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CCSEA GUIDELINES FOR LABORATORY ANIMAL FACILITY

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INTRODUCTION

The Ministry of Fisheries, Animal Husbandry and Dairying have changed the name of the committee that controls and monitors the experiments on animals from the "Committee for the Purpose of Control and Supervision of Experiments on Animals" (CPCSEA), to the "Committee for Control and Supervision of Experiments on Animals (CCSEA") through its order dated January 06, 2023. The guidelines of CPCSEA were implemented in the year 1998. The focus of the latter guidelines was to control and supervise the experiments on the animals that are used in biomedical institutions, veterinary research institutions and research laboratories for educational and research purposes. In 2004, the CPCSEA officially accepted the concept of the 4Rs concept such as replacement, reduction, refinement and rehabilitation of experimental animals to promote human care of affected animals.

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) is a statutory committee established under the Prevention of Cruelty to Animals Act, 1960, by the Government of India. The basic aim of CPCSEA is to ensure ethical treatment and care of animals in education and research so that humane science values are promoted. Laboratory animal houses where scientific work and experiments are conducted on animals fall under rigorous rules and regulations formulated by CCSEA so that animals will not endure any pain or suffering. The guidelines are detailed and encompass areas such as housing animals, their care, breeding, transportation, and experimental procedures, so that the utilization of animals is justified and alternatives are sought. These guidelines are critical in weighing scientific advancement and the protection of animals. Organisations that use laboratory animals must register with CCSEA and also form Institutional Animal Ethics Committees (IAECs) to manage and regulate animal use based on required protocols.

CCSEA guidelines give particular significance to the ethical obligation of replacing, reducing, and refining (3Rs) animals in research. Replacement measures that replace or eliminate the use of animals; reduction measures that

minimise the number of animals used; and refinement are modifications that reduce suffering and maximize animal welfare. These are globally adopted and are a foundation of CCSEA guidelines. Laboratory animal facilities are thus tasked with embracing practices that align with the 3Rs, for example, spending in alternative methods such as computer simulation and in-vitro testing whenever it is possible. These guidelines are pivotal in advancing responsible science because they ensure that laboratory animals' well-being and dignity are upheld throughout all stages of research (Gupta et.al, 2014).

Among the most important topics of the CCSEA guidelines is the infrastructure and management of housing animals. Proper housing guarantees animal health, less stress, and more consistent experimental results. The guidelines provide stipulations for ventilation, lighting, temperature, humidity, noise levels, and sanitation conditions. Environmental enrichment of animals is encouraged to promote natural behavior and mental well-being. Staff members who deal with Animal Care must be well-trained and able to handle, feed, and monitor animals. Furthermore, cage facilities must maintain detailed records of animal use, health, breeding, and death. Regular audits and inspections are done by CCSEA to confirm that the prescribed standards are adhered to (Singh et.al, 2016).

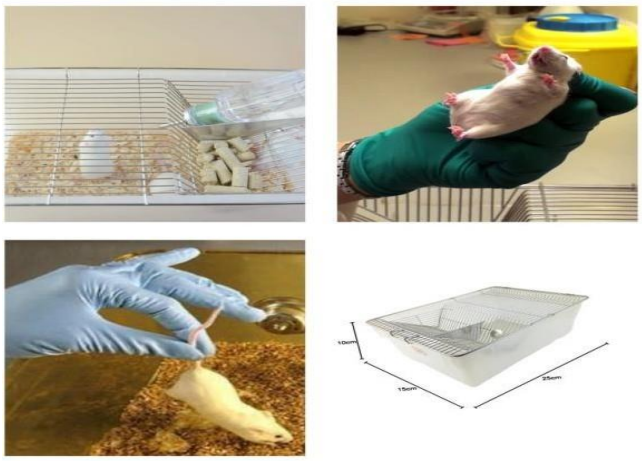

Figure 1: Animal handling and Cages.

The other very important component of the CCSEA framework is review and approval of research involving the use of animals on an ethical basis. Institutional Animal Ethics Committees (IAECs), which are constituted in every registered facility, review the proposals for research to look into the necessity and justification for animal use. The committees are diverse in membership, comprising scientists, veterinarians, and animal welfare organisation members. The IAECs ensure that all procedures recommended in the research plans reduce discomfort and fall under the 3Rs. Only projects with purely ethical and scientific reasons are cleared to carry out. This system of ethical supervision is at the core of humane treatment of laboratory animals and upholds the integrity of the research institute (Patel et.al, 2015).

CCSEA guidelines also include special requirements for the use and care of various species commonly employed in laboratories such as rodents, rabbits, guinea pigs and non-human primates. These species have certain physiological and psychological needs, and the guidelines provide species-specific requirements for housing, feeding, handling, and humane endpoints. Humane endpoints are pre-established criteria for ending an experiment early if an animal is in unbearable pain or distress. This aspect ensures that animal welfare takes priority even during scientific experiments. Also, animals being shipped have to comply with strict protocols to prevent stress and harm. Laboratories handling

import or export of research animals must acquire proper approvals and international standards of care in shipping (Sharma et.al 2013).

Figure 2: Animal images.

In addition, the CCSEA guidelines also promote ongoing education and training programs for everyone engaged in laboratory animal science. Seminars, workshops, and certification programs are advisable to develop a culture of care and responsibility within research institutions. The guidelines also promote public awareness and openness in animal research by supporting publication of ethical procedures and results. By promoting a culture of ethical awareness and scientific integrity, the CPCSEA guidelines help to build responsible biomedical research in India. This system not only conforms to international standards and practices but is also a demonstration of India's dedication to humane animal use in science.

Function of CCSEA

- Registration of the institution/ establishment conducting animal experimentation and breeding of animals for this purpose
- Selection and appointment of nominees in the IAEC of registered establishments
- Approval of animal house facilities based on reports of inspections conducted by CCSEA
- Permission for conducting animal experiments involving the use of animals
- Conduct training programs for the nominees of CCSEA, conduct/ support of conference/ works on animal ethics

What is an animal facility?

- An animal facility is a specialised laboratory exclusively for the purpose of holding and/or breeding specific animals for scientific purposes
- Laboratory animals are very sensitive to their living conditions, housed in an isolated building. Provide natural behaviours and social structure of the study species
- Separated from personnel areas such as offices and most laboratories
- Located as far away from human habitations as possible
- Not exposed to dust, smoke, noise, wild rodents, insects, and birds
- Sharp fluctuation in temperature, humidity, light, sound and ventilation should be avoided.

LITERATURE REVIEW

Akshay R. Yadav *et.al* (2020) Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) is a statutory body formed by the Act of the Indian Parliament under the Prevention of Cruelty to Animals Act 1960. The CPCSEA functions with a brilliant network of volunteers who liaise with the laboratories. For the first time in India: over 665 laboratories are registered with the CPCSEA; Institutional Animal Ethics Committees (IAECs) are constituted in every laboratory, which are only empowered to approve research project proposals that use rats, mice, guinea-pigs or rabbits; every project that uses canines, ovines, bovines or non-human primates can only be conducted if approved by the panel of scientific experts constituted for this purpose; guidelines on laboratory animal care and practice have been formulated and enforced; a protocol for the production of immune biologicals from equines has been formulated and ratified by the Supreme Court of India; the CPCSEA has been deliberating on alternatives and working out modalities to introduce alternatives in basic/regulatory research and education, in keeping with the international arena; the CPCSEA, to date, has rehabilitated and homed over 300 dogs, 150 equines, 200 non-human primates and several cattle, cats, birds, rabbits and mice; the CPCSEA proactively trains and guides scientific and non-scientific personnel on issues of alternatives and laboratory animal welfare; and the CPCSEA has fought legal issues on laboratory animal care and use and have had verdicts that favoured alternatives and animal welfare.

Leonal Rabins *et.al* (2022) in Handbook of Laboratory Animal Handling and Management offers a well-rounded summary of good practices in laboratory animal science, focusing on appropriate animal handling, restraint, and overall care throughout experimentation. The author emphasizes the crucial contribution of laboratory animals to the production of pharmaceuticals, vaccines, and biological research. Rabins refers to the moral structure that regulates animal use, using examples of institutional procedures like those of the Institutional Animal Ethics Committee (IAEC) and the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). The book delineates the legal and ethical requirements involved in conducting humane and scientifically reliable animal research in India. This manual, aimed mainly at postgraduate students in medical and veterinary sciences, is a guideline document that encourages ethical handling of animals while optimizing the scientific value of the experiments. It also stresses the need to harmonize animal care practices with the CPCSEA guidelines so as to achieve uniformity, reliability, and humanitarian quality of experiments in research centers.

Ujwala Ashokrao Jadhao *et al.* (2022) provides a comprehensive overview of laboratory animal handling techniques, highlighting their critical importance in the fields of drug discovery and development. The authors emphasize that for over three centuries, various animal species— including rats, mice, guinea pigs, dogs, cats, and monkeys—have been fundamental in the preclinical evaluation of pharmaceutical compounds before their administration in humans. Their review underscores that the proper handling, housing, transportation, and maintenance of laboratory animals are not merely ethical requirements but are also scientifically imperative. Factors such as cage design, environmental enrichment, sanitation, and nutrition significantly influence both animal welfare and the reliability of experimental data. Inadequate conditions can introduce physiological and psychological stress in animals, leading to skewed or unreliable results.

Deepak kumar *et.al* (2024) The Standard Operating Procedures (SOP) for the Institutional Animal Ethics Committee (IAEC) under the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) provide a structured framework for ethical oversight in animal research. These SOPs are designed to ensure compliance

with national regulations while promoting the welfare of animals used in scientific studies. The SOP outlines the composition, roles, and responsibilities of the IAEC, including the requirement for a minimum quorum for meetings and the mandatory attendance of CPCSEA nominees. It details the process for submitting research proposals, including deadlines and required documentation, ensuring that all submissions undergo thorough ethical review. The SOP also emphasizes the importance of maintaining records related to animal care, procurement, and experimental procedures, in line with CPCSEA guidelines. Moreover, the SOP incorporates the principles of the 3Rs (Replacement, Reduction, Refinement) to minimize animal use and enhance ethical standards in research practices. By adhering to these procedures, institutions can foster a culture of ethical responsibility and scientific integrity in animal research, ultimately contributing to the advancement of humane and scientifically valid experimental methodologies.

AIM AND OBJECTIVES

Aim

The primary aim of the Committee for Control and Supervision of Experiments on Animals (CCSEA) is to ensure ethical treatment, proper care, and humane use of animals in scientific research and education, while promoting alternatives to animal experimentation wherever possible.

Objectives

- To oversee and control experiments on animals to ensure they are conducted ethically and responsibly.
- To minimize pain, suffering, and distress to animals used in research, testing, and education.
- The goal of these guidelines is to promote the humane care of animals used in biomedical and behavioral research and testing.
- To avoid unnecessary pain before, during and after the experiment.
- To provide guidelines for

✓ Housing, care, breeding and maintenance.
✓ Source of experimental animals.
✓ Acceptable experimental procedures for anaesthesia and euthanasia.

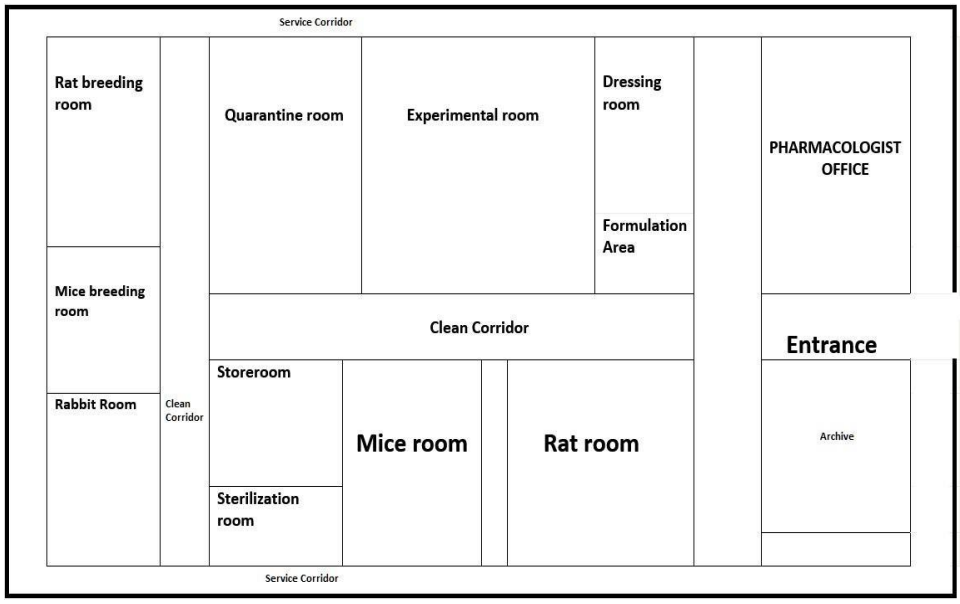

Figure 3: Animal house plan layout.

Key elements of Animal house

- Corridor
- Storeroom
- Sterilization room
- Quarantine room
- Rat room
- Breeding room
- Dressing room
- Rabbit room

KEY GUIDELINES FOR ANIMAL HOUSING

Animal House

- The animal house in the institute is divided into two areas such as large animal houses and small animal houses. There is a pathology laboratory and a medicine laboratory just before the common entry of the contained small and large animal houses. The pathology laboratory is a fully functional lab equipped with modern / latest instruments.
- The facility is in accordance with the needs, considering the environment, equipment and biosafety level required as per the guidelines and laws concerning experiments on animals. The facility also has an autoclave, air handling unit and feed storage rooms. The animal house of the institute is CCSEA-approved.

Large Animal House

- Large animal houses are a restricted area where human entry is through an air shower and animal entry through a holding area. There are a total of six rooms in LAH, of which two room are dedicated for housing calves, one room for sheep and goats, one room for pigs and two entirely separate challenge shed for carrying out challenge tests as desired by the potency testing of the vaccine under consideration.

Figure 4: Animal house.

Small Animal House

- Small animal house encompasses two wings, one for housing a healthy stock of poultry/ duck and another for mice/rats/guinea pig and rabbits and other laboratory animals. Both the wings have committed challenges sheds,

used to conduct potency testing.

- There is a provision for cages as per the requirements of the animals being housed. The design of the housing for laboratory animals provides the physiological conditions and habitat appropriate for the species. Access to these rooms is restricted, and air showers are used by the personnel entering the area. There is an independent clean and dirty corridor for the movement of hazardous and contaminated material to avoid cross-contamination.

Animal Care

- The laboratory houses rats, mice, and rabbits. Each species of an animal is housed in barrier-maintained individual rooms to avoid disease transmission and inter-species conflicts. All efforts are made to maintain the animals under controlled environment conditions [temperature (22-26 ^{o}c), Relative humidity (30–70%), 12 hr alternate light and dark cycle] with 100% fresh air exchange in animal rooms and uninterrupted power and water supply.
- The support staff ensures that every part of animal care, including feeding, watering, restraining, cage cleaning, record keeping and ordering of animals, feeds, bedding material and guarded from dust, smoke, noise, wild rodents, insects and birds, in fact anything that would disturb their habitat. A high degree of hygienic condition (macro and microenvironment) around the animal are maintained as per the CCSEA guidelines

Personal Hygiene

- 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 e.g. showers, change of uniforms, foot wears etc. 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.
- In some circumstances, it is acceptable to use disposable wear such as 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.
- Washing and showering facilities appropriate to the program should be available. Personnel should not be permitted to eat, drink, smoke or apply cosmetics in animal rooms. A separate area or room should be made available for these purposes.

FORMS	PURPOSE
FORM A [as per rule 5(a)]	Application for registration with CCSEA
FORM B (per rule 8(a)	Submission of research protocol(s) on large animals
FORM C	record of animals bred/ acquired
FORM D	Records of animals acquired and experiments performed
FORM E	Record of animals sold

IAEC – INSTITUTIONAL ANIMAL ETHICS COMMITTEE

The Institutional Animal Ethics Committee (IAEC) is a mandatory committee within an institution that uses animals for research, teaching, or testing.

It oversees, approves, and monitors all animal use to ensure it is ethical, humane, and legally compliant.

Objectives

- Supervision by a qualified person
- Due care and humanity to avoid pain
- Experiments on larger animals avoided
- Experiments not performed merely for the purpose of acquiring manual skills
- Animals are properly looked after before experiments
- Suitable records are maintained with respect to experiments performed on animals
- If recovery of animals involves serious suffering, should be destroyed while still insensible.

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 the animal
iv. One scientist in charge of the 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 a 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 Laboratory animals in a given protocol.

B. Nominees from the CCSEA

i. Main Nominee
ii. Link Nominee
iii. Scientist from outside the Institute
iv. Socially Aware Nominee

C. Process for project approval

- The process for project approval in an Institutional Animal Ethics Committee (IAEC) typically involves several key steps: submission of a project proposal in a prescribed form, review by IAEC members, potential revisions based on feedback, and final approval (or rejection).

IAEC Requirements

- The duration of the appointment is for a period of 3 years (coterminous with registration).
- The committee is required to be reconstructed at the time of renewal of registration, and at least half of the members will be replaced.
- 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.
- A member can tender resignation from the committee with proper reasons to do so.
- All members should maintain absolute confidentiality of all discussions during the meeting and sign a

confidentiality form.

- Conflict of interest should be declared by members of the IAEC.
- IAEC is required to formulate to SOP for its working requirements and follow it in all the meetings.

Function of IAEC

- To work for the achievement of objectives.
- Review and approve all types of research proposals involving small animal experiments before the start of the study.
- Monitor the research throughout the study and after completion of study through periodic reports.
- Visit to the animal house and laboratory where the experiments are conducted.

Application Procedures

- All proposals should be submitted in the prescribed application form, the details of which are given under documentation.
- All relevant documents with checklist should be enclosed with application form.
- Required number of copies of the proposal along with the application and documentation in prescribed format duly signed by the principal investigator (PI) and co-investigators/ collaborators should be submitted to IAEC.

Review Procedure

- The meeting of the IAEC should be held on scheduled intervals as prescribed in the concerned SOP of the IAEC, and additional meetings may be held if there are reasons to expedite the review.
- The proposals will be sent to members at least 15 days in advance.
- Decisions will be taken by consensus after discussions. Negative viewpoints should be recorded in the minutes. In case consensus is not reached, the case should be referred to CCSEA.
- Researchers will be invited to offer clarifications if need be.
- The decisions will be minute, and the chairperson's approval taken in writing with signature of all the IAEC members present.

Approval and Implementation

- Upon approval, the project can be initiated, provided all other necessary approvals (e.g., from funding agencies) are obtained.
- The research must adhere to the approved protocol and undergo periodic monitoring by the IAEC.
- Researchers may need to submit yearly progress reports and final reports to the IAEC.

Record Keeping and Archiving

- Final report of the approved projects.
- Record of import of animals with species, source, quantity, usage etc…
- Record of breeding of animals, supply etc, if breeding of animals is undertaken.
- Record of rehabilitation of large animals if done.
- Record of all contract research, if conducted at the institute.
- Copy of all study protocols with enclosed documents, progress reports.

ANIMAL HOUSE FACILITY STANDARD PHYSICAL FACILITIES

Building Materials

It 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.

Corridor(s)

It should be wide enough to facilitate the movement of personnel as well as equipment and should be kept clean.

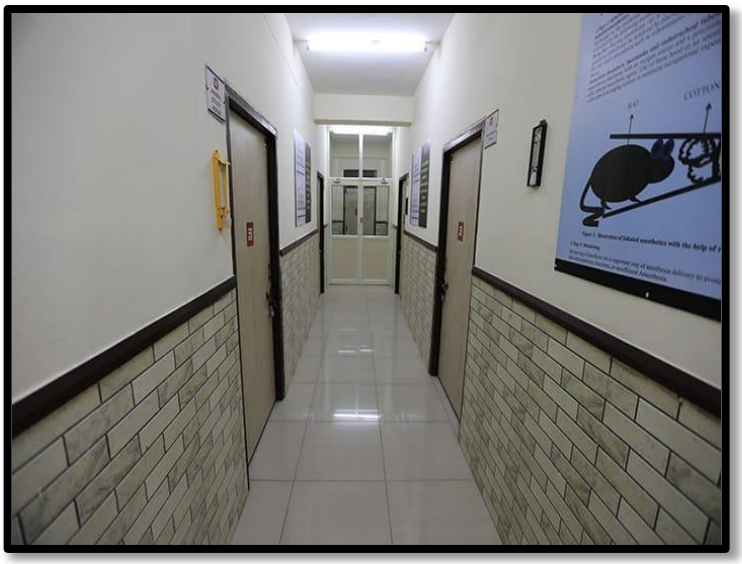

Figure 5: Corridor.

Utilities

Such as water lines, drainpipes, and electrical connections should preferably be accessible through service panels or shafts in corridors outside the animal rooms.

Animal Room Doors

Doors should not rust and should be vermin and dust-proof. They should fit properly within their frames and be provided with an observation window. Door closures may also be provided. Rodent barriers can be provided in the doors of the small animal facilities.

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 sources of light and ventilation. In private rooms, windows can be provided to have visual access to natural environment.

Floors

Floors should be either monolithic or epoxy smooth, moisture proof, nonabsorbent, skid-proof, 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 a minimum number of joints.

Drains

Floor drains are not essential in all rooms used exclusively for housing rodents. Floors 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.

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 the construction of the roof should cater for the needs of local climatic conditions to provide comfort to the animals.

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.

Facilities

For Sanitising Equipment and Supplies. An area for Sanitising cages and ancillary equipment is essential, with an adequate water supply

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.

Quarantine

Quarantine is the separation of newly received animals from those already in the animal facility. It determines microbial status of newly received animals

Minimizes the chance for introduction of pathogens into an established colony Duration – Small animals – 1 week
Large animals – 4 weeks

Figure 6: Separate room for animals.

Veterinary care

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.

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, behavior, and well-being is conveyed to the attending veterinarian.

The veterinarian can also contribute to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care, such as reviewing protocols and proposals, animal husbandry and animal welfare; monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation.

ENVIRONMENT

Temperature and humidity control

Air conditioning is an effective means of regulating these environmental parameters for laboratory animals. Temperature and humidity control prevent variations due to changing climatic conditions or differences in the number and kind of room occupants. Ideally, capability should be provided to allow variations within the range of approximately 18 to 29°C (64.4 to 84.2^{o}F), which includes the temperature ranges usually recommended for common laboratory animals.

The relative humidity should be controllable 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 by appropriate methods for cooling

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.

Power and lighting

The electrical system should be safe and provide appropriate lighting and enough power outlets. It is suggested that a lighting system be installed that provides adequate illumination while people are working in the animal rooms and a lowered intensity of light for the animals. Fluorescent lights are efficient and available in a variety of acceptable fixtures.

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

Noise control

The facility should be provided with noise noise-free environment. Noise control is an important consideration in designing an animal facility. Concrete walls are more effective than metal or plaster walls in containing noise because their density reduces sound transmission.

ANIMAL HUSBANDRY

Weekend and holiday care for the animals is essential. In the event of a disaster (including loss of power), inke sure you are aware of what needs to be done to care for the animals. Make sure you know all species-specific handling procedures Be careful to watch food and bedding supplies and order in advance. Some bedding materials are ordered on an annual basis.

Adequate space, maintenance of body temperature, urination, defecation and reproduction
Keep the animals dry and clean
Polypropylene, polycarbonate and stainless-steel cages should be used

Caging and Housing System

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 minimise experimental variables.

The housing system should:

- ✓ Provide adequate space, 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.

Sheltered or Outdoor Housing

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

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.

Ground-level surfaces of outdoor housing facilities can be 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 a contoured or drained surface. Other surfaces should be able to withstand the elements and be easily maintained.

Social Environment

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

In selecting a suitable social environment, attention should be given to whether the animals are naturally territorial or communal, and accordingly, they should be housed singly or in groups.

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.

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. Non-human primates should have a run for free-ranging activities:

ACTIVITY - Food

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

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 fiber, crude protein, essential vitamins, minerals, crude fat and carbohydrate for providing appropriate nutrition.

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

Figure 7: Food hoppers and water.

Water

Ordinarily animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their requirements. Watering devices, such as drinking tubes and automatic waters if used should be examined routinely to ensure their proper operation. Sometimes it is necessary to train animals to use automatic watering devices.

Sanitation and cleanliness

Cages should be sanitized before the animal is placed in them.

Cages and water bottles can be disinfected by rinsing at a temperature of 82.2^{o} c or by chemical agents such as hypochlorite to destroy pathogenic microbes. Autoclave or gas sterilizers can be used.

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

Cleaning utensils such as mops, pails, and brooms should not be transported between animal rooms.
Where animal waste is removed by hosting 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.

Animal cages, racks, and accessory equipment, such as feeders and watering devices, should be washed and sanitised frequently to keep them clean and contamination-free. Ordinarily, this can be achieved by washing solid-bottom rodent cages and accessories once or twice a week and cages, racks at least monthly

Waste disposal

Wastes should be removed regularly and frequently. All waste should be collected and disposed of in a safe and sanitary manner. The most preferred method of waste disposal is incinerators should comply with all central, state, and local regulations.

STANDARD OPERATING PROCEDURE (SOPs)/ GUIDELINES

The institute should maintain SOP'S describing procedures \methods adapted with regard to animal husbandry, maintenance, breeding, animal house activities microbial tasting 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 SOPs with the signature of each recipient.
- Objectives
- Detailed information of the instruments used in relation to 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 about animal's Normal value of all parameters.
- Hazard identification and risk assessment.

Breeding and Techniques

For initiating a colony, the breeding stock must be procured from CCSEA established breeders or suppliers, ensuring that the genetic makeup and health status of the animal is known. In case of an inbred strain, the characters of the strain with their gene distribution and the number of inbred generations must be known for further propagation. Health status should indicate its origin.

Personnel and Training

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.

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 changeovers with lockers, wash basin, toilets and bathrooms to maintain personal hygiene.

It is also important that a regular medical check-up is arranged for the workers to ensure that they have not picked up any zoonotic infection and that they are not acting as a source of transmission of infection to the animals. The people working in the animal house should not eat, drink, or smoke in the animal room.

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 the importance of hygiene, disinfection and sterilisation. 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.

Record Keeping

- Animal stock register
- Animal receipt register

- Animal issue register
- Mortality register
- Quarantine register
- Health monitoring register
- Treatment register
- Sanitation and disinfection register
- Feed and waterlog register
- Ethical clearance register
- SOP file
- Veterinary care file
- Cage cards register
- Training log register
- Disposal register

Transport of Laboratory Animals

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 the mode of transport, the container, the animal density in cages, food and water during transit, protection from transit infection, injuries and stress.

The mode of transport of animals depends on the distance, seasonal and climate conditions and the species of animals. Animals can be transported by road, rail or air, taking into consideration of above factors. The food and water should be provided in suitable containers or in a suitable form so as to ensure that they get adequate food and, more particularly, water during transit.

Requirements for the transport of laboratory animals

Requirements	Mouse	Rat
Maximum no. of animals per cage	25	25
Material used in transport box	Metal cardboard, synthetic material	Metal cardboard, Synthetic material
Space per animal (cm.sq.)	20-25	80-100
Maximum height of the box (cm)	12	14

Anaesthesia and Euthanasia

Scientists should ensure that the procedures which are considered painful are conducted under appropriate anaesthesia as recommended for each species of animal. It must also be ensured that the anaesthesia is given for the full duration of the experiment, and at no stage is the animal conscious of perceiving pain during the experiment. 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 sacrificed.

Neuromuscular blocking agents must not be used without adequate general anesthesia. In the event of a decision to sacrifice an animal on 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 about large animals which have been euthanized should be maintained.

Anaesthesia

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

Before using actual anaesthetics, the animal is prepared for anaesthesia by overnight fasting and using pre-anaesthetics, which block parasympathetic stimulation of the cardio-pulmonary system and reduce salivary secretion.

Atropine is the most used anticholinergic agent. Local or general anaesthesia may be used, depending on the type of surgical procedure. 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 expert supervision for regional infiltration of surgical sites, nerve blocks and for epidural and spinal anaesthesia.

Several general anaesthetic agents are used in the form of inhalation. General anaesthetics are also used in the form of intravenous or intramuscular injections, such as barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side effects such as excessive 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.

Drugs (mg/kg)	Mouse	Rat
Ketamine HCl	22-24 i/m	22-24 i/m
Pentobarbitone sodium	35 i/v	25 i/v
Pentobarbitone sodium	50 i/p	50 i/p
Thiopentone sodium	25 i/v	20 i/v
Thiopentone sodium	50 i/p	50 i/p
Urethane	-	0.75 i/p

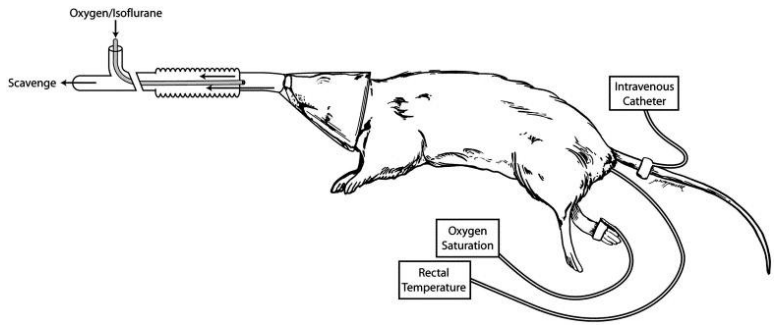

Figure 8: Anesthesia.

Euthanasia

Euthanasia is resorted to events where an animal is required to be sacrificed on termination of an experiment or otherwise for 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 be 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 an euthanasia procedure.

Figure 9: Euthanasia.

PRINCIPLES AND IMPLEMENTATION

The 3R principles—Replacement, Reduction, and Refinement—are fundamental ethical guidelines aimed at promoting humane practices in animal research. The CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) incorporates these principles into its Standard Operating Procedures (SOPs) for the Institutional Animal Ethics Committee (IAEC) as follows:

Replacement

This principle encourages researchers to find alternatives to animal use whenever possible. This can include using in vitro methods, computer modelling, or other non-animal techniques to achieve research objectives. The CPCSEA SOPs mandate that researchers justify the necessity of using animals in their proposals, promoting the exploration of alternatives before approval.

Reduction

Reduction aims to minimise the number of animals used in experiments. CPCSEA SOPs require researchers to design studies that use the smallest number of animals necessary to achieve valid results. This includes statistical planning to ensure that the sample size is adequate to meet research goals without unnecessary duplication of experiments.

Refinement

Refinement focuses on enhancing animal welfare by minimising pain and distress. CPCSEA SOPs emphasise the need for researchers to adopt practices that improve the living conditions of animals and reduce suffering during procedures. This may involve using an anaesthesia, analgesia, and improved housing conditions, as well as training personnel to handle animals humanely.

CONCLUSION

Use of animals in research is a highly debatable topic. Though their use has led to several discoveries and an understanding of many aspects of science but their use in certain sectors needs to be justified. There are national and international laws which govern the use of animals in research, all of which are based on the principles of the 4Rs-replacement, reduction and refinement and the rehabilitation of the use of animals in research.

All institutions involved in animal research must develop and abide by the ethical review processes which promote good animal welfare practices by ensuring that the use of animals at the designated establishment is justified. With the availability of many alternatives, the lives of many animals can now be secure.

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