



CPCSEA GUIDLINES TO CONDUCT EXPERIMENT IN ANIMALS

(Pharmacological and Toxicological Screening Methods)

INTRODUCTION

- The 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.
- Revived in 1998, under the committed chairpersonship of Meneka Gandhi.
- The CPCSEA guidelines are a set of regulatory measures and recommendations aimed at promoting the ethical treatment of animals used in research and experimentation.
- These guidelines provide a framework for researchers, institutions, and ethics committees to ensure that experiments involving animals are conducted in a manner that minimizes harm and complies with established ethical standards.

- Its main purpose is to ensure that animals are not subjected to unnecessary pain or suffering during experiments and that the use of animals is minimized wherever possible.
- Head Quarters at Chennai.

Core Members:

- ❖ Smt. Maneka Gandhi- Chair person
- ❖ Mr. A.K. Joshi- member secretary

Sub-Committee Members:

- ❖ Dr. Manju Sharma (Secretary, Department of Biotechnology members)
- ❖ Dr. Vasanth Muthuswamy (Sr. DDG, Indian Council of Medical Research)

COMPOSITION

This committee is composed of:

- Members of the scientific community
- Regulatory Authority
- Animal activists
- The committee has 10 experts and 3 official members

Ministry of
Environment and
Forests
(Animal welfare)

CPCSEA

IAEC

IBSC/IBC

IAEC: Institutional animals ethical committee
IBSC/IBC: Institutional biosafety ethical committee

CPCSEA AND IAEC

- Role of CPCSEA is to monitor animal experiments through ethics committees set up in Institutions (IAEC).
- CPCSEA Nominee- important link between CPCSEA and IAEC.
- IAEC scrutinize all project proposals for experimentation on animals.
- ✓ For small animals- give the final approval
- ✓ For large animals- make its recommendation to SCLA (**Sub-Committee on large animals**).

IAEC COMPOSITION

- **A biological Scientist.**
- **Two Scientists from different bio disciplines.**
- **A Veterinarian involved in care of Animals.**
- **Scientist In- Charge of animal house Facility.**
- The Chairman (preferably Head of the Institution/ Department) and Member Secretary need to be nominated from above five members.
- Other members: Main Nominee, Link Nominee nominated by CPCSEA.
- The validity Of IAEC is for 3 years.

❖ Objective:

- The goal of these guidelines is to promote the human care of animal use in biomedical and behavioural research and testing.
- To avoid unnecessary pain before, during and after experiment.
- Guidelines for housing, caret breeding and maintenance of animals should be provided.
- To regulate experimentation on the animal, the committee has formulated "Breeding of & experiments on animals(control & supervision) rules, 1998" which were amended in 2001 & then in2006.

FUNCTIONS

- 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.

QUARANTINE, STABILIZATION AND SEPARATION

- 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 mimminizes the chance for introduction of pathogens into an established colony.
- The duration at quarantine in small lab animals from one week to one month to one week to one month and large animals allowed up to 6 weeks.
- For non-human primates the period varies from 2 to 3 months depending on the reaction of TB testing.
- 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.
- Different species should ideally be housed in different rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators shall be suitable alternatives.

SURVEILLANCE, DIAGNOSIS, TREATMENT AND CONTROL OF DISEASE

- All animals should be observed for signs of illness, injury, or abnormal behaviour.
- Unexpected deaths and signs of illness should be reported; Post-mortem examination should be reported for timely delivery of veterinary medical care.
- If animals are known to be exposed to an infectious agent the group should be kept intact and isolated during the process of diagnosis, treatment, and control.
- Diagnosis clinical laboratory may be made available.

ANIMAL HUSBANDRY

- Caging and outdoor housing:
 - Caging should be designed carefully to facilitate animal well being, and also to minimize experimental variables.
 - Polypropylene, polycarbonates and stainless steel cages should be used to house small lab animals.
 - Outer housing should be accessible to all animals with sufficient ventilation, furnishing and to prevent the accumulation of waste materials.

➤ Social environment:

- The social environment includes all interactions among those able to communicate.
- Population density can affect reproduction, Metabolism, immune response & behaviour.
- Non-human primate should have a ranging activities
- FOOD
- BEDDING
- WATER
- SANITATION & CLEANLINESS

➤ Waste disposal:

- Waste should be removed regularly and frequently.
- Hazardous waste should be rendered safe by sterilization and decontamination.
- Most preferred method of waste disposal is incineration.

➤ 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.

➤ Record Keeping:

- 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.
- Health monitoring Records.
- Rehabilitation Records, wherever required,

ANIMAL HUSBANDRY AND MANAGEMENT

➤ ANIMAL CARE AND TECHNICAL PERSONNEL

- 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.
- Institutions should have policies governing experimentation with hazardous agents
- Personnel should change clothing as often as is necessary to maintain personal hygiene.

➤ SANITATION AND CLEANLINESS

- Animal room, corridors, storage spaces and other areas should be cleaned with appropriate detergents and disinfectants,
- For larger animals, such as dogs, cats, and nonhuman primates, soiled litter material should be removed twice daily.
- Water bottles, sipper nozzles stoppers, and other watering equipment should be washed and then sanitized by rinsing with water of at least 82.2°C (180°F) or appropriated chemical agents to destroy pathogenic organisms.
- Sanitation practices should be monitored appropriately

➤ 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:
- Animal must be observed regularly for sign of illness, injury, or abnormal behaviour.
- Any anomalies must be reported to veterinarian.
- In case of contagious disease-animal must be isolated from healthy animal.

ANIMAL PROCUREMENT

- All animals must be acquired lawfully as per the CPCSEA guidelines.
- A health surveillance program for screening incoming animals should be carried out before purchase to assess animal quality.
- 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.

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 while working in animal rooms.
- 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.

TRANSPORT OF LABORATORY ANIMALS

- 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.
- 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 of animals from one place to another is very important and must be undertaken with care.

STANDARD OPERATING PROCEDURES (SOP's):

- A SOP should contain the following items:
 - Name of the Author o Title of the sop o Date of approval o Reference of previous SOP on the same subject and date
 - (Issue number and Date) o Location and distribution of SOP's with sign of each recipient, o 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 o Normal value of all parameters
Hazard identification and risk assessment.


ANAESTHESIA AND EUTHANASIA:

➤ ANESTHESIA:

- Anesthesia is a medical treatment/process that prevents organism from feeling pain during surgery.
- 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.
- Neuromuscular blocking agents must not be used without adequate general anaesthesia.

➤ 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 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.

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