# JAI NARAIN VYAS UNIVERSITY JODHPUR
# ANIMAL ETHICS POLICY

## PREAMBLE

The University is following the guidelines and established procedures issued by Committee for Control and Supervision of Experiments on Animals (CCSEA, formerly known as CPCSEA), which is a statutory committee set up in 1991 under Prevention of Cruelty to Animals Act 1960, in the Ministry of Environment, Forests and Climate Change (GOI) to ensure humane and ethical treatment of animals during the course of scientific research/ studies/ experimentation on them (https://cpcsea.nic.in/Auth/index.aspx).

## Function of CPCSEA

All establishments engaged in research and education involving animals, are required to comply with the various guidelines, norms and stipulations set out by CPCSEA.
The main functions of CPCSEA are:

- Registration of establishments conducting animal experimentation or breeding of animals for this purpose.
- Selection and appointment of nominees in the Institutional Animal Ethics Committees of registered establishments.
- Approval of Animal House Facilities on the basis of reports of inspections conducted by CPCSEA.
- Permission for conducting experiments involving use of animals.
- Recommendation for import of animals for use in experiments.
- Action against establishments in case of violation of any legal norm/stipulation.

## Institutional Animals Ethics Committee (IAEC)

Every establishment constituted and operated in accordance with the procedures specified by CPCSEA is required to constitute an Institutional Animals Ethics Committee (IAEC). IAEC may approve experiments on animals, up to the phylogenetic level of rodents (e.g. mice, rats and rabbits). However, IAEC is not empowered to clear research project proposals that involve experimentation on animals higher on the phylogenetic scale than rodents. In such cases, IAEC may consider proposals for scientific experiments involving animals above the sentience level of rodents, and forward its recommendations for consideration by CPCSEA. IAEC is required to monitor the research throughout the study and after completion of study, IAEC shall obtain the periodic reports on research development and shall ensure visit to animal house facility and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

### Standard Operating Procedures (SOP) for IAEC

1. Objective:

प्रोफेसर (डॉ.) कन्हैया लाल श्रीवास्तव
कुलपति
जय नारायण व्यास विश्वविद्यालय
जोधपुर (राजस्थान)

The motto of Prevention of Cruelty to Animals (PCA) Act 1960 as amended in 1982, is to prevent infliction of unnecessary pain or suffering on animals. The Central Government as enumerated under PCA Act 1960 has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. For this purpose, the Government has made "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" as amended during 2001 and 2006, to regulate the experimentation on animals.

The objective of this SOP is to contribute to the effective functioning of the Institutional Animals Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding of and Experimentation (Control and Supervision) Rules 1998, as amended in 2001 and 2006.

2. IAEC has been designed to secure the following objectives:

(a) Every experiment shall be performed by or under the supervision of a person duly qualified in that behalf, that is, Degree holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;

(b) That experiments are performed with due care and humanity and as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals from feeling pain;

(c) That animals who, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily medically allowed to death while still under influence of anaesthetic;

(d) That experiments on animals are avoided wherever it is possible to do so.

(e) That experiments on larger animals are avoided when it is possible to achieve the same results by experiments on small laboratory animals like guinea-pigs, rabbits, mice, rats etc;

(f) That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;

(g) That animals intended for the performance of experiments are properly looked after before, during and after experiments;

(h) That suitable records are maintained with respect to experiments performed on animals.

**Functions of IAEC**

As defined in "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" "Institutional Animals Ethics Committee (IAEC)" means a body comprising of a group of persons recognized and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;

The primary duty of IAEC is to work for achievement of the objectives as mentioned above. IAEC should focus mainly on ensuring ethical and methodical handling of animals during and after experiments, so that they have less suffering.

IAEC will review and approve all types of protocols for research involving small animal experimentation before the start of the study. For approval of experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.

IAEC is required to monitor the research throughout the study and after completion of study, IAEC shall obtain the periodic reports on research development and shall ensure visit to animal house facility and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

**Composition of IAEC**

Institutional Animals Ethics committee shall include eight members as follows:

A. IAEC members from the establishment (05 members):

i. One biological scientist

ii. Two scientists from different biological disciplines

iii. One veterinarian involved in the care of animal

iv. One scientist in charge of animal facility of the establishment concerned

The Chairperson of the Committee and Member Secretary would be nominated by the establishment from amongst the above five members. However, if the establishment wants to propose its administrative head, who is from non-scientific background, as Chairperson, then six members of IAEC may be proposed.

Having a Veterinarian in IAEC is mandatory for judging level of care and handling of Laboratory animals in a given protocol.

B. Nominees from the CPCSEA:

i. Main Nominee (01)

ii. Link Nominee *

iii. Scientist from outside the Institute (01)

iv. Socially Aware Nominee (01)

***Link Nominee shall substitute the main nominee in case main nominee conveys his unavailability in writing to the chairperson of the IAEC in advance as per described procedure.*** The CPCSEA shall endeavour that nominees appointed by CPCSEA in any private establishment should not be from the establishments which is having the same objectives as to the establishment where the nominees are being nominated, so as to avoid the conflict of interest between the establishments. In addition to the above IAEC members, a specialist may be co-opted of the relevant field while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.

**The minimum qualification for the IAEC Members is as below:** i. B.V.Sc. or ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or iii. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or iv. M. Pharm. with experience in animal handling and animal research, or v. MD/ MS with research experience in laboratory animal handling.

**The qualification for Nominee(s) of CPCSEA is as under:** I. The minimum qualification for Nominee should be: i. B.V.Sc. or ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or iii. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or iv. M. Pharm. with experience in animal handling and animal research, or v. MD/ MS with research experience in laboratory animal handling. II. The minimum qualification for Socially Aware nominee should be at least Graduate from any subject. Preference will be given to those with a background in Biological Sciences.

**Upper age limit for the Nominees of CPCSEA:**
The upper age limit for the Nominees of CPCSEA is 65 years. However, the nominees who are already working in the IAECs and are above 65 years of age will be allowed to be continued till the end of their tenure in the present IAECs.

**Authority under which IAEC is constituted and duration:**
The IAEC of an establishment is constituted by CPCSEA at the time of registration for a period of 5 years. During these 5 years, revision in IAECs may be made in deserving cases with the approval of CPCSEA. The IAEC would be reconstituted at the time of renewal, duly approved by CPCSEA, for another 5 years. The establishments are required to send names of 5 members at the time of constitution and at every reconstitution. It is mandatory that atleast half of the members of IAEC are new at the time of reconstitution.

**IAEC requirements:**
a. The duration of appointment is for a period of 5 years (coterminous with registration).
b. The committee is required to be reconstituted at the time of renewal of registration, and at least half of the internal IAEC members is required be replaced at the time of renewal.
c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so.
e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
f. Conflict of interest should be declared by members of the IAEC.
g. IAEC is required to formulate a SOP for its working requirements and follow it in all the meetings.
h. Foreign Nationals shall not be allowed as member of the IAECs of any establishments.

**Follow up procedures**
a. Reports of Research Protocols/ Project completion report should be submitted for consideration of IAEC of the establishment at prescribed intervals for review and it should not exceed the timeline of the research as mentioned in the Form B.
b. Final report should be submitted to the IAEC of the establishment at the end of study.
c. All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated to IAEC.

d. Protocol deviation, if any, should be informed with adequate justifications to IAEC and in case of large animals, it should be intimated to CPCSEA immediately for consideration of CPCSEA. The procedural deviations in research protocol shall be treated as a fresh research protocol by CPCSEA.

e. Any new information related to the study should be communicated to IAEC immediately.

f. Premature termination of study should be notified to the IAEC with reasons along with summary of the data obtained so far.
g. Change of investigators / sites should be informed and approval of IAEC should be undertaken first.

**Record keeping and Archiving:**
a. IAEC shall maintain the Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.
b. Copy of all study protocols with enclosed documents, progress reports shall be maintained by IAEC.
c. Minutes of all meetings duly signed by the Chairperson and the members shall be maintained by IAEC.
d. Copy of all existing relevant national and international guidelines on animal ethics and laws along with amendments shall be maintained by IAEC.
e. Copy of all correspondence with members, researchers and other regulatory bodies shall be maintained by IAEC.
f. Project completion report of the approved projects shall be maintained by IAEC.
g. Record of Breeding of animals, supply etc, if breeding of animals is undertaken shall be maintained by IAEC.
h. Record of import of animals with species, source, quantity, usage etc shall be maintained by IAEC.
i. Record of all Contract research, if conducted at the institute shall be maintained by IAEC.
j. Record of rehabilitation of large animals, if done, shall be maintained by IAEC.
k. All documents should be archived for period as prescribed in the SOP formulated by the IAEC of concerned establishment.

## EXPERIMENTATION ON ANIMALS

(1) It shall be the duty of the Committee to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them, and for the purpose it may, by notification in the Gazette of India and subject to the condition of previous publication, make such rules as it may think fit in relation to the conduct of such experiments.
(2) In particular, and without prejudice to the generality of the foregoing power, rules made by the Committee shall be designed to secure the following objects, namely:

(a) that in cases where experiments are performed in any institution, the responsibility therefore is placed on the person in charge of the institution and that, in cases where experiments are performed outside an institution by individuals, the individuals, are performed outside an institution by individuals, the individuals, are qualified in that behalf and the experiments are performed on their full responsibility;
(b) that experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals feeling pain;
(c) that animals which, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;

(d) that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
(e) that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, frogs and rats;
(f) that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
(g) that animals intended for the performance of experiments are properly looked after both before and after experiments;
(h) that suitable records are maintained with respect to experiments performed on animals
(3) In making any rules under this section, the Committee shall be guided by such directions as the Central Government (consistently with the objects for which the Committee is set up) may give to it, and the Central Government is hereby authorised to give such direction.
(4) All rules made by the Committee shall be binding on all individuals performing experiments outside institutions and on persons incharge of institutions in which experiments are performed.

**Stocking of animals:**
The animals shall be stocked by the breeder and the establishment in the following manner:
(a) animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises kept tidy, hygienic and the animals protected from drought and extremes of weather;
(b) animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided;
(c) where standards have been laid down by the Indian Standards Institution, the cages, the stable, as the case may be, shall conform to those standards;
(d) animals attendants must be suitably trained and experienced in the duties allotted to them,
(e) animals shall be looked after, before and after the experiments by a trained and experienced attendant;
(f) there-shall be satisfactory arrangement for looking after the animals during off hours and on holidays.

**Permission of the Committee required for conducting experiments:**
(a) Every registered establishment before acquiring an animal or conducting any experiment on an animal/animals shall apply for permission of the Committee or the Institutional Animals Ethics Committee recognised for the purpose by the Committee along with the details contained in the specified format to the Member Secretary of the Committee or the Institutional Animals Ethics Committee, as the case may be.
(b) The Member Secretary of the Committee or the Institutional Animals Ethics Committee, shall cause the application for permission to be brought before the Committee/Institutional Animals Ethics Committee as the case may be, and the Committee/ Institutional Animals Ethics Committee after scrutiny of the application, if satisfied, may grant permission to the establishment stating the name of the species and the number of animals that can be acquired for carrying out the experiments.
(c) The Committee or Institutional Animals Ethics Committee, as the case may be, may, while granting permission for conducting experiments on animals, put conditions as it may deem fit

to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.

(d) The Committee may require the establishments and Institutional Animals Ethics Committees and persons carrying on experiments on animals to forward to the Committee such information as it may require, on completion of experiments for which the permission has been granted.

**Performance of experiments:**

In conducting experiments on animals, regard shall be had to the following conditions, namely:

(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;

(b) experiments shall be performed with due care and humanity;

(c) animals intended for the performance of experiments are properly looked both before and after experiments;

(d) experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic to prevent the animal feeling pain and it shall remain so throughout the experiment. Anaesthesia shall be administered by a Veterinary Surgeon trained in methods of anaesthesia or a Scientist/technician so trained for this purpose and who shall remain present near the animal till the completion of the experiment;

(e) animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anaesthesia;

(f) when there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment;

(g) the experiment shall not be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions;

(h) experiments shall not be performed by way of an illustration;

(i) experiments shall not be performed as a public demonstration;

(j) the substance known as Urari or Curari or any such paralysan shall riot be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness;

(k) no experiment the result of which is already conclusively known, shall be repeated without previous justification;

(l) there shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain;

(m) dogs held for experimental purposes shall not be debarked.

(n) where experiments are performed in any institution, the responsibility therefor is placed on the person in charge of the institution and in cases where experiments are performed outside an institution by an individual qualified in that behalf, the-experiments, are performed on his responsibility.

**Transfer and acquisition of animals for experiment:**

(a) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these' rules.
(b) An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment.
(c) Every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.
(d) The animals used for experimentation in a production/ breed improvement programme may be given out by the breeder' institution for domestic use.
(e) No animal shall be imported by a breeder or an establishment which is available in the country.
(f) A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments on animals.

**Records:**
(a) Every, establishment/Institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format.
(b) Every establishment/Institutional Animals Ethics Committee shall furnish such information, as the Committee may from time to time require in the specified format.
(c) All laboratories shall inform the exact number/ species of animals to the Member Secretary or any officer authorised in this regard by the Committee as per the specified format.

**Contract animal experiments:**
No establishment shall contract or undertake to perform contract research or experiments on contract basis on behalf of any other establishment or research or educational Institution, This shall not apply to collaborative research between academic institutions.

## GUIDELINES ON THE REGULATION OF SCIENTIFIC EXPERIMENTS ON ANIMALS

**Background**
The use of animals in scientific research has been an area of concern in India, given the sharp polarization of views between animal welfare activists and the scientific community of the country regarding use of animals. This led to proliferation of litigation, which impeded the pace of research. In order to eliminate the potential for conflict, it was considered necessary to examine the international norms regarding the use of animals in scientific experiments, update regulations, streamline and simplify procedures, while ensuring ethical use of animals and reducing infliction of pain and stress on animals, during experimentation. Compliance is also required with CPCSEA Guidelines for Laboratory animal facility.

**CPCSEA Guidelines on specific aspects regarding the use of animals in scientific experiments:**

**Need to avoid/minimize pain and suffering inflicted on experimental animals**
Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals

that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anaesthesia.

**Proper care, handling and use of experimental animals**

The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.

**Agricultural production research**

The conventional regulatory framework may not be applied regarding use of experimental animals in agricultural production research. The practitioners would be responsible for self-regulation, based on operational guidelines to be framed by CPCSEA.

**Powers of the Institutional Animals Ethics Committee (IAEC)**

IAEC is not empowered to clear research project proposals that involve experiments on animals higher on the phylogenetic scale than rodents.

**Inspection of animal house facilities**

Both announced and unannounced visits by duly authorized personnel (only) to inspect the animal house facilities of institutes may be carried out. However, the personnel undertaking inspections may not order either temporary or permanent closure of the animal house facility, or suspension of registration of the animal facility, or impose any other penalty, but must report their finding to the CPCSEA for further action.

**Procedures for approval of scientific experiments on animals**

Definition of experiment In terms of Rule 2 (e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, "Experiments" means any programme or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical or chemical nature; and includes the use of animals(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering, or significant gains in the well-being for people of the country or for combating any disease, whether of human beings, animals or plants.

**Experimental animals which are subject to regulation The relative sentience of different species of animals are as follows:**

Invertebrates (e.g., cockroaches) <Birds <Rodents <Canines/Felines <Bovine/Equines <Primates (e.g., Rhesus Macaque)<More evolved Primates (e.g., chimpanzee)

Anything higher than invertebrates in terms of level of sentience requires regulation. Thus rats, mice, birds, and farm animals are also subject to regulation.

**Approval of animal house facilities**

In terms of Rule 5 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, approval of animal house facilities by CPCSEA is required to be obtained, for premises where experiments are to be conducted.

**Use of animals in experiments**

In terms of Rule 9 (bb) of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure, and

the experiment should be designed with the minimum number of animals to give statistically valid results at 95% degree of confidence. Replacement alternatives, not involving experiments on animals, should be given due and full consideration and sound justification must be provided, in case alternatives, though available, are not used.

**Procurement of animals**

In terms of Rule 10 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended,

(i) an establishment shall acquire animals for experiments from registered breeders only;

(ii) in case of non-availability of animals from registered breeders, the animals may be procured from alternative legal sources;

(iii) in case the animal is procured from alternative legal sources, the same shall be procured after taking written permission from the authority competent under the law for the time being in force, to give such permission; and Replacement alternatives, not involving experiments on animals, should be given due and full consideration, and sound justification must be provided, in case alternatives, though available, are not used.

**Welfare of animals during use in experiments**

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, personnel using the experimental animals shall be responsible for the welfare of the animals during their use in experiments. The CPCSEA Guidelines for Laboratory Animal Facility also spell out the baseline procedures to be followed when using animals in the course of scientific experimentation, including quarantine and animal care.

**Aftercare and rehabilitation of animals after use in scientific experiments**

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall be responsible for the aftercare and rehabilitation of the animals after experimentation. Costs of aftercare and rehabilitation of the animals after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals. Rehabilitation treatment of an animal after experimentation shall extend till the point the animals is able to resume a normal existence by providing a lumpsum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span. The establishment undertaking experiments or duly licensed and authorized animal welfare organizations under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

**Situations where euthanasia of animals is permissible**

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall not euthanize animals except in situations as defined below:

(i) When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner; or

(ii) If during the course of experimental procedure, the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering; or

(iii) Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

## CPCSEA GUIDELINES FOR LABORATORY ANIMAL FACILITY – 2015

Good Laboratory Practices (GLP) for animal facilities is intended to assure quality maintenance and welfare of animals used in laboratory studies while conducting biomedical and behavioural research and testing of products.

**GOAL**

The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal well being, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

**VETERINARY CARE**

a. Adequate veterinary care must be provided and is the responsibility of a veterinarian or a person who has training or experience in laboratory animal sciences and medicine.

b. Daily observation of animals can be accomplished by someone other than a veterinarian; however, a mechanism of direct and frequent communication should be adopted so that timely and accurate information on problems in animal health, behaviour, and well being is conveyed to the attending veterinarian.

c. The veterinarian can also help the establishment in designing appropriate policies and procedures for ancillary aspects of veterinary care, such as use of appropriate methods to prevent and control diseases (e.g. vaccination and other prophylaxis, disease monitoring and surveillance, quarantine and isolation), operative and post-operative care, diagnosis and treatment of diseases as well as injuries. reviewing protocols and proposals, animal husbandry and animal welfare; monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation. Institutional requirements will determine the need for full-time or part-time or consultative veterinary services.

**ANIMAL PROCUREMENT**

a. All animals (like cattle, buffalo, sheep, goat, pigs, equine etc.) must be acquired lawfully as per the CPCSEA guidelines. Small animals and dogs can be procured from registered breeders. Large animals can be procured from farm, farmers or as per guidance of wild life department, as is done in case of macaques. Cats can be bred for their use

. Rodents can be imported from abroad after necessary licence from Director General of Foreign trade (DGFT) is obtained for import.

b. A health surveillance program for screening incoming animals should be carried out before purchase to assess animal quality. Methods of transportation should also be taken into account.

c. Each consignment of animals should be inspected for compliance with procurement specifications, and the animals should be quarantined and stabilized according to procedures appropriate for the species and circumstances.

**QUARANTINE, STABILIZATION AND SEPARATION**

a. Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined. An effective quarantine minimizes the chance for introduction of pathogens into an established colony. The duration at quarantine in small lab animals is from one week to one month and large animals allowed up to 6 weeks (cat, dog, monkey, etc). However,

duration of quarantine can be increased depending on type of infection / suspected infection noticed in the animals.

b. Effective quarantine procedures should be used for non-human primates to help limit exposure of humans to zoonotic infections. The period varies from 2 to 3 months depending on the reaction of TB testing. Any macaque found positive for TB for at least two times and shows signs of weight loss or ill health should be euthanized as is practiced internationally to prevent spreading of TB to workers and other macaques.

c. Regardless of the duration of quarantine, newly received animals should be given a period for physiologic, psychologic and nutritional stabilization before their use. The length of time stabilization will depend on the type and duration of animal transportation, the species involved and the intended use of the animals.

d. Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioural changes due to interspecies conflict.

e. Such separation is usually accomplished by housing different species in separate rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators can be used as suitable alternatives.

f. In some instances, it shall be acceptable to house different species in the same room, for example, if two species have a similar pathogenic status and are behaviourally compatible. Separate set of personnel should be identified for taking care of these infected (sick) animals and other workers should be restricted from entering in to the facilities unless otherwise required and after handling these animals they should not be handling any other animals in the facilities

**SURVEILLANCE, DIAGNOSIS, TREATMENT AND CONTROL OF DISEASE**

(a) All animals should be observed for signs of illness, injury, or abnormal behaviour by animal house staff. As a rule, this should occur daily, but more-frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. It is imperative that appropriate methods be in place for disease surveillance and diagnosis.

(b) Post-mortem examination and signs of illness, distress, or other deviations from normal health condition in animals should be reported promptly to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals in the colony. If an entire room of animals is known or believed to be exposed to an infectious agent (e.g. *Mycobacterium tuberculosis* in non-human primates), the group should be kept intact and isolated during the process of diagnosis, treatment, and control. Animals suffering from contagious diseases like Tuberculosis etc. must be euthanized as is practiced internationally to prevent its spread to other animals and often animal handlers.

(c) The isolation, quarantine and stabilization programs for newly arrived animals are necessary to provide time to assess their health status, allow them to recover from the stress of shipment and an opportunity to adapt to their new environment. The extent of these programs depends on several factors, including species and source of the animals as well as their intended use. For some animals, such as rodents obtained from reliable sources for which health status is known, visual inspection on arrival may suffice. For species such as nonhuman primates, farm animals, wild animals, dogs, cats and non-specific pathogen free rabbits and rodents, appropriate quarantine and isolation procedures must be employed.

(d) Preventive medicine programs such as vaccinations, ecto- and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular species and source. Only animals of defined health status should be used in research and testing unless a specific, naturally occurring or induced disease state is being studied. Systems should be established to protect animals within the institution from exposure to diseases.
(e) Transgenic and mutant animals may be particularly susceptible to diseases and may require special protection to ensure their health. Systems to prevent spread of disease may include facility design features, containment/isolation equipment, and use of standard operating procedures. Training of animal care and research staff is essential to prevent spread of animal diseases.
(f) Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic and microbiological agents that may cause overt or unapparent disease. Additionally, cells, tissues, fluids, and transplantable tumors that are to be used in animals should be monitored for infectious or parasitic agents that may cause disease in animals. The type and intensity of monitoring necessary will depend upon professional veterinary judgment and the species, source, use and number of animals housed and used in the facility.
(g) Diagnostic laboratory services must be available and used as appropriate. Laboratory services should include necropsy, histopathology, microbiology, clinical pathology, serology, and parasitology as well as other routine or specialized laboratory procedures, as needed. It is not necessary that all of these services be available within the animal facility (Facilities from other laboratories with appropriate capabilities may be used).
(h) Animals with infectious / contagious disease must be isolated from others by placing them in isolation units or separate rooms appropriate for the containment of the agents of concern. In certain circumstances, when an entire group of animals is known or suspected to be exposed or infected, it may be appropriate to keep the group intact during the time necessary for diagnosis and treatment, for taking other control measures, or for completion of a project.
(i) The veterinarian must have authority to use appropriate treatment or control measures, including euthanasia in consultation with at least one more additional veterinarian if required, following diagnosis of an animal disease or injury. If possible, the veterinarian should discuss the situation with the principal investigator to determine a course of action consistent with experimental goals. However, if the principal investigator is not available, or if agreement cannot be reached, the veterinarian must have authority to act to protect the health and wellbeing of the institutional animal colony and workers.

**ANIMAL CARE AND TECHNICAL PERSONNEL**

(a) Animal care programs require technical and husbandry support. Institutions should employ people trained in laboratory animal science or provide for both formal and on-the-job training to ensure effective implementation of the program.

**PERSONAL HYGIENE**

(a) It is essential that the animal care staff maintain a high standard of personal cleanliness. Facilities and supplies for meeting this obligation should be provided with appropriate Personnel Protective Equipment (PPE) e.g. showers, change of uniforms, footwear etc.
(b) Clothing suitable for use in the animal facility should be supplied and laundered by the institution. A commercial laundering service is acceptable in many situations; however, institutional facilities should be used to decontaminate clothing exposed to potentially

hazardous microbial agents or toxic substances. It is acceptable to use disposable gloves, masks, head covers, coats, coveralls and shoe covers. Personnel should change clothing as often as is necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility.

(c) Washing and showering facilities appropriate to the program should be available. Personnel should not be permitted to eat, drink, smoke or apply cosmetics and perfumes in animal rooms. They should finish the work with animals as early as possible and sit somewhere else, outside and not in the animal rooms / areas. A separate area or room should be made available for these purposes.

**ANIMAL EXPERIMENTATION INVOLVING HAZARDOUS AGENTS**

(a) Institutions should have policies governing experimentation with hazardous agents. Institutional Bio-safety Committee whose members are knowledgeable about hazardous agents are in place in most of the higher-level education, research institutes and in many pharmaceutical industries for taking care of safety issues. This committee shall also examine the proposal on animal experiments involving hazardous agents in addition to its existing functions.

(b) Since the use of animals in such studies requires special considerations, the procedures and the facilities to be used must be reviewed by both the Institutional Bio-safety committee and Institutional Animal Ethics Committee (IAEC). Disposing of tissues and fluids from such used animals must also be appropriately governed as per the laid in practices of the institution / biosafety regulation.

**MULTIPLE SURGICAL PROCEDURES ON SINGLE ANIMAL**

(a) Multiple surgical procedures on a single animal for any testing or experiment are not to be practiced unless specified in a protocol only approved by the IAEC.

(b) Individual animals should not be used in more than one experiment, either in the same or different projects, without the express approval of the IAEC. However, it is noted that appropriate re-use of animals may reduce the total number of animals used in a project, result in better design of experiments, and reduce stress or avoid pain to additional animals. Animals that are used in more than one experiment should be permitted to recover fully from the first experiment before the subsequent experiment is performed. Certification of attending veterinarian is however, required before subjecting animal to the second experiment.

**DURATIONS OF EXPERIMENTS**

No animal should be used for experimentation for more than 3 years unless adequate justification is provided.

**PHYSICAL RESTRAINT**

(a) Brief physical restraint of animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or with devices be suitable in size and design for the animal being held and operated properly to minimize stress and avoid injury to the animal.

(b) Prolonged restraint of any animal, including the chairing of non-human primates, should be avoided unless essential to the research objectives. Less restrictive systems, such as the tether system or the pole and collar system should be used when compatible with research objectives.

(c) Following points should be considered during handling and restraining animals:-

i. Animals should be handled by competent individuals trained in methods that cause minimal distress and injury (for example, a person with a publication to his/her credit and post/experience in relevant techniques for handling animals is preferable).
ii. The use of restraint devices is sometimes essential for the welfare of the animal and safety of the handler. Restraint devices should be used to the minimum
iii. extent, for the minimum period required to accomplish the purpose of the experiment and be appropriate for the animal.
iv. Tranquilisers or anaesthetics may initially be used to aid restraint but they may prolong recovery from the procedure. When these agents have been used, recovery of the animals should be closely monitored.
(d) The following are important guidelines for the use of restraint equipments:
i. Restraint devices cannot be used simply as a convenience in handling or managing animals. The period of restraint should be the minimum required to accomplish the research objectives. Animals to be placed in restraint devices should be given training to adapt to the equipment, prior to initiation of the experimentation.
ii. Provision should be made for observation of the animal at appropriate intervals. Veterinary care should be provided if symptoms or illness associated with restraint are observed. The presence of illness, or severe behavioural change should be dealt with by temporary or permanent removal of the animal from restraint related protocol.

**LOCATION OF ANIMAL FACILITIES TO LABORATORIES**

Good animal husbandry and human comfort and health protection require physical separation of animal facilities from personnel areas such as offices, break room, training and education room.

 Laboratory animals are very sensitive to their living conditions. It is important that they shall be housed in an isolated building located as far away from human habitations as possible and not exposed to dust, smoke, noise, wild rodents, insects and birds. The building, cages and environment of animal rooms are the major factors, which affect the quality of animals.

 This separation can be accomplished by having the animal quarters in a separate building, wing, floor, or room. Careful planning should make it possible to place animal housing areas adjacent to or near laboratories, but separated from them by barriers such as entry locks, corridors, or floors.

 While planning an animal facility the space should be well divided for various activities. The animal rooms should occupy about 50-60% of the total constructed area and the remaining area should be utilized for services such as stores, washing, office and staff, machine rooms, quarantine and corridors. The environment of animal room (Macro-Environment) and animal cage (Microenvironment) are factors on which the production and experimental efficiency of the animal depends. Since animals are very sensitive to environmental changes, sharp fluctuations in temperature, humidity, light, sound and ventilation should be avoided.

**FUNCTIONAL AREAS**

(a) The size and nature of a facility will determine whether areas for separate service functions are possible or necessary. Sufficient animal area required to:

- Ensure separation of species or isolation of individual projects when necessary;
- Receive, quarantine, and isolate animals; and
- Provide for animal housing.

(b) In facilities that are small, maintain few animals or maintain animals under special conditions (e.g., facilities exclusively used for housing germfree colonies or animals in runs and pens) some functional areas listed below could be unnecessary or included in a multipurpose area. Professional judgement must be exercised when developing a practical system for animal care.

- Specialized laboratories or
- Individual areas contiguous with or near animal housing areas for such activities as surgery, intensive care, necropsy, radiography, preparation of special diets, experimental manipulation, treatment, and diagnostic laboratory procedures containment facilities or
- Equipment, if hazardous biological, physical, or chemical agents are to be used
- Receiving and storage areas for food, bedding
- Pharmaceuticals and biologics, and supplies
- Space for administration, supervision, and direction of the facility
- Showers, sinks, lockers and toilets for personnel
- An area for washing and sterilization equipment and supplies,
- An autoclave for equipment
- Food, and bedding; and separate areas
- For holding soiled and cleaned equipment
- An area for repairing cages and equipment
- An area to store wastes prior to incineration or removal

**PHYSICAL FACILITIES**

The physical condition and design of animal facility determine, to a great extent, the efficiency and economy of this operation. The design and size of an animal facility depend on the scope of institutional research activities, animals to be housed, physical relationship to the rest of the institution, and geographic location. A well planned, properly maintained facility is an important element in good animal care.

(a) Housing facility should be compatible with the needs of the species to be housed.

(b) Housing Facilities should be designed and operated to facilitate control of environmental factors to exclude vermin and limit contamination associated with the housing of animals, delivery of food, water, bedding, and the entry of people and other animals.

(c) Housing Facilities should be maintained in good repair. Walls and floors should be constructed of durable materials with surfaces that can be cleaned and disinfected readily.

(d) Housing Facilities should be kept clean and tidy and operated to achieve maximum possible hygiene.

(e) There should be a pest control programme to monitor and control vermin.

(f) There should be adequate and appropriate storage areas for food, bedding and equipment.

(g) Deodorants designed to mask animal odours should not be used in Housing Facilities as they may expose animals to volatile compounds which can alter metabolic processes. In addition, deodorants must not be used as a substitute for good cage and equipment cleaning practices and good ventilation.

(h) Cleaning practices should be monitored on a regular basis to ensure effective hygiene and sanitation. This may include visual inspection, monitoring water temperatures and microbiological testing of surfaces after cleaning.
(i) There should be proper water supply and drainage.
(j) There should be adequate contingency plans to cover such emergencies as flooding and fire, or the breakdown of lighting, heating, cooling or ventilation.
(k) In the interest of disease prevention and general animal welfare, access to the Housing Facilities by unauthorised persons should be restricted.

I. **Building Materials** should be selected to facilitate efficient and hygienic operation of animal facilities. Durable, moisture-proof, fire-resistant, seamless materials are most desirable for interior surfaces including vermin and pest resistance.
II. **Corridor(s)** should be wide enough to facilitate the movement of personnel as well as equipments and should be kept clean.
III. **Utilities** such as water lines, drain pipes, and electrical connections should preferably be accessible through service panels or shafts in corridors outside the animal rooms.
IV. **Animal Room Doors**
Doors should not be rust and should be vermin and dust proof. They should fit properly within their frames and provided with an observation window. Door closures may also be provided. Rodent barriers can be provided in the doors of the small animal facilities.
V. **Exterior Windows**
Windows are not recommended for small animal facilities. However, where power failures are frequent and backup power is not available, they may be necessary to provide alternate source of light and ventilation. In primate rooms, windows can be provided to have visual access to natural environment.
VI. **Floors**
Floors should be or either monolithic or epoxy smooth, moisture proof, nonabsorbent, skidproof, resistant to wear, acid, solvents and adverse effects of detergents/ disinfectants. They should be capable of supporting racks, equipment, and stored items without becoming gouged, cracked, or pitted, with minimum number of joints.
VII. **Drains**
Floor drains are not essential in all rooms used exclusively for housing rodents. Floor in such rooms can be maintained satisfactorily by wet vacuuming or mopping with appropriate disinfectants or cleaning compounds. Where floor drains are used, the floors should be sloped and drain taps kept filled with water or corrosion free mesh. To prevent high humidity, drainage must be adequate to allow rapid removal of water and drying of surfaces. At the inlet and outlets of the drains should be fitted with wire mesh guard to prevent wild rodent entry
VIII. **Walls & Ceilings**
Walls should be free of cracks, unsealed utility penetrations, or imperfect junctions with doors, ceilings, floors and corners.
Surface materials should be capable of withstanding scrubbing with detergents, disinfectants and the impact of water under high pressure. Materials used for construction of roof should cater needs of local climatic condition to provide comfort to the animals.
IX. **Storage Areas**
Separate storage areas should be designed for feed, bedding, cages and materials not in use. Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal tissue waste.

X. **Facilities For Sanitizing Equipment And Supplies**

An area for sanitizing cages and ancillary equipment is essential with adequate water supply

XI. **Experimental Area**

All experimental procedures in small animals should be carried out in a separate area away from the place where animals are housed. Aseptic surgery for large animals should include separate functional areas for surgical support, like a preparation area, the operating theatre room or rooms, and an area for post operative care and for treatment of animals.

**ENVIRONMENT**

(a) **Temperature And Humidity Control**

Air conditioning is an effective means of regulating these environmental parameters for laboratory animals. Temperature and humidity control prevents variations due to changing climatic conditions keeping in view of the variations in the number of room occupants the range should be within or approximately between 18 to 29°C (64.4 to 84.2oF) all times.

The relative humidity should be under control within the range of 30% to 70% throughout the year. For larger animals a comfortable zone (18 to 37°C) should be maintained. During extreme summer appropriate methods e.g. sprinklers should be adopted for cooling open enclosures of large animals.

(b) **Ventilation**

In renovating existing or in building new animal facilities, consideration should be given to the ventilation of the animals' primary enclosures.

Heating, ventilation, and air-conditioning systems should be designed with 12-15 air cycles per hour so that operation can be continued with a standby system. The animal facility and human occupancy areas should be ventilated separately.

(c) **Power And Lighting**

The electrical system should be safe and provide appropriate lighting and with sufficient number of power points lighting system be installed provide adequate illumination for people to work in the animal rooms and a lowered intensity of light for the animals. Fluorescent lights are efficient and less than 400 lux is preferable for rodent facilities.

A time-controlled lighting system should be used if possible to ensure a regular diurnal lighting cycle wherever required. Emergency power should be available in the event of power failure.

(d) **Noise Control**

The facility should be provided with noise free environment. Noise control is an important consideration in designing the animal facility. Concrete walls are more effective than metal or plaster walls because their density reduces sound transmission. Preferably less than 85 dB is desirable for rodents and non human primates.

**ANIMAL HUSBANDRY**

i. **Caging of Housing System**

(a) The caging or housing system is one of the most important elements in the physical and social environment of research animals. It should be designed carefully to facilitate animal well being, meet research requirements, and minimize experimental variables.

**The housing system should:**

- Provide space that is adequate, permit freedom of movement and normal postural adjustments, and have a resting place appropriate to the species;
- Provide a comfortable environment

- Provide an escape proof enclosure that confines animal safety
- Provide easy access to food and water;
- Provide adequate ventilation
- Meet the biological needs of the animals, e.g., maintenance of body temperature, urination, defecation, and reproduction;
- Keep the animals dry and clean, consistent with species requirements;
- Facilitate research while maintaining good health of the animals.

(b) They should be constructed of sturdy, durable materials and designed to minimize cross-infection between adjoining units. Polypropylene, polycarbonate and stainless steel cages should be used to house small lab animals, Monkeys should be housed in cages made of steel or painted mild steel.

(c) To simplify servicing and sanitation, cages should have smooth, impervious surfaces that neither attract nor retain dirt and a minimum number of ledges, angles, and corners in which dirt or water can accumulate. The design should allow inspection of cage occupants without disturbing them. Feeding and watering devices should be easily accessible for filling, changing, cleaning and servicing.

(d) Cages, runs and pens must be kept in good condition to prevent injuries to animals, promote physical comfort, and facilitate sanitation and servicing. Particular attention must be given to eliminate sharp edges and broken wires, keeping cage floors in good condition. International guidelines can be referred from time to time to improve caging facilities.

ii. **Sheltered or Outdoor Housing**

(a) When animals are maintained in outdoor runs, pens, or other large enclosures, there must be protection from extremes in temperature or other harsh whether conditions an adequate protective and escape mechanism for submissive animals especially in monkeys by way of providing indoor portion of run. Shelter should have sufficient ventilation, and should be designed to prevent accumulation of waste materials and excessive moisture.

(b) Houses, dens, boxes, shelves, perches, and other furnishings should be constructed in a manner and made of materials that allow cleaning or replacement in accordance with generally accepted husbandry practices when the furnishings are soiled or worn out.

(c) Ground-level surfaces of outdoor housing facilities can be cemented or covered with absorbent bedding, sand, gravel, grass, or similar material that can be removed or replaced when that is needed to ensure appropriate sanitation. Accumulation of animal waste and stagnant water should be avoided by, for example, using contoured or drained surface. Other surfaces should be able to withstand the elements and be easily maintained.

(d) In case of open runs of macaques, it is obvious in our country (unlike others) to have outside animals and local macaques frequenting the colony pens and runs increasing risk of contracting contagious diseases. Hence, it is advisable to cover such open pens with additional layers of materials (double fencing) to separate outside animals physically from the animals belonging to the colony. Initiation of such practices may reduce spread of infectious diseases like TB etc. found more frequently in Indian colonies of macaques in various establishments and thought to be unavoidable.

**SOCIAL ENVIRONMENT**

(a) The social environment includes all interactions among individuals of a group or among those able to communicate. The effects of social environment in caged animals vary with the species.

(b) In selecting a suitable social environment, attention should be given whether the animals are naturally territorial or communal and accordingly they should be housed single or in groups.
(c) When appropriate, group housing should be considered for communal animals. In grouping animals, it is important to take into account population density and ability to disperse; initial familiarity among animals; and age, sex, and social rank.
(d) Population density can affect reproduction, metabolism, immune responses, and behaviour. Group composition should be held as stable as possible, particularly for canine, non-human primates, and other highly social mammals, because mixing of groups or introducing new members can alter behavioural and physiological functions.
(e) Non-human primates should have a run for free ranging activities.

**ACTIVITY**

(a) Provision should be made for animals with specialized locomotor pattern to express their natural habitat, especially when the animals are held for long periods. e.g., artificial trees, ropes, bars, and perches are appropriate for non-human primates.
(b) Cages are often used for short-term (up to 3 months) housing of dogs and may be necessary for postsurgical care, isolation of sick dogs, and metabolic studies.
(c) Pens, runs, or other out-of-cage space provide more opportunity for exercise, and their use is encouraged when holding dogs for long periods.

**FOOD**

(a) Animals should be fed with palatable, non-contaminated, and nutritionally adequate food daily unless the experimental protocol requires otherwise.
(b) Feeders should allow easy access, while avoiding contamination by urine and faeces.

(c) Food should be provided in sufficient amounts to ensure normal growth in immature animals and to maintain normal body weight, reproduction, and lactation in adults.
(d) Food should contain adequate nutrition, with proper formulation and preparation; and ensure free from chemical and microbial contaminants; bio-availability of nutrients should be at par with the nutritional requirements of the animal. The animal feed should contain moisture, crude fibre, crude protein, essential vitamins, minerals, crude fat and carbohydrate for providing appropriate nutrition.
(e) Laboratory animal diets should not be manufactured or stored in facilities used earlier for farm feeds or any products containing additives such as rodenticides, insecticides, hormones, antibiotics, fumigants, or other potential toxicants.
(f) Areas in which diets are processed or stored should be kept clean and enclosed to prevent entry of insects or other animals.
(g) Precautions should be taken if perishable items such as meats, fruits, and vegetables are fed, because these are potential sources of microbiological and chemical contamination and can also lead to variation in the amount of nutrients consumed.
(h) Diet should ideally be free from heavy metals (e.g., Lead, Arsenic, Cadmium, Nickel, Mercury), naturally occurring toxins and other contaminants. Exposure to extremes of relative humidity, unsanitary conditions, light, oxygen, and insects hasten the deterioration of food.
(i) Meats, fruits, vegetables, and other perishable items should be refrigerated if required to be stored. Unused, open food should be stored in vermin proof conditions to minimize contamination and to avoid potential spread of disease causing agents.

(j) Food hoppers should not be transferred from room to room unless cleaned and properly sanitized.

**BEDDING**

(a) Bedding should be absorbent, free from toxic chemicals or other substances that cause irritation, injure animals or personnel, and of a type not readily eaten by animals. Bedding should be used in amounts sufficient to keep animals dry between cage changes without coming into contact with watering tubes.

(b) Bedding should be removed and replaced periodically with fresh materials as often as necessary to keep the animals clean and dry. The frequency is a matter of professional judgement of animal care personnel in consultation with the investigation depending on the number of animals and size of cages. In general it is ideal to change the bedding twice a week or whenever requires.

(c) The desirable criteria for rodent contact bedding is ammonia binding, sterilizable, deleterious products not formed as a result of sterilization, easily stored, non - desiccating to the animal, uncontaminated, unlikely to be chewed or mouthed, non - toxic, non - malodorous, nestable, disposable by incineration, readily available, remains stable during use, manifests batch uniformity, optimizes normal animal behaviour, non - deleterious to cage - washers, non - injurious and non - hazardous to personnel, non - nutritious and non - palatable.

(d) Nesting materials for newly delivered pups should be provided wherever needed (e.g. Paper cuttings, tissue paper, cotton etc.).

**WATER**

(a) Animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their requirements. Periodic monitoring of microbial contamination in water is necessary.

(b) Watering devices, such as drinking nozzles and automatic waterers should be examined routinely to ensure their proper operation. Sometimes it is necessary to train animals to drink water from automatic watering devices.

(c) Animals should receive appropriate, uncontaminated and nutritionally adequate food according to accepted requirements for the species. The food should be in sufficient quantity and of appropriate composition to maintain normal growth of immature animals, normal weight of adult animals or provide for the requirements of pregnancy or lactation.

(d) When animals are fed in groups, there should be sufficient trough space or feeding points to cater to the number and size of animals that eat together at one time so as to avoid undesirable competition for food, especially if feed is restricted.

(e) Uneaten perishable food should be removed promptly unless contrary to the eating habits or needs of the species. Any alteration to dietary regimes should be gradual.

**SANITATION AND CLEANLINESS**

(a) Sanitation is an essential activity in an animal facility. Animal rooms, corridors, storage spaces, and other areas should be properly cleaned with appropriate detergents and disinfectants as often as necessary to keep them free of dirt, debris, and harmful agents of contamination.

(b) Cleaning utensils, such as mops, pails, and brooms, should not be transported between animal rooms.

(c) Where animal waste is removed by hosing or flushing, this should be done at least twice a day. Animals should be kept dry during such procedures. For larger animals, such as dogs, cats, and non - human primates, soiled litter material should be removed twice daily.
(d) Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipments, such as feeders and watering devices, should be washed and sanitized frequently to keep them clean and contamination free. Generally this can be achieved by washing solid bottom rodent cages and accessories once or twice a week and cages, racks at least monthly.
(e) Wire - bottom cages other than rodent cages should be washed at least every 2 weeks. It is good practice to have extra cages available at all times so that a systematic cage-washing schedule can be maintained. Cages can be disinfected by rinsing at a temperature of 82.2C (180oF) or higher for a period long enough to ensure the destruction of vegetative pathogenic organisms.
(f) Disinfection can also be accomplished with appropriate chemicals. Equipments should be rinsed free of chemicals prior to use. Periodic microbiologic monitoring is useful to determine the efficacy of disinfection or sterilization procedures.
(g) Rabbits and some rodents, such as guinea pigs, mice and hamsters, produce urine with high concentration of proteins ammonia and minerals. Minerals and organic compounds in the urine from these animals often adhere to cage surfaces and necessitate treatment with acid solutions before washing.

(h) Water bottles, sipper nozzles stoppers, and other watering equipment should be washed and then sanitized by rinsing with water of at least 82.2oC (180oF) or appropriated chemicals agents (e.g. Sodium Hyperchlorite) to destroy pathogenic organisms, if bottles are washed by hand, mechanized brushes at the washing sink are useful, and provision should be made for dipping or soaking the water bottles in detergents and disinfectant solutions. A two – compartment sink or tub is adequate for this purpose.

(i) Some means for sterilizing equipments and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present. Routine sterilization of cages, feed and bedding is also essential besides care is taken to use clean materials from reliable sources. Where hazardous biological, chemical, or physical agents are used, a system of equipment monitoring might be appropriate.
(j) Deodorants or chemical agents other than germicidal agents should not be used to mask animal odours. Such products are not a substitute for good sanitation.

**ASSESSING THE EFFECTIVENESS OF SANITATION**

(a) Sanitation practices should be monitored appropriately to ensure effectiveness of the process and materials being cleaned; it can include visual inspection of the materials, monitoring of water temperatures, or microbiologic monitoring.
(b) The intensity of animal odours particularly that of ammonia should not be used as the sole means of assessing the effectiveness of the sanitation program.
(c) A decision to change the frequency of such bedding changes or cage washing should be based on factors such as the concentration of ammonia, appearance of the cage, condition of the bedding and number and size of the animals housed in the cage.
(d) Autoclaving: Chemical Indicator - batch wise assessment; Biological indicator - Periodical assessment.

**WASTE DISPOSAL**

(a) Wastes should be removed regularly and frequently. All waste should be collected and disposed off in a safe and sanitary manner. The most preferred method of waste disposal is incineration. Incinerators should be in compliance with all central, state, and local Public Health and Pollution Control Board regulations.

(b) Waste containers containing animal tissues, carcasses, and hazardous wastes should be lined with leak - proof, disposable liners. If wastes must be stored before removal, the waste storage area should be separated from other storage facilities and free of flies, cockroaches, rodents, and other vermin. Cold storage might be necessary to prevent decomposition of biological wastes. Hazardous wastes should be rendered safe by disinfection, decontamination, or other appropriate means before they are disposed of from an animal facility.

**PEST CONTROL**

Adaptation of Programs designed to prevent, control, or eliminate the presence of or infestations by pests are essential in an animal home environment. Best results can be achieved by giving contracts to people/firm specialized in pest control.

**EMERGENCY, WEEKEND AND HOLIDAY CARE**

There should be an institutional policy to care animals by qualified personnel every day, including weekends and holidays, to safeguards their well - being including emergency veterinary care. In the event of an emergency, institutional security personnel and fire or police officials should be able to reach responsible persons for the animals. That can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animals facilities or by placing them in the security department or near telephone. A disaster plan that takes into account both personnel and animals should be prepared as part of the overall safety plan for the animal facility.

**RECORD KEEPING**

It is essential that animal House should maintain following records:

- Animal House plans, which includes typical floor plan, all fixtures etc.
- Animal House staff record - both technical and non - technical
- Health record of staff and animals
- All SOPs relevant to experiments, care, breeding and management of animals
- Breeding, stock, purchase and sales records
- Minutes of institutional Animals Ethics Committee Meetings
- Records of experiments conducted with the number of animals used (copy of Form D)
- Mortality, Post-mortem Record, wherever required.
- Clinical record of sick animals.
- Training record of staff involved in animal activities
- Water, feed and bedding materials analysis report
- Health monitoring Records.
- Rehabilitation Records, wherever required.

**STANDARD OPERATING PROCEDURES (SOPs) / Guidelines**

The Institute should maintain SOPs describing procedures / methods adapted with regard to Animal Husbandry, maintenance, breeding, animal house activities microbial testing and experimentation.

A SOP should contain the following items:

- Name of the Author
- Title of the SOP
- Date of approval
- Reference of previous SOP on the same subject and date (Issue number and Date)
- Location and distribution of SOP's with sign of each recipient.
- Objectives
- Detailed information of the instruments used in relation with animals with methodology (Model no., Serial no., Date of commissioning, etc)
- The name of the manufacturer of the reagents and the methodology of the analysis pertaining to animals
- Normal value of all parameters
- Hazard identification and risk assessment

**PERSONNEL AND TRAINING**

(a) The selection of animal facility staff, particularly the staff working in animal rooms or involved in transportation, is a critical component in the management of an animal facility.

(b) The staff must be provided with all required protective clothing (face masks, head covers, aprons, gloves, gumboots, other footwear etc.) while working in animal rooms. Facilities should be provided for change over with lockers, wash basin, toilets and bathrooms to maintain personal hygiene. It is also important a regular medical check-up is arranged for the workers to ensure that they have not picked up any zoonotic infection and also that they are not acting as a source of transmission of infection to the animals. The persons working in animal house should not eat, drink, smoke in animal room and have all required vaccination, particularly against Tetanus and other zoonotic diseases.

(c) Initial in-house training of staff at all levels is essential. A few weeks must be spent on the training of the newly recruited staff, teaching them the animal handling techniques, cleaning of cages and importance of hygiene, disinfection and sterilization. They should also be made familiar with the activities of normal healthy and sick animals so that they are able to spot the sick animal during their daily routine check-up of cages.

**TRANSPORT OF LABORATORY ANIMALS**

(a) The transport of animals from one place to another is very important and must be undertaken with care. The main considerations for transport of animals are, mode of transport, containers, animal density in cages, food and water during transit, protection from transit infections, injuries and stress.

(b) The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable movement and protection from possible injuries. Sometimes injuries can be avoided by reducing space but parallely decreasing time of transportation. The food and water should be provided in suitable containers or in suitable form so as to ensure that they get adequate food and more particularly fluid during transit. The transport containers (cages

or crates) should be of appropriate size and only a permissible number of animals should be accommodated in each container to avoid overcrowding and infighting.

**ANAESTHESIA AND EUTHANASIA**

(a) The investigators should ensure that the procedures, which are considered painful, are conducted under appropriate anaesthesia as recommended for each species of animals.

(b) It must also be ensured that the anaesthesia is given for the full duration of experiment and at no stage the animal is conscious to perceive pain during the procedure. If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irreparable injury, the animal should be humanely sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia.

(c) In the event of a decision to sacrifice an animal or termination of an experiment or otherwise an approved method of euthanasia should be adopted and the investigator must ensure that the animal is clinically dead before it is sent for disposal. The data of all the animals, that have been euthanized, should be maintained.

I. **Anaesthesia**

(a) Unless contrary to the achievement of the results of study, sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment. Anaesthetic agents generally affect cardiovascular, respiratory and thermo-regulatory mechanism in addition to central nervous system.

(b) Before using actual anaesthetics the animals are prepared for anaesthesia by overnight fasting and using pre-anaesthetics, which block parasympathetic stimulation of cardio-pulmonary system and reduce salivary secretion. Atropine is most commonly used anti-cholinergic agent. Local or general anaesthesia may be used, depending on the type of surgical procedure.

(c) Local anaesthetics are used to block the nerve supply to a limited area and are used only for minor and rapid procedures. This should be carried out under an expert supervision for regional infiltration of surgical site, nerve blocks and for epidural and spinal anaesthesia.

(d) A number of general anaesthetic agents are used in the form of inhalants. General anaesthetics are also used in the form of intravenous or intra-muscular injections such as barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side - effects such as excess salivation, convulsions, excitement and disorientation should be suitably prevented and controlled. The animal should remain under veterinary care till it completely recovers from anaesthesia and postoperative stress.

II. **Euthanasia**

Euthanasia should be resorted to events where an animal is required to be sacrificed to reduce suffering or to limit spread of infections or for termination of an experiment or for other ethical reasons. The procedure should be carried out quickly and painlessly in an atmosphere free from fear or anxiety. For accepting an euthanasia method as humane it should have an initial depressive action on the central nervous system for immediate insensitivity to pain. The choice of a method will depend on the nature of study, the species of animal to be killed. The method should in all cases meet the following requirements:

(a) Death, without causing anxiety, pain or distress with minimum time lag phase.

(b) Minimum physiological and psychological disturbances.

(c) Compatibility with the purpose of study and minimum emotional effect on the operator.

(d) Location should be separate from animal rooms and free from environmental contaminants.

Tranquilizers have to be administered to larger species such as monkeys, dogs and cats before a procedure of euthanasia.

**LABORATORY ANIMAL ETHICS**

All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view, it is important that such considerations are taken care at the individual level, at institutional level and finally at the national level. Interaction amongst people working in animal house should be organised once in a while to discuss ethical issues favouring wellbeing of animals

**TRANSGENIC ANIMALS**

Transgenic animals are those animals, into whose germ line foreign gene(s) have been engineered, whereas knockout animals are those whose specific gene(s) have been disrupted leading to loss of function. These animals can be bred to establish transgenic animal strains. Transgenic animals are used to study the biological functions of specific genes, to develop animal models for diseases of humans or animals, to produce therapeutic products, vaccines and for biological screening, etc. These can be either developed in the laboratory or procured for R&D purpose from registered scientific/academic institutions or commercial firms, generally from abroad with approval from appropriate authorities.

**MAINTENANCE**

Housing, feeding, ventilation, lighting, sanitation and routine management practices for such animals are similar to those for the other animals of the species as given in guidelines. However, special care has to be taken with transgenic/gene knockout animals where the animals can become susceptible to diseases where special conditions of maintenance are required due to the altered metabolic activities. The transgenic and knockout animals carry additional genes or lack genes compared to the wild population. To avoid the spread of the genes in wild population, care should be taken to ensure that these are not inadvertently released in the wild to prevent cross breeding with other animals. The transgenic and knockout animals should be maintained in clean room environment or in animal isolators.

**DISPOSAL**

The transgenic and knockout animals should be first euthanized and then disposed off as described elsewhere in the guidelines. A record of disposal and the manner of disposal should be kept as a matter of routine.

**BREEDING AND GENETICS**

For initiating a colony, the breeding stock must be procured from established breeders or suppliers ensuring that genetic makeup and health status of animal is known. In case of an inbred strain, the characters of the strain with their gene distribution and the number of inbred generation must be known for further propagation. The health status should indicate their origin, e.g. conventional, specific pathogen free or transgenic, gnotobiotic or knockout stock.

As per the above guidelines, our university has constituted Institutional Animals Ethics Committee (IAEC), approved by **CPCSEA** (Annexure-I).

प्रोफेसर (डॉ.) कन्हैया लाल श्रीवास्तव
कुलपति
जय नारायण व्यास विश्वविद्यालय
जोधपुर (राजस्थान)

F.No:25/499/2010-AWD
Date: 28/Mar/2018

To,

Dr. Ashok Purohit,Chairman, IAEC
Department of Zoology
Jai Narain Vyas University, Jaipur- 342001 Rajasthan
E-mail:purohit1411@rediffmail.com
Mobile:9413118800/

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)-regarding

Sir,

The registration of Animal House Facility of your establishment with CPCSEA has been renewed for a period of five years from the date of issue of this letter.

2. The new registration number of Animal House Facility of your establishment is 1646/GO/a/12/CPCSEA for Research for Education purpose on small animals. Henceforth, the new registration number may kindly be quoted in all your correspondences in future.

3. The CPCSEA has accepted the following members recommended by the establishment.

| Name of the IAEC Members | Designation in IAEC |
|---|---|
| 1) Dr Ashok Kumar Purohit | Scientist Incharge of Animal House Facility, Chairperson |
| 2) Dr. Heera Ram | Biological Scientist, Member Secretary |
| 3) Dr. Jaykaran Charan | Scientist from different biological discipline |
| 4) Dr. Prasunpriya Nayak | Scientist from different biological discipline |
| 5) Dr. Sajay Krishna Vyas | Veterinarian |

4. CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

| Details of Nominee(s) | Nominated as |
|---|---|
| 1) Dr. Subhash Chand<br>Assistant Professor, Dept. Of Extension Education, Post Graduate Institute of Veterinary Education and Research (PGIVER), N.H.-11, Agra Road (Oppo. Chanda Garden), Jamdoli, Jaipur 302031<br>Contact No :08290010544<br>Email :dryadavsubhash@gmail.com | Main Nominee |
| 2) Shri Charanjeet Singh<br>Asstt. Professor, Arya College of Pharmacy, SP-40, RIICO Industrial Area Kukas, Delhi Road, Jaipur, Rajasthan - 302028<br>Contact No :9413084600<br>Email :charanjeet2004@gmail.com | Link Nominee |
| 3) Dr. Mohan Lal Yadav<br>Veterinary Officer, In-Charge, Govt. Veterinary Hospital - Bilaheri, Teh. Kotkasim, Dist. Alwar, Rajasthan<br>Contact No :7597809380<br>Email :drymohan@gmail.com | Scientist from outside the Institute |
| 4) Mr. Sunil Chhimpa<br>Lab No. 34, Dept of Zoology, University of Rajasthan, Jaipur – 302004, Rajasthan<br>Contact No :9414926365<br>Email :suneel.chhimpa@rediffmail.com | Socially Aware Nominee |

*(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)*

5. The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

6. You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

7. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings .Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC.Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year.Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

8. It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval ( procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours faithfully,

(S. Gowri Shankar)
Deputy Secretary (AW) & Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.