

Institutional Animal Ethics Committee (IAEC),

Nellore - 524003, Andhra Pradesh.

Registered with CPCSEA (No.: 1859/PO/Re/16/CPCSEA), Government of India

Standard Operating Procedure (SOP); Version -2; 2021



Foreword

Laboratory research animals are biologically similar to humans and they are susceptible to many health problems such as cardiovascular disorders, cancer, diabetes, Alzheimer's etc., with pathology similar to us. Hence, in the past centuries they were used in research to find therapies for various human ailments and will remain as the main stay model to understand and find solution to human health problems. Because, so far no other model was found to replace the complex biological functions of living, breathing, whole-organ system with pulmonary, circulatory systems etc., like those in humans. Animals have shorter life cycle on comparison to humans, research studies can be done throughout their entire life span and across several generations to understand the underlying genetic and epigenetic mechanisms and can be correlated with the disease onset and progression. The inheritance/susceptibility to disease in the offspring's and genomic imprinting can also be investigated. Ageing studies and drugs that increase the lifespan can be studied at ease in animal models. The versatility of genetic engineering to produce different transgenic animals is a boon to understand various diseases and develop interventions using modern molecular tools.

The well-being of research animals is of utmost importance for the biomedical research. If they are not treated well, then the research outcome and the knowledge derived may not be reproducible, gold standard of science. Improper maintenance of the light/dark cycles in animal house could affect their biological rhythm, which in turn will influence the results of the research. Thus, our Institutional Animal Ethics Committee (IAEC) was formed to emphasize the human care of laboratory animals and to reduce the animal suffering while performing experiments to achieve scientific aims; and framed this SOP to be a guide for researchers and all the personnel involved in animal care and research in our institution. I believe that this SOP is easy to understand and follow. Any suggestions to improve it are welcome



Dean

July 10, 2021

(Dr. Surya Prakasa Rao)

	Name	Designation in IAEC	Signature & Date
Prepared by	Dr. Sivakumar Vijayaraghavalu	Member Secretary	 July 10, 2021
Reviewed & Approved by	Dr. Surya Prakasa Rao	Chairman	 July 10, 2021

CONTENTS

S. No.	Particulars	Page Number
1.	Standard Operating Procedures (SOP) For IAEC	1
2.	Objectives	1
3.	Functions	2
4.	Composition of IAEC	2
5.	Institution nominated IAEC Members	3
6.	CPCSEA nominee for IAEC Members	3
7.	Membership Duration and Responsibilities	4
8.	Role of CPCSEA nominee and IAEC Members	4
9.	Quorum Requirements	9
10.	Conduct of the Meetings	9
11.	Application Procedure	9
12.	Review Procedure	10
13.	Decision Making	10
14.	Communication of the Decision	11
15.	Follow up Procedures	11
16.	Record Keeping and Archiving	11
17.	Updating IAEC members	12

18.	Reporting to CPCSEA	12
19.	Reimbursement to CPCSEA Representative	12
20.	Guidelines	12
21.	Animal Care	12
22.	Animal Procurement	13
23.	Quarantine	14
24.	Stabilization	14
25.	Separation	14
26.	Surveillance, Diagnosis, Treatment and Control of Disease	14
27.	Animal Care and Technical Personnel	15
28.	Personal Hygiene	15
29.	Multiple Surgical Procedures on Single Animal	15
30.	Durations of Experiments	16
31.	Physical Restraint	16
32.	Physical Facilities	16
33.	Location of Animal Facilities to Laboratories	17
34.	Functional Areas	17
35.	Animal Room Doors	18
36.	Environment	20

37.	Animal Husbandry	21
38.	Food	22
39.	Bedding	23
40.	Water	23
41.	Sanitation and Cleanliness	24
42.	Assessing the Effectiveness of Sanitation	25
43.	Waste Disposal	25
44.	Pest Control	25
45.	Emergency, Weekend and Holiday Care	25
46.	Performance of Experiments	26
47.	Documentation	27
48.	Elements of Review	28
49.	Form B – as per rule 8(a)* for Submission of Research Protocol (s)	29
50.	Form C: Record or animal bred/acquired	35
51.	Form D: Record or animal acquired and experiments performed	35
52.	Review of Projects in the IAEC Meeting	36
53.	Biodata and Consent Format for IAEC Members	37
54.	Fees Payable to CPCSEA	38
55.	Renewal of Registration & Reconstitution of IAEC	40

56.	Revision of IAEC	42
57.	Change of Nominee Request	42
58.	Submission of Minutes of IAEC Meeting	43
59.	Submission of Research Protocol(s) on Large Animals	44
60.	Amendment of Registration	46
61.	Submission of Inspection Report(s) by the Nominee of CPCSEA	47

IAEC - SOP, Narayana Medical College, Nellore, Andhra Pradesh

IAEC of Narayana Medical College (NMC), Nellore is registered with 'Committee for the Purpose of Control and Supervision of Experiments on Animals' (CPCSEA), Ministry of Environment, Forest and Climate Change, Animal welfare division, Government of India for research and education purpose vide registration no. (1859/PO/Re/16/CPCSEA). IAEC has been constituted to supervise and evaluate all aspects of the animal care and use program in the institution under Rule 5(a) of the breeding and Experiment on Animals (Control and Supervision) rules 1998; with a goal to perform scientific research involving experiments on animals ensuring ethical use of animals so that they are not subjected to unnecessary pain and sufferings.

Objectives:

The objective of this SOP is to contribute to the effective functioning of the 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. As well to review the following -

1. Form-B - Application for Permission for Animal Experiments [as per rule 8(a) for Submission of Research Protocol(s)] – Revised;
2. Form-C - Record of Animals bred / acquired – Revised and
3. Form-D - Record of Animals Acquired and Experiments performed – Revised, and inspect animal facilities, as well uphold 3R's principles of (Replacement, Reduction and Refinement) ensuring adherence to CPCSEA guidelines.
4. To promote humane care of animals used in education and biomedical research.

Functions:

The functions of IAEC are as follows:

- Review proposed use of animals in research and require any modifications necessary for approval or withhold approval prior to use of animals
- Approve research involving animals which conform to the various guidelines for use of animals in research
- Review periodically the Institute's animal facility
- Review and investigate legitimate concerns involving the care and use of animals during research
- Ensure that all personnel involved in animal care and use are appropriately qualified to carry out the proposed activities.

Composition of Institutional Animal Ethics Committee (IAEC):

1. A biological scientist (Chairperson)
2. Scientists from different biological disciplines (Member Secretary)
3. Scientists from different biological disciplines
4. One veterinarian involved in the care of animals
5. A scientist in charge animal house facility
6. Main nominee of CPCSEA
7. Link nominee of CPCSEA
8. A scientist from outside the institute – CPCSEA nominee
9. One socially aware person – CPCSEA nominee

Except CPCSEA nominees, all IAEC members are nominated by the Institution.

Table 1 – Institution nominated IAEC members

S. No.	Name of Member	Designation in IAEC	Designation in Narayana Medical College (NMC)
1.	Dr. V. Surya Prakasa Rao	Chairman & Biological Scientist	Dean, NMC
2.	Dr. Sivakumar Vijayaraghavalu	Member- Secretary & scientist from different biological discipline	Professor & Head, Narayana Translational Research and Incubation Centre (NTRIC), NMC.
3.	Dr. R. Venkataiah	Veterinarian	Veterinary Doctor, Dept. of Pharmacology, NMC.
4.	Mr. M. Vasanth Kumar	Scientist I/C of animal house facility	Assistant Professor, NTRIC, NMC.
5.	Mr. V. Bhopal Chandra	Scientist from different biological discipline	Tutor, Dept. of Pharmacology, NMC.

Table 2 – CPCSEA nominated IAEC members

S. No.	Name of Member	Designation in IAEC	Organization
1.	Prof. A. Sreedevi	Main Nominee	Professor & Head, Sri Padmavati Mahila Visvavidyalayam, Tirupati, Andhra Pradesh
2.	Dr. S. Vairamuthu	Link Nominee	Professor & Head, Centralized Clinical Laboratory, Madras Veterinary College, Chennai, Tamil Nadu
3.	Dr. K. Umamaheswara Rao	Scientist from outside of the Institute	Professor & Head, Dept. of Pharmacology, Sri Padmavathi Medical College for Women, Tirupati, A.P.
4.	Dr. Balagani Pavan Kumar	Socially aware Nominee	Principal, Gokula Krishna College of Pharmacy, Sullurpet, Nellore, A.P.

Authority under which IAEC are constituted and duration:

- Five names against serial numbers 1- 5 will be sent from the institute to CPCSEA for approval.
- The duration of IAEC will be for the period of 5 years.
- The IAEC will be reconstituted at the time of renewal of registration to CPCSEA.
- Changes can be made in deserving cases with the approval of CPCSEA.

Membership duration and responsibilities:

- The duration of membership will be for 5 years (coinciding with renewal of registration).
- The committee will be reconstituted 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 long-term non-availability (three consecutive meetings) or death
- Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term.
Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- Conflict of interest should be declared by members of IAEC.
- A member can tender resignation from the committee.

Role of IAEC members – Internal & CPCSEA nominees

Internal IAEC Members -

Chairperson:

- Responsible for conducting at least 2 IAEC meetings in a calendar year.
- Will sign and approve the meeting minutes.
- Will recommend the appointment of internal IAEC members to the head of the institution.
- Will encourage the institute members to attend National and International training programs/conferences/seminars related to animal

ethics.

- Improving the quality of research projects/animal ethics committee submissions and review.
- If the Chairperson is not available or has conflict of interest, an ad-hoc Chairperson should be elected from amongst the present members to preside the IAEC activities.

Member Secretary:

- Responsible for organizing the meetings, maintaining the records and communicating with all concerned.
- Preparing the meeting minutes and getting the approval from the Chairperson and all other IAEC members before communicating it to the researcher(s).
- Submitting copy of the meeting minutes to CPCSEA via its online portal within 15 days' post meeting; otherwise the meeting will be considered as invalid.
- Communicating the IAEC decision on the submitted study protocols in writing to the principal investigator (PI).
- Informing the major or minor revisions recommended by the IAEC or the reasons for rejections will be informed to the PI.
- Any updates/notifications in the CPCSEA website will be brought to the attention of the IAEC members.

Veterinarian:

- Establishment of appropriate policies and procedures for ancillary aspects of veterinary care, such as reviewing protocols and proposals, animal husbandry and animal welfare.
- Providing adequate veterinary care.
- Monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation.
- Observation of animal's health, behavior and wellbeing.
- Instructs and trains the animal technicians about the human care of animals

Scientist from different biological discipline:

- Learn about the overall goal/mandate of the institute and keep themselves abreast with the current and past work done by the institute in animal studies and thus be able to link the new studies proposed and avoid repetition of the study
- Analyze and advice the appropriate animal numbers for the given practical subjects in the curriculum of the institution.
- Evaluate the merits and demerits on the basis of 3R's principles and advises the committee regarding the animal usage for education and research.
- Educate and update themselves about the regulatory toxicology work and instruct the animal researchers to perform experiments accordingly.
- Familiarize themselves with various guidelines for registration of products such as pesticide, drugs and pharma, biotechnology etc; thereby can guide the animal researchers appropriately.

Scientist in charge of Animal House facility:

- Responsible for providing basic care for animal subjects, supervising lab assistants, collecting data, analyzing results and publishing results in peer-reviewed journals or corporate reports.
- Visiting the animal house to ensure proper treatment of experimental animals and are attended more often than non-experimental animals.
- Assessment of animal health and wellbeing prior purchase; methods of transport and inspection of each consignment to be in compliance with procurement specifications.
- Monitors the quarantine of purchased animals.
- Supervises food water ad libitum and inspects their quality.
- Periodically evaluates the stock availability.

CPCSEA nominees

Main nominee of CPCSEA:

- Ensures the well-being and welfare of the animals housed or kept for experiments/ breeding.
- Reviews the rules governing housing, experimentation and after care of the animals.
- Visits the animal house at least once in a calendar year and submit the report to CPCSEA office within a month from the date of inspection.
- Forward the copy of the meeting minutes to CPCSEA within 15 days from the date of meeting of animal house.
- Notifies CPCSEA; if no meetings were conducted at the institution for 6 months.
- Ensures no repetition of previously conducted study(ies) or studies with similar outcome.
- Emphasize the 3R's principle to reduce the animal number without compromising the scientific experiments.
- Ensures that all ongoing and the projects that to be implemented have been represented and documented in 'Form B' with signature and date.
- Approval and record maintenance of the reviewed study protocols.
- Can seek any other expert reviewer to analyze the merits of the submitted protocol post consulting the CPCSEA.

Link nominee of CPCSEA:

- Conducts the meetings on behalf of main nominee; when he/she is not available and/or has conflict of interest.
- Reviews animal research proposals; suggests major or minor revisions; votes to approve or reject it.
- Suspend the research activity which does not adhere to guidelines for use of animals in research and take corrective action.
- Ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities

Scientist from outside the institute:

- Emphasize the animal experimentation, husbandry conditions, humane way of dealing with animals, handling procedures etc., as per the CPCSEA guidelines.
- Review the submitted study protocol for alternatives to animal experiments, reduction in number of experimental animals and refinement of study procedures to reduce the animal distress.
- Ensures ethical consideration and well-being of experimental animals followed by the researchers
- Inspect and ensure the animals are located in a quiet atmosphere, undisturbed by traffic & premises are kept tidy and hygienic conditions were maintained.

Socially aware Nominee:

- Socially aware nominee presence is compulsory in all cases referred to CPCSEA and in cases when research protocols involving small animals and large animals will be considered and at least in one meeting in a calendar year.
- Will go through the protocol of the experiment/ proposals and if in doubt regarding the justification for the experiment and whether it could be carried out using smaller or a lesser number of animals; raise the issue in IAEC meeting and clarify.
- Ensure the enrichment of environment and provision for socializing.
- Any protocol which uses animals other than guinea pigs, rabbits, rats, mice should be first cleared by the IAEC and then sent to CPCSEA for clearance.
- Cross check with other available documents such as animal house records.
- Check for any discrepancies regarding number of animals declared and number of animals in the animal house through a physical count.

Quorum Requirements:

- A minimum of 6 members are required to compose a quorum.
- All decisions should be taken in meeting and not by circulation of proposals.
- Presence of CPCSEA main nominee is must.
- Link nominee can attend in case main nominee conveys his unavailability in writing.
- Socially aware member's presence is compulsory in proposals referred to CPCSEA and at least one meeting in a calendar year.

Conduct of the meetings:

The Chairperson will conduct all meetings of the IAEC. If, for reasons beyond control, the Chairperson is not available, or has conflict of interest, an alternate Chairperson will be elected from the members by the members present. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson & nominee of CPCSEA before communicating to the Principal Investigator. In any case the meeting should not be held without the presence of CPCSEA member or nominee.

Participation of investigators / experts in IAEC:

- If needed, IAEC may call upon subject experts for offering special opinion for the selected research projects.
- Subject experts can review and suggest the revisions required in the protocol but cannot take part in the decision making
- Investigators whose proposals are to be discussed can be called to present their case to IAEC.

Application Procedure:

- All proposals should be submitted in the prescribed application form, copies of which will be available from the Member Secretary.
- All relevant documents with check list should be enclosed with application form.
- Ten copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator and

Co-investigators/Collaborators should be forwarded by the Head of the Department to the IAEC.

- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

Review Procedure:

- Meetings of IAEC shall be held every 6 months, for which the month will be decided at the end of previous meeting. Additional meetings will be held as and when necessary.
- Even if there are no projects, it is mandatory to call for an IAEC meeting at least once in a year to discuss matters related with maintenance of the animals. The member secretary must be present with all available records at every IAEC meeting.
- The copy of the application/ proposals will be sent to CPCSEA nominee and to all the members 15 days before the meeting.
- The meeting date will be intimated to the PI; He/She should be available to offer clarifications if necessary.
- The decision will be taken by consensus after discussion. Negative view point will be recorded in the minutes. If consensus is not reached, the case will be referred to CPCSEA.
- Independent Consultants/Expert will be invited to offer their opinion on specific proposals if needed.
- The decisions will be recorded in minutes, approved by chairman and will be signed by all the IAEC members present.

Decision Making:

- Decision will be taken by discussion before arriving at consensus.
- A member having conflict of interest should inform the chair person and withdraw during the decision procedure of concerned application. It should be recorded in minutes.
- The quorum of the meeting should be complete at the time of decision making.
- Only members shall take decision. Experts/ invitees/ investigators will only offer their opinion.
- Decision may be to approve, reject or revise the proposal. Specific suggestions for modification and reasons for rejection should be given.

- In case of conditional decisions, clear suggestions for revision and procedure for re-reviewing the application should be specified.
- Modified proposal's review may be expedited through identified members.

Communication of the decision:

- The decision of IAEC will be communicated by Member Secretary in writing.
- Suggestions for modification will be communicated by IAEC. If revision is to be made, the revised document in required number of copies should be submitted within a fortnight.
- Reasons for rejection will be informed to the researchers.
- Schedule/ plan of ongoing review will be informed to the PI.

Follow up procedures:

- Reports of ongoing research projects should be submitted every 6 months, before next IAEC meeting.
- Final report should be submitted at the end of the study.
- All serious Adverse Events (SAEs) & the interventions should be intimated.
- Protocol deviation, if any should be informed with adequate justification.
- Any amendment to the protocol should be resubmitted to IAEC for renewed approval.
- Premature termination of the study should be notified with reasons along with summary of the data obtained so far.
- Change of Investigators / sites should be informed for approval of IAEC.
- Any new information related to the study should be communicated.

Record keeping and archiving:

All the following documents should be stored for a period of 5 years.

- Minutes of all the IAEC meetings duly signed by the Chairperson and CPCSEA nominees, copy of all correspondence with members,

researchers and other regulatory bodies.

- Curriculum Vitae (CV) of all members of IAEC including training programmes in animal ethics.
- Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
- All study related documents (study projects with enclosed documents) should be archived for minimum of 5 years after the completion of study. A copy of filled proforma related to the projects shall remain with the PI for minimum of 5 years.

Updating IAEC members:

- All relevant information on animal ethics will be brought to the attention of the members of IAEC by the Member Secretary.
- Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research related to the animal ethics to help in improving the quality of research projects/animal ethics committee submissions and review.

Reporting to CPCSEA:

A copy of the meeting minutes should be submitted to IAEC within 15 days' post meeting. Inspection report of the animal house should be sent once in a calendar year.

Reimbursement to CPCSEA representative:

CPCSEA nominees or authorized persons appointed by CPCSEA for inspection of the establishment are required to be paid Rs. 5000/- each as sitting fees and reimbursement of actual expenditure incurred in this regard.

Guidelines

Animal Care:

1. Cages should be checked first thing every day in the morning, to note the condition of the animals. A staff member will check the animal cages daily for visible signs of change or distress, such as leaky bottles, birth of new pups, decrease in food or water consumption, blood

in cage, wounds, secretions around the eyes, nose and genital area, respiratory distress, constipation, diarrhea, swelling, sluggishness, gait, dull coat or loss of hair. All concerns will be reported to the supervisor and depending on the severity of the concern, the attending veterinarian will be notified.

2. Cages should be changed at least once per week or more often as needed; while doing so, wellbeing of animals also should be checked.
3. Water bottles should be checked every day and fresh water should be added as needed.
4. Sterilize the water bottles once in a week
5. Shelves, cage holders, lids and bonnets should be cleaned at least once in a month
6. Room should be sanitized every three to six months.
7. Floors should be cleaned every day.
8. Feeding plates should be wiped weekly.
9. Each cage must have an identification card with the following information: protocol number, investigator's name, date received, strain, sex, date of birth, and number of animals per cage.
10. Only items that are essential to the animal care of that room should be stored in the animal housing room.
11. The floor drains should be checked every day and flush out if necessary.
12. Doors should be sanitized once in a week.

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 to assess animal quality. Methods of transportation should also be taken into account.

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

Quarantine

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 of quarantine for small lab animals ranges from one week to one month.

Stabilization

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.

Separation

Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioral changes due to interspecies conflict. Such separation is usually accomplished by housing different species in separate rooms, cubicles or cages. If two species have a similar pathogen status and are behaviorally compatible, it shall be acceptable to house different species in the same room.

People 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

All animals should be observed for signs of illness, injury, or abnormal behavior by animal house staff daily, but more-frequent observations might be warranted, 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.

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, the group should be kept intact and isolated during the process of diagnosis, treatment and control. Diagnostic clinical laboratory may be made available.

Animal care and technical personnel

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

It is essential that the animal care staff maintain a high standard of personal cleanliness by using appropriate Personnel Protective Equipment (PPE) e.g. change of uniforms, footwear 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. 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.

Washing 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.

Multiple surgical procedures on single animal

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.

Durations of Experiments

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

Physical Restraint

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.

Important guidelines for the use of restraint equipment:

- 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.
- Provision should be made for observation of the animal at appropriate intervals. Veterinary care should be provided if lesions or illness associated with restraint are observed. The presence of lesions, illness, or severe behavioral change should be dealt with by the temporary or permanent removal of the animal from restraint.

Physical Facilities

The physical condition, 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.

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.
- 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

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
- Specialized laboratories or
- Receiving and storage areas for food, bedding

- Pharmaceuticals and biologics, and supplies
- Space for administration, supervision, and direction of the facility
- 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 to store wastes prior to incineration or removal

Physical Facilities

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.

Corridor(s) should be wide enough to facilitate the movement of personnel as well as equipment and should be kept clean.

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.

Animal room doors - should not be rust, 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.

Exterior 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.

Floors - Floors should be either monolithic or epoxy smooth, moisture proof, non-absorbent, skid- proof, resistant to wear, acid, solvents, adverse effects of detergents and disinfectants.

They should be capable of supporting racks, equipment, and stored items without becoming gouged, cracked, or pitted, with minimum number of joints. A continuous moisture-proof membrane might be needed. If sills are installed at the entrance to a room, they should be designed to allow for convenient passage of equipment.

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 outlet of the drains should be fitted with wire mesh guard to prevent wild rodent entry

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.

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 sanitizing equipment and supplies - An area for sanitizing cages and ancillary equipment is essential with 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.

Environment

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 84.2 °F) all times.

The relative humidity should be under control within the range of 30% to 70% throughout the year. During extreme summer appropriate methods e.g. sprinklers should be adopted 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 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. 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 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.

ANIMAL HUSBANDRY

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 wellbeing, 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 safely
- 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

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.

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. 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.

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. 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. 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 behavior. Group composition should be held as stable as possible, because mixing of groups or introducing new members can alter behavioral and physiological functions.

Animal Activity - Provision should be made for animals with specialized locomotor pattern to express their natural habitat, especially when the animals are held for long periods. Cages are often used for short-term (up to 3 months) housing for postsurgical care, isolation of sick animal and metabolic studies.

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 feces. 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; bioavailability 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. Diet should

be free from heavy metals (e.g., Lead, Arsenic, Cadmium, Nickel, Mercury), naturally occurring toxins and other contaminants.

Areas in which diets are processed or stored should be kept clean and enclosed to prevent entry of insects or other animals. Exposure to extremes of relative humidity, unsanitary conditions, light, oxygen, and insects hasten the deterioration of food. Food hoppers should not be transferred from room to room unless cleaned and properly sanitized.

Bedding - 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. 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.

The desirable criteria for rodent contact bedding is ammonia binding, serializable, 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, optimizes normal animal behavior, non - deleterious to cage - washers, non - injurious and non - hazardous to personnel, non - nutritious and non - palatable. Nesting materials for newly delivered pups should be provided wherever needed (e.g. Paper cuttings, tissue paper, cotton etc.).

Water - Animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their requirements. Periodic monitoring of microbial contamination in water is necessary. 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. It is better to replace fresh water bottles every day than to refill them, however, if bottles are to be refilled, care should be taken that each bottle is replaced on the cage properly from where it was removed.

Sanitation and Cleanliness - 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. Cleaning utensils, such as mops, pails, and brooms, should not be transported between animal rooms.

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. Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipment, 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.

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 82.2°C (180°F) or higher for a period long enough to ensure the destruction of vegetative pathogenic organisms. Disinfection can also be accomplished with appropriate chemicals. Equipment should be rinsed free of chemicals prior to use. Periodic microbiologic monitoring is useful to determine the efficacy of disinfection or sterilization procedures.

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. 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 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.

Some means for sterilizing equipment 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. Deodorants or chemical agents other than germicidal agents should not be used to mask animal odors. Such products are not a substitute for good sanitation.

Assessing the effectiveness of sanitation - 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. The intensity of animal odors particularly that of ammonia should not be used as the sole means of assessing the effectiveness of the sanitation program. 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. Autoclaving: Chemical Indicator - batch wise assessment; Biological indicator - Periodical assessment.

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 incineration. Incinerators should be in compliance with all central, state, and local Public Health and Pollution Control Board regulations.

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.

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.

Emergency, Weekend and Holiday Care - Animals should be cared for by qualified personnel every day, including weekends and holidays, to safeguard 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 people responsible for the animals. That can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animal facilities or by placing them in the security department or telephone center. 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.

Performance of experiments:

- Experiments shall be performed under supervision of a qualified person (Veterinarian/ Post graduates in life sciences/ trained laboratory technician) and under the responsibility of the person performing the experiment.
- Experiment shall be performed with due care and humanity.
- Animals intended for the performance of experiments shall be properly looked after both before and after experiments.
- Personnel using experimental animal(s) shall be responsible for the welfare of animal(s) during their use in experiments.
- Investigators shall be responsible for the aftercare and rehabilitation of animal(s) after experimentation, and shall not euthanize the animal(s) except in situations as defined.
- The following parameters shall be adopted for application of euthanasia, namely;
- 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.
- If during the course of anesthesia/experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.
- Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

- Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence. It is mandatory that the cost of after care and rehabilitation should be met from the contingency of the project.
- Experiments involving operative procedures shall be performed under anesthesia to be administered by a veterinary surgeon/scientist/technician so trained for the purpose.
- Experiments shall not be performed by way of an illustration/ as a public demonstration.
- No experiment the result of which is already conclusively known shall be repeated without justification.

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 of at the individual level, institutional level and finally at the national level.

Documentation:

All research proposals should be submitted with the following documents:

- Title of the project
- Names of the Principal Investigator and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Endorsement of the name of Head of the Department.
- Protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant annexure like proforma, Curriculum Vitae of outside members, undertaking etc. to be used in the study.

- Any other information relevant to the study.
- Agreement to submit six monthly progress report and final report at the end of study.
- The PI should provide the details of other ongoing research projects related to the Animal studies (Title of the project, Date of starting and duration, source and amount of funding).

Elements of review:

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks/harms to the animals.
- Protocol and proforma of the study.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure in the animal house.

Form B - per rule 8(a)* for Submission of Research Protocol (s)

Application for Permission for Animal Experiments

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

Section -I

1.	Name and address of the establishment	
2.	Registration number and date of registration.	
3.	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C	
4.	Place where the animals are presently kept (or proposed to be kept).	
5.	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	
6.	Date and Duration of experiment.	
7.	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	

Signature Name and Designation of the Investigator

Date:

Place:

Section -II

*Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee/ CPCSEA,
for new experiments or extensions of ongoing experiments using animals.*

1. Project / Dissertation / Thesis Title:

2. Principal Investigator / Research Guide / Advisor:

- a. Name;
- b. Designation
- c. Dept. / Div./ Lab
- d. Telephone No.
- e. E-mail Id
- f. Experience in Lab animal experimentation

3. List of all individuals authorized to conduct procedures under this proposal.

- a. Name
- b. Designation
- c. Department
- d. Telephone No.
- e. E-mail Id
- f. Experience in Lab animal experimentation

4. Funding Source / Proposed Funding Source with complete address (Please attach the proof)

5. Duration of the animal experiment.

- a. Date of initiation (Proposed)
- b. Date of completion (Proposed)

6. Describe details of study plan to justify the use of animals (Enclose Annexure)

7. Animals required

- a. Species and Strain
- b. Age and Weight
- c. Gender
- d. Number to be used (Year-wise breakups and total figures needed; tabulate)
- e. Number of days each animal will be housed.

8. Rationale for animal usage

- a. Why is animal usage necessary for these studies?
- b. Whether similar study has been conducted on in vitro models? If yes, describe the leading points to justify the requirement of animal experiment.
- c. Why are the particular species selected?
- d. Why is the estimated number of animals essential?
- e. Are similar experiments conducted in the past in your establishment?
- f. If yes, justify why new experiment is required?
- g. Have similar experiments been conducted by any other organization in same or other in vivo models? If yes, enclose the reference.

9. Describe the procedures in detail:

- a. Describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments)
- b. Furnish details of injections schedule Substances:
- c. Doses:
- d. Sites:
- e. Volumes:
- f. Blood withdrawal Details: Volumes: Sites :
- g. Radiation (dosage and schedules):
- h. Nature of compound/Broad Classification of drug/NCE:

10. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures? If yes, justify.

11. Will survival surgery be done?

If yes, the following to be described.

- a. List and describe all surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of personnel's involved.
- c. Describe post-operative care
- d. Justify if major survival surgery is to be performed more than once on a single animal.

12. Describe post-experimentation procedures.

- a. Scope for Reuse:
- b. Rehabilitation (Name and Address, where the animals are proposed to be rehabilitated):
- c. Describe method of Euthanasia (If required in the protocol):
- d. Method of carcass disposal after euthanasia:

13. Describe animal transportation methods if extra-institutional transport is envisaged.

Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the

Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified).

If, your project involved use of any of the below mentioned agent, attach copy of the approval certificates of the respective agencies:

- a. Radio nucleotides (AERB)
- b. Microorganisms / Biological infectious Agents (IBSC)
- c. Recombinant DNA (RCGM)

14. Any other Hazardous Chemical / Drugs

Investigator's Declaration

1. I certify that the research proposal submitted is not unnecessarily duplicative of previously reported research.
2. I certify that, I am qualified and have experience in the experimentation on animals.
3. For procedures listed under item 10, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
4. I will obtain approval from the IAEC/ CPCSEA before initiating any changes in this study.
5. I certify that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body).
6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.
7. I shall maintain all the records as per format (Form D) and submit to Institutional Animal Ethics Committee (IAEC).
8. I certify that, I will not initiate the study before approval from IAEC/CPCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC/CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature

Name of Investigator

Date:

Certificate

This is to certify that the project proposal no. _____ entitled _____ submitted by Dr. /Mr./Ms. _____ has been approved/recommended by the IAEC of _____ (organization) in its meeting held on _____ (date) and _____ (number and species of animals) have been sanctioned under this.

Authorized by	Name	Signature	Date
Chairperson:			
Member Secretary:			
Main Nominee of CPCSEA:			

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

CHECK-LIST (To be submitted for consideration of CPCSEA)

1. Title of the protocol
2. Name and address of the Institute submitting proposal, with Ref No. If any
3. CPCSEA Registration No. and valid up to
4. Status of Institute and its accreditation, if any DST/ICMR/DBT/CSIR/Public funded Institution/ State/ Central University/ College/ ISO-NABL certified lab/ GLP certified lab/ others
5. Type of research work – i. Academic; ii. Research
6. Composition of IAEC as per approved guidelines, names and addresses of establishment / members to which they represent

7. Detailed IAEC meeting minutes signed by the members
8. Recommendations of IAEC
9. The date of last inspection of animal house facility and approval details conveyed by CPCSEA
10. Name of the PI with designation, qualification and work experience with animals
11. Name of the Co- Principal Investigator with designation, qualification and work experience with Animals
12. Source of procurement of animals, types, number, age & sex
13. Information regarding import / export of animals / material before and after experimentation
14. A signed declaration by Principal Investigator is attached with proposal

Signature of Chairman IAEC

Principal Investigator

For official use only Date of receipt of the protocol and number of copies / CD CPCSEA Reference number
New proposal / revised proposal Signature of Expert Consultant, CPC

N.B. These forms are to be maintained by the Investigator

Form C: Record or animal bred/acquired: (to be maintained by the breeder/Establishment)

Date of entry	No. of animals (specify species, sex & age)	No. of the bred (specify date, Species & Sex)	No. of animals acquired (specify date, species, sex & age.)	Name, address & Date of acquire	No. of animals transferred (specify date, Species & Sex)	Name, address & regd. No. to whom transferred .	Signature

Form D: Record or animal acquired and experiments performed: (to be maintained by the investigator)

Date of Entry	No. of animals (specify species, sex and age.)	Name, address and registration No. of the bidder from whom acquired with voucher / bill No.	Date and Particulars of order of Grand of permission by the committee	Date / Period of experiment	Name and Address of the person authoring the experiment	Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied with (signature)

Review of Projects in the IAEC Meeting

1. Date of IAEC meeting:
2. Name of the projects:
3. Name of the PI:
4. Duration of the project:
5. No. of animals approved in the IAEC:
6. No. of animals used till date:
7. Project status: completed/ongoing
8. Brief progress report:
9. Remarks:

Signature of the PI & Date

Biodata and consent format for IAEC members

Name:			Sex:		
Date of Birth (dd/mm/yy):					
Professional Mailing Address (Include institutional name)					
Telephone (Office) :			Mobile Number :		
Telephone (Residence):			E-Mail:		
Academic Qualifications (Most current qualification first):					
Degree / Certificate	Subject	Year	Institution, Country		
Professional Experience:					
Month and Year	Title	Institution / Company, Country			
Experience in animal handling/ research:					
Month and Year	Area of Specialization	Institution / Company, Country			

<p>Consent:</p> <p>I hereby give my consent to be the member of the IAEC of NMC</p> <p>I undertake to follow all the rules and guidelines of the CPCSEA.</p>
<p>Signature:</p> <p>Date:</p>

Fees Payable to CPCSEA

S. No.	Purpose	Code	Fee to be charged in INR	
			Small animals	Large animals
1.	Registration for the purpose of Research for education	Re	10,000	10,000
2.	Registration for the purpose of Research for commercial	Rc	10,000	10,000
3.	Registration for the purpose of Research	R	10,000	10,000
4.	Registration for the purpose of Non- Research Commercial (i.e. Production of Hyper immune Plasma and Serum)	NRc	-	10,000
5.	Registration for Breeding for in-house use	Bi	15,000	25,000
6.	Registration for Breeding for the purpose of Trade	Bt	25,000	25,000
7.	Renewal for the purpose of Research for education	Re	2,500*	2,500*

8.	Renewal for the purpose of Research for commercial	Rc	2,500*	2,500*
9.	Renewal for the purpose of Research	R	2,500*	2,500*
10.	Renewal for the purpose of Non- Research Commercial (i.e. Production of Hyper immune Plasma and Serum)	NRc	-	2,500*
11.	Renewal for Breeding for in-house use	Bi	2,500*	2,500*
12.	Renewal for Breeding for the purpose of Trade	Bt	2,500*	2,500*
13.	Revision of IAEC	-	1,000	
14.	Protocol on Large Animals (educational) where the Joint Director (Research) or Dean (Research) or competent authority equivalent to Joint Director (Research) or Dean (Research) would certify that the particular protocol under this category is a thesis project (per protocol)	-	1,000	
15.	Protocol on Large Animals (educational other than thesis project) (per protocol)	-	5,000	
16.	Protocol on Large Animals (non- educational) (per protocol)	-	5,000	

The establishments which are not doing efforts to renew their Animal House Facilities before the date of expiry of the registration, they shall be charged registration fee for the respective purpose as per fee structure (enclosed) in place of renewal fee.

Note:

- The establishments which are applying for registration with CPCSEA, for different purposes are required to submit the fee(s) as per their purpose(s). If the purpose is more than one, the fee is to be added accordingly.
- The establishments already registered with CPCSEA and applying for renewal of registration are required to submit the renewal fee(s) as per their purpose(s) (as mentioned in the table above). If the purpose is more than one, the fee is to be added accordingly.

All communications must be addressed to:

Member Secretary (CPCSEA), Office of the CPCSEA,
Animal Welfare Division, 5th Floor, Vayu Block,
Indira Paryavaran Bhawan, Jor Bagh Road,
New Delhi – 110003. Phone: 011-24695232, 24695424,
E-mail: cpcsea-mef@gov.in, Website: <http://cpcsea.nic.in>

Renewal of Registration & Reconstitution of IAEC

As per the guidelines of CPCSEA, every establishment registered with CPCSEA is required to be renewed. The IAEC of the establishment(s) is valid up to the validity of renewal of registration. Therefore, IAEC must be reconstituted at the time of renewal of registration. The term for renewal of registration and reconstitution of the IAEC of the establishment is 5 Years as per extant guidelines.

List of documents required:

1. The biodata and consent letters of Five (5) IAEC members (all from science background including one Veterinarian having at least BVSc degree). At least half of the internal members are required to be replaced at the time of Reconstitution of IAEC.
2. The minutes of IAEC meetings of the previous five years, bearing the signature (with date) of all the IAEC members. The minimum of 6 members are required to compose a quorum.
3. The Annual Inspection Report of the Animal House Facility and Annual statement of large animals use of the previous five years duly signed (with date) by the Main Nominee / Link Nominee (if Main Nominee is not available).

4. The establishments are required to deposit the renewal fee through 'online payment gateway' as per revised fee in the prescribed column at the time of the submission of online application for renewal of registration ([http://cpcsea.nic.in/WriteReadData/LnPdf/Fee Structure order.pdf](http://cpcsea.nic.in/WriteReadData/LnPdf/Fee%20Structure%20order.pdf))

Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page of Website of CPCSEA (<http://cpcsea.nic.in>) by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: The establishment is required to upload the biodata and consent letters of each existing IAEC members (in a single PDF file; Maximum file size: 1 MB) on click on the tab IAEC members.

Step 3: The establishment is required to click on tab viz. Renewal Reconstitution request; and fill the details of proposed Five (5) IAEC members for reconstitution of IAEC, Upload their biodata and consent letters along with the details in a single PDF file (Maximum file size: 1MB).

Step 4: After furnishing the above details, the establishment is required to click on Final Submit button; payment detail page will display; click on Make Payment; pay the renewal fee through 'online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Note:

1. The establishment shall apply in advance (40 days) for renewal of registration & reconstitution of IAEC before the expiry date.
2. The fees which have already been paid through DD for renewal of registration for the same period will display to the establishment and will be adjusted at the time of online payment.

3. Adherence to the Guidelines of CPCSEA issued from time to time. Establishments not adhering to the Guidelines of CPCSEA are liable for action as per Rules.
 4. Submission of annual inspection reports and annual statement of Large Animal Use by the Main Nominee regularly.
 5. The animal house facility of the establishment will also be inspected by external nominees / Members of CPCSEA at any time / within the span of renewal.
-

Revision of IAEC

If any establishment desires to replace of their any internal IAEC member, they are required to send the request for revision along with the biodata and consent letter of the proposed member(s) and the Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of revision of IAEC has been recommended for approval by the IAEC, *in a single PDF file*.

Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the **Revision of IAEC** tab.

Step 3: Click on **edit** button in front of the IAEC member to whom the establishment wants to change/revise and then click on **update** to save the changes. (Ensure that all the details of each IAEC members are filled in complete manner).

Step 4: Furnish the reason for Revision of IAEC, date of the IAEC meeting, Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of revision of IAEC has been recommended for approval by the IAEC, *in a single PDF file* (Maximum file size: 1MB) and the Remarks related to Minutes of IAEC meetings.

Step 5: Click on **Submit**; After submit, payment detail page will display; Click on **Make Payment** and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Change of Nominee Request

If any establishment desires to replace of their IAEC nominee nominated by CPCSEA, they are required to send the request for Change Nominee and the Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of Change Nominee has been recommended for approval by the IAEC, *in a single PDF file*.

Procedure for applying online

Step 1: The user is required to login through User Login Window at Home Page by selecting '*Establishment Login*' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the **Change Nominee** tab.

Step 3: Tick the checkbox in front of the IAEC Nominee for whom the establishment wants to submit the request to change; furnish the reason for Change of Nominee in the Text Area displaying in from the ticked nominee

Step 4: Furnish the date of the IAEC meeting, Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal to change the nominee has been discussed and recommended to CPCSEA by all the IAEC members.

Step 5: Click on **Submit**.

Submission of Minutes of IAEC meeting

For renewal of registration, it is required to upload the Minutes of IAEC meeting regularly through online panel.

Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page by selecting '*Establishment Login*' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the tab viz. **Upload Minutes**; furnish the details such as Date of Minutes of IAEC meeting, copy of the Minutes of IAEC meeting

with the signed attendance sheet and Remarks related to Minutes of IAEC meetings; Click on **Submit** Button.

Step 3: The establishment can see the status / submit the reply in response to the clarification sought by CPCSEA on click on View Minutes Tab in reference to the Minutes of IAEC meeting submitted by the establishment.

Note: The meeting must be conducted with the required quorum as per the CPCSEA guidelines and the minutes must be signed by all the approved members of IAEC who have attended the meeting.

Submission of Research Protocol (s) on Large Animals

Any establishment conducting experiments on large animals is required to send the protocols to O/o CPCSEA for their approval.

Note: The establishments are required to get their Animal House Facilities approved and registered/renewed for housing large animals before commencing any research on them.

List of requisite documents for protocol:

1. Checklist of the Protocol (Completely filled and duly signed by the Principal Investigator).
2. Completely filled form 'B' (Section I & II) duly signed by the Principal Investigator along with Investigator's declaration and Certificate (signed by Main Nominee of CPCSEA and Chairman of IAEC).
3. Minutes of the IAEC meeting with the signed attendance sheet, wherein the protocol has been recommended by the IAEC and forwarded to CPCSEA for approval. The IAEC meeting should be conducted with all the approved IAEC members, wherein the presence of CPCSEA nominee and Socially Aware Nominee is mandatory. In case the Main Nominee conveys his/ her unavailability, Link Nominee may be invited in place of Main Nominee.
4. Rodent Study Data (wherever required).

5. The establishments are required to deposit the fee for Research Protocol through 'online payment gateway' as per revised fee (Rs. 1000/- for educational Protocols and Rs. 5000/- for non-educational Protocols) in the prescribed column at the time of the submission of Research Protocol (s) online.

Note:

- *No Hard Copies of any of the above documents are to be submitted until asked for.*
- *All the formats (Checklist, Form B, format of Investigator's declaration and Certificate, Format of Rat Study Data) are available on the website: http://cpcsea.nic.in/Content/53_1_FORMS.aspx.*

Note: *"The research protocols dealing with withdrawal of or **below 0.6ml/kg body wt.** of blood from large animals on weekly basis for the purposes of the experimentation on feeding trials, breeding experiments and live-stock management studies which require blood collection from the experimental animals to further study the clinical parameters and for the purpose of clinical disease diagnosis, field studies or thesis studies, may be approved by the IAEC. **This will be applicable for ICMR, ICAR, Veterinary and Agriculture Universities and Government funded institutions handling large animals.**"*

Procedure for Submission of online Protocol

Step 1: The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the Tab Viz. **New Research Protocol**; a form will display wherein requisite details to be filled for submission of Research Protocol such as title of the protocol, details of species etc.

Step 3: Upload the requisite files in the above form such as Checklist, Form B, Investigator Declaration, Certificate, Minutes of IAEC meeting, Rodent Study data (if applicable) and Guidelines/ References related to your research protocol. (*The maximum size of each file is displaying in front of the column*)

Step 4: Tick in front of the IAEC members who have attended the IAEC meeting and recommended the research protocol to CPCSEA for approval (*Ensure the required quorum of the IAEC meeting as per the CPCSEA guidelines and the presence of CPCSEA nominee and Socially Aware Nominee*).

Step 5: Click on **Submit Button**, after submit, payment detail page will display; Click on **Make Payment** and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Amendment of Registration

Any establishment registered with CPCSEA can amend the Name, Address of the Animal House Facility, Purpose of registration and expand their Animal House Facility (Small / Large) through Amendment process.

Procedure for applying online:

Step 1: The user is required to login through User Login Window at Home Page by selecting '*Establishment Login*' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.

Step 2: Click on the tab viz. **Amendment of registration**; Select the type of Amendment from the following:

- i. Amendment in the Name of the establishment.
- ii. Amendment in the Address of the establishment (Location of the Animal House Facility).

- iii. Amendment in the Purpose of registration with CPCSEA.
- iv. Amendment in the Type of Animal House Facility (Small / Large).

Step 3: After selection of Type of Amendment, the establishment is required to fill up the requisite details and upload the requisite documents.

Step 4: After furnishing the above details, click on **Submit** Button. In case of Amendment in the Purpose of registration with CPCSEA and Amendment in the Type of Animal House Facility (Small / Large), requisite fee will be applicable and will be pay through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Submission of Inspection Report(s) by the Nominee of CPCSEA

1. Inspection Reports / Annual Inspection Reports will be filled online by the concerned Nominee of the establishment. CPCSEA have provided the User ID and password to Nominees of CPCSEA for online processing. Therefore, Nominees are requested to visit their online panel to fill up the Inspection Reports / Annual Inspection Report of the Animal House Facility (s) of all
2. the establishments allotted as and when required. Annual statement of large animal's use will also be uploaded by the Nominees.
3. Annual Inspection Reports and Annual statement of large animals use of the previous five years are must for considering the renewal of registration of the establishments.
4. In case of Small and Large animal House Facility, the concerned Nominee of the establishment required to upload the Inspection Reports / Annual Inspection Reports of Both the facilities (Small and Large).
5. The Main Nominee of the concerned establishment is required to ensure conduct of the IAEC meetings as stipulated in the guidelines of CPCSEA and to upload the Annual Inspection Report of the Animal House Facility in the prescribed format regularly to the O/o CPCSEA.
6. While filling up the online Inspection reports, nominees need to specify each column as per the CPCSEA Guidelines for Laboratory

Animal Facility 2015. Nominees must avoid to write “as per guidelines or satisfactory or as per norms” in the columns of inspection report.

7. Nominees need to clearly indicate in the concerned column whether the Animal House Facility of the concerned establishment is recommended for consideration of Registration / Renewal.
8. Nominees will not upload the minutes of IAEC meetings as the same will be uploaded by the establishments.

Procedure for Submission of Online

Step 1: The user is required to login through User Login Window at Home Page by selecting ‘Nominee Login’ in User type and put the User Name & Password which is given to each Nominee(s) of CPCSEA.

Step 2: Nominee can see the details of Inspection ordered to him/her in three separate tabs viz. Inspection ordered for New Registration, Inspection ordered as an external nominee and CPCSEA Nominee in the IAEC of the establishments.

Step 3: The nominee can submit the Inspection Report(s) of the establishment(s) allotted to him/her from the above mentioned two tabs and submit the Annual Inspection Report(s) of any establishment(s) allotted to him/her through the third tab viz. CPCSEA Nominee in the IAEC of the establishment. The Annual Statement of Large Animal Use will also be submitted from this tab.

Step 4: The nominee can see the details/ status/ remarks of CPCSEA in reference to the any of the Annual Inspection report(s) submitted by him/her in the tab Annual Inspection Report and can also the details/ status/ remarks of CPCSEA in reference to the any Annual Statement of Large Animal Use submitted by him/her in the tab Annual Statement of Large Animal Use.

Step 5: The Nominee can view the remarks / send the reply in reference to the any online request(s) of any establishment(s) allotted to him/her from the tab Remark Window.

Step 6: For submission of Inspection Reports/ Annual Inspection Reports, the nominee(s) need to specify the details in each column as per the CPCSEA Guidelines and upload him/her signature and photographs of Animal House Facility at the time of Inspection in a single PDF file

(Maximum File Size: 1 MB).

Step 7: The Nominee can also save the details before submission the Inspection Reports / Annual Inspection Reports to CPCSEA on click on Save Button.

Step 8: For final submission of Inspection Report(s) / Annual Inspection Report(s) to CPCSEA, click on **Submit** Button.