification*.

- 16.3.l State the *source of the animals*, the institution's name, and provide permits as required.
- 16.3.m Justification and *details of the procedures*, which may cause pain or distress but in which anesthesia cannot be used.
- 16.3.n The planned *termination* of the animal and justification for this.
- 16.3.o Measures taken to *minimize pain* must be detailed.
- 16.3.p The justification for the use of *any animal used* in a previous research.
- 16.3.q Maximum *time the animals* will be held for the research.
- 16.3.r Note any *health risks* to other animals or staff members. Note the safety of the environment for the working personnel.
- 16.3.s A *signed declaration* by a responsible researcher stating that he/she is currently licensed or authorized to perform research involving animals.
- 16.3.t State the expected *date to begin and to complete* the research.
- 16.3.u Note any other factors/issues, which need ethical consideration for the full review of this submitted proposal.
- 16.3.v Adequacy of *training and experience* of personnel in the procedures used.
- 16.3.w Conduct of *multiple major* operative procedures.
- 16.3.x *Criteria and process* for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- 16.3.y Post-procedure care.
- 16.3.z Method of *euthanasia and disposal* of the animal.

17. Posting of the Animal Guidelines

The NHRC/Executive Board *strongly recommends that a copy of these guidelines* be posted in all animal research facilities. NHRC recommends that all research personnel become acquainted with the ethical guidelines and use them as indicated.

The *ethical guidelines should be posted* in every laboratory, teaching facility and applied setting where animals are being used in research.

SECTION B

The Ethical Review Board for the Care and Use of Animals in Health Research in Nepal

The NHRC Ethical Review Board for Animals (ERBA) is established as per the Nepal Health Research Council Act, 1991, Section 10, Sub Committee may be constituted: The Executive Board (EB) may, as required, constitute Ethical Review Committees for Animals (ERCA) to assist the Executive Board in carrying out its functions. These ERB As must follow the guidelines of NHRC.

Therefore, the Executive Board has constituted the following Committee that shall be called the Ethical Review Board for Animals (ERBA) in Health Research in Nepal.

Composition of the ERBA

The members of the Board will consist of the following:

The Executive Board of Nepal Health Research Council (NHRC) can adjust the composition of the ERBA as required.

1. *Chairperson* : Member, Nepal Health Research Council Executive Board designated by the Executive Board of NHRC.
2. *Member* : Representative, Royal Drug Research Laboratory
Department of Drug Administration, Ministry of Health.
3. *Member* : Representative designated by the Executive Board
of Nepal Veterinary Council.
4. *Member* : Representative, Directorate of Animal Health, Department of Livestock Service, (DLS).
5. *Member* : Representative of Animal Welfare Organization
nominated by the Executive Board of NHRC.
6. *Member* : Representative, Department of National Park and Wild Life
Conservation.
7. *Member* : Representative of Animal Health Research Division,
Nepal Agricultural Research Council (NARC).
8. *Member* : Focal Point Representative, Ministry of Health.
9. *Member* : Representative, Ministry of Home.
10. *Member* : Representative, Ministry of Law, Justice and
Parliamentary Affairs.
11. *Member* : Representative, Nepal Medical Council.

12. *Member* : Expert nominated by the Nepal Health Research Council.

13. *Member -Secretary* : Member Secretary of NHRC.

1. Office/Officers of the Ethical Review Board for Animals (ERBA)

1.1 The ERBA shall have *clearly defined Officers* that include a Chairperson and a Secretary.

1.1.a The *Chairperson's responsibilities* (or one so delegated) include: calling of the meetings, setting the agenda, notification of decisions.

1.1.b The *Secretary's responsibilities* include: keeping and circulating the minutes of all the meetings among the committee members.

2. ERBA Records/Secretarial Reporting

2.1 The ERBA *shall prepare and maintain adequate documentation* of all ERB activities including the following:

2.1.a Copies of all research *proposals reviewed*.

2.1.b Copies of all research *reports submitted* by the researcher.

2.1.c *Minutes of all ERBA meetings*, which indicate the attendance at the meeting, actions taken by the ERB, consensus/voting records on all decisions, the basis for requiring changes in or disproving research and a written summary of the decisions of issues and their resolutions.

2.1.d Records of *reviewing/monitoring* activities.

2.1.e Copies of *all correspondence* between the ERBA and the researcher. This includes a copy of any decisions and any advice or requirement sent to the researcher.

2.1.f An-up-to-date *list of all ERBA* members, including CV data.

2.1.g *Written procedures* for the ERBA functioning.

2.1.h Record of all *income and expenses* of the ERBA.

2.1.i A *record of the notification* of the completion, or premature suspension or termination of a study.

2.1.j Final *summary and/or final reports* of all suspended/terminated or completed research studies.

2.1.k The *ERBA files shall be retained* in an active file for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection by authorized personnel.

3. Role, Duty and Responsibility of the ERBA

- 3.1 The *ERBA is legally viewed* as the protector of the ethical standards and scientific quality of all health research involving animals and has the authority to do whatever is necessary to enforce those standards. It has the duty to investigate all health research projects before they are carried out and to make sure they follow all ethical guidelines.
- 3.2 The *ERBA has the authority* to demand research protocol modifications. The ERBA has the authority to enforce, monitor, suspend or stop any health research involving animals that does not fulfill the established guidelines.
- 3.3 The ERBA shall ensure that all health research approved by the ERBA is *conducted as per* the decisions by the ERBA. The ERBA has the authority to examine and comment on all institutional plans and policies, which may affect animal welfare.
- 3.4 The ERBA has the authority to facilitate the formulation of *regional and local level ethical committees* according to needs.
- 3.5 The ERBA can *develop a mechanism* for accountability among committee members, for conducting meetings of the committee, for reviewing research proposals, for decision-making and for developing an overall working mechanism for the ERB.
- 3.6 The ERBA should ensure that a *full review of all ethical/scientific* aspects of a health research proposal involving animals should be reviewed. The tasks of the ERBA should be executed free from bias and influence.
- 3.7 The ERBA should provide a *timely review* of all health research proposals.
- 3.8 The ERBA should be involved in ongoing *monitoring/ evaluation* of health research involving animals.
- 3.9 The ERBA has the *responsibility to monitor* the researchers, laboratories, managers or any employees to ensure that they comply with the terms and conditions in these guidelines and to take appropriate steps, including termination of a research as required. The ERB will also monitor the acquisition, transport, production, housing, care, use and disposal of all animals.
- 3.10 The ERBA will require that the *researchers be properly trained* to treat all animals in health research humanely.
- 3.11 The ERBA *will ensure that all animals* used in health research are well fed and kept in a proper environment as per the guidelines.
- 3.12 The ERBA will ensure that procedures for *health research involving animals conform* to the ethical guidelines.
- 3.13 The ERBA will ensure that only *competent personnel* perform all health research involving animals.

- 3.14 The ERBA will have *regular meetings* to review submitted proposals and to monitor ongoing research.
- 3.15 The ERBA shall *keep a record* of the variety of animal species used in health research.
- 3.16 The ERBA will have *due regard for* the requirements of relevant regulatory agencies and applicable laws of HMG.
- 3.17 The ERBA will *keep a record* of all ERBA meetings and decisions.
- 3.18 The ERBA will update and correct these guidelines as required.

4. Membership to the ERBA

- 4.1 The *Executive Board (EB) of NHRC* determines membership of the ERBA.
- 4.2 The members of the *ERBA should represent* the various interests of the research community.
- 4.3 *Members of the ERBA should be multi-disciplinary and multi-sectorial* in composition, including relevant scientific expertise, balanced age and gender distribution and laypersons representing the interests and concerns of the community.
- 4.4 The *Executive Board of NHRC* will decide the number of ERBA members.
- 4.5 An *ERBA member should provide* his/her full name, profession and affiliation. This should be kept in the ERBA file.
- 4.6 All ERBA members should be capable of making *an adequate time commitment* to the ERBA.
- 4.7 The ERBA members should have sensitivity *to community* attitudes.
- 4.8 The ERBA members shall be able to ascertain the acceptability of proposed research in terms of *institutional commitments and regulations*, applicable law and standards of professional conduct and practice.
- 4.9 No ERBA may have a member participate in the review of any health research proposal in which the member has a *conflicting interest*, except to provide information requested by ERBA.
- 4.10 All ERBA members should consider all ERBA deliberations as *strictly confidential*.
- 4.11 *All expenses*, within or related to the ERBA, should be duly recorded.
- 4.12 The *duration of the appointment* to the ERBA is for a period of three years representing above-said organizations/ministries. Members can be re-nominated. Membership in the ERBA should be staggered so that ERBA members do not leave the ERBA all at the same time.

- 4.13 If a member of the ERBA is deemed not to have adhered to the guidelines and policies, *the following disqualification procedure* may be enacted:
- (The values striven for here are justice and due process.)
- 4.13.a *A sealed and confidential letter* will be submitted to the Chairman of the ERBA that clearly states the reasons why a member of the ERBA is being suggested for disqualification from the ERBA. The one submitting the letter must sign the letter.
- 4.13.b *Upon reception* of this letter the Chairman of the ERBA will review the letter and determine that it is authentic. The Chairman will then call in the one who wrote the letter to verify its contents. After this the Chairman will then call in the person suggested for disqualification and with him/her review the submitted letter. The Chairman will then give the person suggested for disqualification the opportunity to respond in writing to the submitted letter.
- 4.13.c *Two options* are now available to the person suggested for disqualification:
- 4.13.c.1 *The first option* is that he/she can submit a letter of resignation to the Chairman of the ERBA and follow the resignation procedure.
- 4.13.c.2 *The second option* is that he/she submits a written response to the Chairman of the ERBA who then presents the case to the members of the ERBA for their review and final decision. A decision will be reached by voting of the ERBA members taken at 50% plus 1. The person who requests the disqualification and the one suggested for disqualification will not participate in the voting.
- 4.13.c.3 *The final decision* will be made by the Executive Board of NHRC.
- 4.13.d *The final decision* of the ERBA will be submitted to the individual suggested for disqualification as well as to the individual who submitted the letter suggesting the disqualification.
- 4.14.e *A written record* will be kept of all disqualification proceedings. It is understood that such matters are highly confidential and all attempts should be made for due process.
- 4.15 At any time a member of the ERBA can submit his/her *letter of resignation* to the Chairperson of the ERBA. The ERBA Chairman then submits this letter as well as his recommendation to the Chairman of the NHRC/Executive Board. The NHRC/EB reviews the letter and makes the final decision. The final decision is then communicated from the Chairman of the EB to the ERBA

Chairman who then communicates the decision to the individual who originally submitted the resignation letter.

5. ERBA Meetings

- 5.1 The *ERBA meets* every two months/or as often as required. All meetings are announced well in advance. The members of the ERBA should be given sufficient time to review all relevant documents for the meeting.
- 5.2 *Minutes* should be taken for each meeting, and minutes from the previous meeting should be approved.
- 5.3 The researcher, independent consultants, and others may be *invited to an ERBA meeting*, as circumstances require. The presence of the researcher or independent consultant should be to assist the ERBA to reach a conclusion and to help them with additional information and clarification but they are not to be involved in the final decision (either by consensus or voting).
- 5.4 The ERBA meetings should *provide sufficient time* for a full review and discussion of agenda material.
- 5.5 *Only ERBA members who attend* the ERBA meeting should participate in the decision(s) of the meeting.
- 5.6 The *quorum required* for ERBA meetings is 50% or more of the total ERBA membership.
- 5.7 *If an ERBA member misses three consecutive meetings*, this could be considered grounds for disqualification from the ERBA.

6. Decision-Making Process of the ERBA

- 6.1 The ERBA will attempt to arrive at *all decisions through consensus*. When consensus is unlikely or not possible, it is recommended that a vote be taken.
- 6.2 In cases of *needed revision*, clear suggestions for revision and the procedure for having the application re-submitted for review should be stated.
- 6.3 A *negative decision* should be supported by reasons that are clearly stated.

7. Communicating Decisions from the ERBA

- 7.1 The ERBA shall notify the researcher in writing of its decision to *approve or disprove* the proposed research activity or of *modifications required*. This should be accomplished within two weeks of the ERBA meeting.
- 7.2 If the ERBA decides to *disprove a research activity*, it shall include in its written notification a clear statement of the reasons for its decision and give the researcher an opportunity to respond in writing and/or in person.
- 7.3 In the case of an *approved decision*, the ERBA sends information regarding the responsibilities of the applicant such as: confirmation of the acceptance, any

requirements imposed by the ERBA, submission of progress reports, the need to notify the ERBA in cases of protocol amendments, the need to report serious and unexpected adverse events related to the conduct of the study and any other information the ERBA expects to receive in order to perform ongoing review and monitoring leading to the final report of the research project.

8. Ongoing Review by the ERBA

- 8.1 The ERBA shall conduct *ongoing review and monitoring* of all approved health research involving animals at intervals appropriate to the research and shall have the authority to observe or have a third party observe the research.
 - 8.1.a The ERBA has *the right, duty and responsibility* to review/monitor all approved research involving animals.
 - 8.1.b *As per the decision by the EB/NHRC* a fee for the ethical review/monitoring should be included in the Protocol.
- 8.2 The following instances or events require the follow-up review of the research:
 - 8.2.a *Any Protocol amendments* likely to affect the conduct of the study.
 - 8.2.b Serious and unexpected *adverse events* related to the conduct of the study.
 - 8.2.c *Any event or new information* that may affect the benefits/risks ratio of the study.
 - 2.2.d *Any decisions resulting from the review* should be issued and communicated to the researcher indicating any modification, suspension, or termination of the ERBA's original decision or confirmation that the decision is still valid.
- 8.3 All health research proposals involving animals should have a statement stating the *method of review/monitoring*.

9. Suspension or Termination of an Approved Research

- 9.1 The ERBA shall have the *authority to suspend or terminate* any approved health research involving animals that is not being conducted in accordance with the ERBA's requirements, or that has been associated with unexpected harmful consequences.
- 9.2 *Any suspension or termination* of an approved research shall include a statement of the reasons for the ERBA's action, and shall be reported promptly to the researcher.
- 9.3 If a researcher decides to terminate the research, he/she should *promptly inform the ERBA* or this decision and provide the reasons. A summary report of the study should be submitted to the ERBA.

- 9.4 In the case of a suspended or terminated research study the ERBA can *recommend that appropriate action* be taken by the NHRC/EB.

10. Independent Consultation

The ERBA may call upon or establish a *standing list of independent consultants* who may provide special expertise to the ERBA on Proposed Research Protocols.

11. Co-operation with other ERBA

- 11.1 Health *research involving animals may involve more than one institution*. While conducting co-operative animal research projects, each ERBA is responsible for the ethical conduct of the research.
- 11.2 With the approval of the NHRC/ERBA, institutions participating in a co-operative project may enter into a *joint review arrangement*, rely upon the review of another qualified ERBA or make similar arrangements for avoiding duplication of effort.
- 11.3. *Terms of reference* for the co-operation should be formulated beforehand.

12. Updating of the Ethical Guidelines

- 12.1 Suggestions for the updating/amending of these ethical guidelines can be made with a 2/3rd vote of the members of the ERBA. These suggestions will then be submitted to the EB/NHRC for final decision.
- 12.2 *All updated guidelines* will be included in the existing ethical guidelines and a notice of any change in the guidelines will be appropriately distributed and concerned parties will be informed.

13. Externally Sponsored Research

The ERBA will consider the following conditions in reviewing an *externally sponsored research proposal*:

- 13.1 The *research is responsive to the human health needs and priorities* of Nepal as well as being sensitive to the existing culture and social values.
- 13.2 The research *cannot be carried out* reasonably well in the sponsor's country.
- 13.3 The research protocol has the *approval of an ERBA/IRBA* of the country of the sponsor.
- 13.4 The sponsor should consider means in which the *research capability of Nepal can be strengthened*.
- 13.5 External sponsors should *apply insurance* when and where appropriate.
- 13.6 In the case of *transferring biological samples* to another country, a MOU has to be signed by the sponsor and NHRC/ERBA defining

clearly the purpose for the transfer, the material that is being transferred, ownership of intellectual property rights, and provisions for privacy protection.

- 13.7 In the case of the export/import of live animals import/export permit should be obtained through DLS as demanded by Animal Health & Livestock Service Act 2055.

SECTION C

APPENDIX 1

List of Domestic/Wild/Lab Animals

The following list given below is of domestic and wild animals that can be kept in a laboratory. Generally animals that are not mentioned in this Appendix 1 will not be considered for animal research.

The researcher should follow the Civil Act 2020 (*Muluki Ain 2020 Mahal-7 Chaupayako*) Provision in this regard for conducting experiments on animals.

A. Wild Animals

1. Macaca monkey
2. Wild boar
3. Snakes
4. All species of birds
5. Rats
6. Guinea pig
7. Hare
8. Mice
9. Frog
10. Squirrel
11. Crocodile (Marsh Crocodile & Gharial Crocodile)
12. Black Buck
13. Chital/deer
14. Fish

B. Domestic Animals

1. Buffalo/ Cattle
2. Sheep
3. Goat
4. Horse
5. Dog
6. Cat
7. Duck
8. Turkey
9. Chicken
10. Pigeon
11. Quail
12. Pig

C. Laboratory Animals

1. Mice
2. Rabbit

3. Guinea Pig
4. Chinchilla

SECTION C

APPENDIX 2

List of Participants at the Consultative Meeting on the Development of the Ethical Guidelines for the Care and Use of Animals in Research in Nepal (16 December 2004)

Participants

1. Dr. Anil Kumar Mishra
Member Secretary
Nepal Health Research Council
Ramshah Path, Kathmandu
2. Ms. Anupa Pandey
Sociologist
Nepal Health Research Council
Ramshah Path, Kathmandu
3. Dr. Bhoj Raj Joshi
Nepal Agriculture Research Council
Singha Durbar Plaza, Kathmandu
4. Mr. Bhupendra Bahadur Thapa
Director
Department of Drug Administration
Bijulibazar, Kathmandu
5. Ms. Chetna Thapa
Former Secretary to Ethical Review Board
Nepal Health Research Council
Ramshah Path, Kathmandu
6. Professor Chitra Kumar Gurung
Assistant Dean
Institute of Medicine
Maharajung, Kathmandu
7. Dr. Durga Dutt Joshi
Director
National Zoonoses & Food Hygiene Research Centre

Tahachal, Kathmandu

8. Mr. Dhan Prasad Sharma Poudel
Section Officer
Ministry of Health
Ramshah Path, Kathmandu
9. Dr. Dhoj Raj Khanal
Nepal Agriculture Research Council
Singha Durbar Plaza, Kathmandu
10. Dr. Govinda Prasad Ojha
Member
Ethical Review Board
Nepal Health Research Council
Ramshah Path, Kathmandu
11. Dr. Gyanendra Nath Gangol
Veterinary Epidemiologist
Department of Animal Health
Tripureswor, Kathmandu
12. Dr. Ghan Raj Ratala
Animal Health Directorate
Tripureswor, Kathmandu
13. Mr. Harihar Dahal
Member
Ethical Review Board
Nepal Health Research Council
Ramshah Path, Kathmandu
14. Fr. Joseph Leo Thaler M.M.
Research Collaborator
Nepal Health Research Council
Ramshah Path, Kathmandu
15. Mr. Kailash Prasad Subedi
Law and Parliamentary Secretary
Singha Durbar, Kathmandu
16. Professor (Dr.) Mahendra Nepal
Institution of Medicine
Maharajgunj, Kathmandu
17. Dr. Meera Ojha
Focal Point Chief
Ministry of Health

Ramshah Path, Kathmandu

18. Dr. Nar Bahadur Rajawar
Nepal Veterinary Council
Harihar Bhawan, Lalitpur
19. Dr. Prakash Ghimire
Epidemiology and Disease Control Division,DHS
Teku, Kathmandu
20. Ms. Pearl Banmali
Research Officer
Nepal Health Research council
Ramshah Path, Kathmandu
21. Professor (Dr.) Ramesh Kant Adhikari
Coordinator
Ethical Review Board
Nepal Health Research council
Ramshah Path, Kathmandu
22. Dr. Ramesh Prasad Archarya
Member
Ethical Review Board
Nepal Health Research council
Ramshah Path, Kathmandu
23. Dr. Rebati Man Shrestha
Veterinary Laboratory
Tripureswor, Kathmandu
24. Mr. Rishi Raj Bhandari
Under Secretary (Law)
Ministry of Health
Ramshah Path, Kathmandu
25. Dr. Rajendra Kumar BC
Chief /RO
Health Research Section
Nepal Health Research Council
Ramshah Path, Kathmandu
26. Mr. Suman Ghimire
Ministry of Home
Singha Durbar, Kathmandu
27. Mr. Shyam Bajimay
National Conservation Department
Kathmandu

28. Mr. S. B. Pandey
Nepal Agriculture Research Council
Singha Durbar, Kathmandu
29. Mr. Santosh Shrestha
Consultant (Environment Health)
Nepal Health Research Council
Ramshah Path, Kathmandu
30. Ms. Shailee Singh Rathour
Secretary to Ethical Review Board
Nepal Health Research Council
Ramshah Path, Kathmandu

SECTION D

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National Animal Welfare Advisory Committee www.maf.govt.nz/AnimalWelfare/

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