

जयराम रमेश
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GOVERNMENT OF INDIA
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MESSAGE

I extend my best wishes, on the occasion of the Animal welfare fortnight, to all the members of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Institutional Animal Ethics Committee (IAEC) and to everyone who is actively associated with Animal welfare activities.

I am pleased to know that CPCSEA has put together a comprehensive manual on the 'Standard Operating Procedure' to be followed for the Institutional Animal Ethics Committee with the objective of ensuring uniformity in methods among all such committees in the country. Such a work has been long overdue and it is my sincere hope that it will go a long way in preventing the infliction of unnecessary pain or suffering on animals.

The guiding legislation in this regard is the Prevention of Cruelty to Animal (PCA) Act 1960 which provides for performance of experiments on animals for the purpose of advancement of knowledge or of knowledge which will be useful for saving lives and/or alleviating the suffering of human beings, animals or plants. However, the Act intends for such experiments to be performed with due care so as to minimize the pain inflicted on the animals.

I am glad to note that CPCSEA has made commendable strides since the Rules for Experimentation on Animals (Control and Supervision) were first notified in 1968 under the above legislation. It is also heartening to note that CPCSEA guidelines are being implemented effectively in more than 1300 establishments/institutions across the country.

I am sure that this manual will encourage IAEC members including researchers and animal facility managers to upgrade and improve their capacity for the welfare of research animals.

I wish all the individuals and groups involved, great success in their objectives and commend them on their work in furtherance of animal welfare.

Jairam Ramesh
(Jairam Ramesh)



सत्यमेव जयते

मु. फ़ै. फ़ारूकी

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M.F. Farooqui

Additional Secretary

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नई दिल्ली-110 003
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6th January, 2010

MESSAGE

The Prevention of Cruelty to Animal (PCA) Act 1960 provide for performance of experiments on animals for the purpose mitigation of sufferings and saving the lives of human beings and animals.

The Central Government has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) as per clause 15 of PCA Act, which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. For this purpose, the Government has made "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" as amended, to regulate the experimentation on animals.

This **Standard Operating Procedure (SOP) for Institutional Animal Ethics Committee (IAEC)** has been designed to bring out uniformity in the working IAEC so that consistent views are taken while reviewing the proposals entailing use of animals for experimentation. This manual explains in clear and simple terms, the CPCSEA approved procedure and rules position.

I would like to thank all the members of CPCSEA and Member Secretary for their sincere and dedicated effort in preparing the SOP. I hope that this would be a useful document for the IAEC members, principal investigators, researchers. Any suggestions to improve the SOP are most welcome.

I also take this opportunity to wish you all a very happy new year.

(M. F. Farooqui)

FOREWORD

Experimentation on animals in course of medical research and education is covered by provisions of the **Prevention of Cruelty to Animals Act, 1960** and *Breeding of and Experiments on Animals (Control & Supervision) Rules of 1998, 2001 and 2006* framed under the Act. These are enforced by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960. Under these provisions, the concerned establishments are required to get themselves registered with CPCSEA, form IAEC, get their Animal House Facilities inspected, and also get specific projects for research cleared by CPCSEA before commencing the research on animals. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

In an amendment brought out in 2006 in the Rules for Breeding of and Experiments on Animals (Control & Supervision), powers to permit experiments on small animals were given to Institutional Animal Ethics Committee (IAEC) of the establishments. Only proposals for conducting experiments on large animals are required to be sent to CPCSEA for approval. Accordingly, it is important that all the IAEC members are fully aware of the extant rules and guidelines. It may be noted that approvals given by IAEC's which are not in accordance with the extant rules are invalid.

This document is a step to apprise the IAEC members about the rules and guidelines and provides a compilation of the same and would serve as an important document for all IAEC's. It also describes the objectives, role of IAEC, formation, procedure in which the meeting are to be conducted and other relevant information like decision making, reporting, record keeping etc.

ANJANI KUMAR
Member Secretary

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CPCSEA Standard Operating Procedures (SOP) for IAEC

1. Objective:

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

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

IAEC has been designed to secure the following objectives:

- (a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
- (b) that experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anesthetic of sufficient power to prevent the animals feeling pain;
- (c) that animals which, in the course of experiments under the influence of anesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;
- (d) that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
- (e) that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, mice, rats etc;

- (f) that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- (g) that animals intended for the performance of experiments are properly looked after both before and after experiments;
- (h) that suitable records are maintained with respect to experiments performed on animals

2. Functions of IAEC

As defined in “Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998”

"Institutional Animals Ethics Committee" means a body comprising of a group of persons recognized and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;

The primary duty of IAEC is to work for achievement of the objectives as mentioned above.

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

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

3. Composition of IAEC

Institutional Animals Ethics committee shall include eight members as follows.

1. A biological scientist,
2. Two scientists from different biological disciplines,
3. A veterinarian involved in the care of animal,
4. Scientist in charge of animals facility of the establishment concerned,
5. A scientist from, outside the institute,
6. A non scientific socially aware member and
7. A nominee of CPCSEA

Specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from amongst the eight members. Members against Serial number 5,6 and 7 will be nominated by CPCSEA, with a provision of a Link nominee for CPCSEA nominee.

4. Authority under which IAEC is constituted and duration:

CPCSEA constitutes the IAEC on receipt of five (5) names against serial numbers 1-4 from the institute. The duration of IAEC is for a period of 3 years and is required to be reconstituted at the time of renewal of registration. However, changes may be made in deserving cases with the approval of CPCSEA.

5. IAEC requirements:

- a. The duration of appointment is for a period of 3 years (coterminous with registration).
- b. The committee is required to be reconstituted at the time of renewal of registration, and at least half of the members will be replaced.
- c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- f. Conflict of interest should be declared by members of the IAEC.
- g. IAEC is required to formulate a SOP for its working requirements and follow it in all the meetings.

6. Quorum requirements:

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

7. Conduct of business:

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, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

8. Participation by Investigators / experts in IAEC.

IAEC may call upon subject experts who may provide special review of selected research protocols, if need be. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IAEC. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

9. Application Procedures:

- a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation.
- b. All relevant documents with checklist should be enclosed with application form
- c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be submitted to IAEC.

11. Review procedures:

- a. 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 do expedited review.
- b. The proposals will be sent to members at least 15 days in advance.
- c. Decisions will be taken by consensus after discussions. Negative view points should be recorded in the minutes. In case consensus is not reached, the case should be referred to CPCSEA.
- d. Researchers will be invited to offer clarifications if need be.
- e. Independent consultants/Experts will be invited to offer their opinion on specific Research proposals if needed.
- f. The decisions will be minuted and Chairperson's approval taken in writing with signature of all the IAEC members present.

14. Decision-making

- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- c. Decisions will be made only in meetings where quorum is complete.
- d. Only members can make the decision. The experts / investigators / invitees will only offer their opinions.
- e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- g. Modified proposals may be reviewed by an expedited review through identified members.
- h. Procedures for appeal by the researchers should be clearly defined.

15. Communicating the decision

- a. Decision will be communicated by the Member Secretary in writing.
- b. Suggestions for modifications, if any, should be sent by IAEC.
- c. Reasons for rejection should be informed to the researchers.
- d. The schedule / plan of ongoing review by the IAEC should be communicated to the PI.

16. Follow up procedures

- a. Reports should be submitted at prescribed intervals for review.
- b. Final report should be submitted at the end of study.
- c. All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated.
- d. Protocol deviation, if any, should be informed with adequate justifications.
- e. Any amendment to the protocol should be resubmitted to IAEC for renewed approval.
- f. Any new information related to the study should be communicated
- g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- h. Change of investigators / sites should be informed and approval of IAEC should be taken.

17. Record keeping and Archiving

- a. Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.
- b. Copy of all study protocols with enclosed documents, progress reports.
- c. Minutes of all meetings duly signed by the Chairperson and the members.
- d. Copy of all existing relevant national and international guidelines on animal ethics and laws along with amendments.
- e. Copy of all correspondence with members, researchers and other regulatory bodies.
- f. Final report of the approved projects.
- g. Record of Breeding of animals, supply etc, if breeding of animals is undertaken.
- h. Record of import of animals with species, source, quantity, usage etc.
- i. Record of all Contract research, if conducted at the institute.
- j. Record of rehabilitation of large animals if done.
- k. All documents should be archived for period as prescribed in the concerned SOP of the IAEC. However, this should not be less than one year.

18. Updating IAEC members

- a. All relevant new guidelines and amendments to the Rules and Act should be brought to the attention of the members.
- b. Members should be encouraged to attend national and international training programs / workshops / conferences in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

19. Reporting to CPCSEA

- a. IAEC is required to send a copy of minutes of IAEC meeting to CPCSEA within 15 days.
- b. Inspection report of animal house with photographs by IAEC members is required to be sent once in a calendar year. If action is required, the facility must provide ATR within 30days.

20. Reimbursement to CPCSEA representative

CPCSEA representative(s) on the IAEC or authorized person(s) sent for inspection of the establishment(s) are required to be paid Rs. 1000/- each as sitting fees and reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

21. Fees Payable to CPCSEA

Registration fee of Rs. 1,000/- and renewal fee of Rs. 500/- is to be paid by Demand Draft in favor of CPCSEA payable at New Delhi (as applicable).

22. All communications must be addressed to:

Member Secretary, CPCSEA,
Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001
Phone : 011-23318553
Email : cpcsea@rediffmail.com

GUIDELINES
ON THE REGULATION OF
SCIENTIFIC EXPERIMENTS
ON ANIMALS

Ministry of Environment & Forests
(Animal Welfare Division)

Government of India

June 2007

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INTRODUCTION

1.1 Background

The use of animals in scientific research has been an area of concern in India, given the sharp polarization of views between animal welfare activists and the scientific community of the country regarding use of animals. This led to proliferation of litigation, which impeded the pace of research.

In order to eliminate the potential for conflict, it was considered necessary to examine the international norms regarding the use of animals in scientific experiments, update regulations, streamline and simplify procedures, while ensuring ethical use of animals and reducing infliction of pain and stress on animals, during experimentation.

1.2 Process of Evolution of the Guidelines

Against this backdrop, in 2004, the Ministry of Environment and Forests set out to create a sound and cohesive regulatory framework for the use of animals in experimentation. A consultative Group was set up, to facilitate interaction with a wide spectrum of stakeholders, both within and outside the government, including the scientific community, as also animal welfare activists. To clarify the underlying ethical principles, a professor of Philosophy was also associated in the exercise.

Recognizing the intrinsic worth of animals as sentient beings, the consultative Group enunciated the underlying ethical principles and identified objectives of scientific experiments which would justify the use of animals in the cause of scientific advancement and promoting human welfare while ensuring humane treatment of such animals.

Deliberations of the Group led to a consensus between hitherto divergent viewpoints. Six brainstorming sessions were held, wherein the principles and practices of utilization and care of animals in testing, research and training were finalized.

The report of the consultative Group was communicated to the Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA) in terms of Section 17 (3) of the Prevention of Cruelty to Animals Act, 1960. The report was accepted by CPCSEA in its meeting held on 20 December 2004, and formed the basis of the Breeding of and Experiments on Animals (control and supervision) Amendment rules, 2006.

The report has been well received and its impact may be noted from the fact of speedy settlement of pending court cases and absence of any new court case.

However, in order to clarify various aspects regarding the use of experimental animals, there was a perceived need for a comprehensive set of Guidelines that could be used as reference material by the Scientific establishment. Regarding ethical use of animals in scientific experiments. The present Guidelines respond to that need.

1.3 Aim

The aim of these Guidelines is to ensure humane and ethical treatment of animals, while facilitating legitimate scientific research involving experiments on animals.

2. Statutory provisions regarding scientific experiments on animals

Persons engaged in conducting scientific experiments on animals must act in conformity with the provisions of the prevention of Cruelty to Animals Act, 1960, and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended.

These provisions are enforced by the independent Committee for the Purpose of Control and supervision of Experimentation on animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960, in the Ministry of Environment and Forests.

2.1 Other legal provisions regarding animal experimentation

Compliance is also required with CPCSEA Guidelines for Laboratory animal facility.

3. Principles for scientific experiments on animals, relevant changes in Rules and guidelines for specific situations evolved by the Consultative Group accepted by CPCSEA

3.1 Ethical principles adopted by CPCSEA for use of animals in scientific experiments

Principle 1

“Experiments on animals” (including experiments involving operations on animals) may be carried out for the purposes of advancement by new discovery of physiological knowledge; or of knowledge which is expected to be useful for saving or prolonging human life or alleviating suffering; or for significant gains in the well-being for the people of the country; or for combating any disease, whether of human being, animals or plants.

Principle 2

Animals lowest on the phylogenetic scale (i.e., with the least degree of sentience), which may give scientifically valid results, should be used for any

Experimental procedure. Experiments should be designed with the minimum number of animals to give statistically valid results at 95% level of confidence. Alternatives not involving animal testing should be given due and full consideration and sound justification provided, if alternative, when available, are not used.

Principle 3

Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anesthesia.

Principle 4

Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. Investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation, and may be permitted to euthanize

Animals only in the following situations:

- (a) When the animal is paralyzed and is not able to perform its natural functions; it becomes incapable of independent locomotion; and/or can no longer perceive the environment in an intelligible manner.
- (b) During the course of experimental procedure the animal has been left with a severe recurring pain and the animal exhibits obvious signs of long term extreme pain and suffering.
- (c) In situations where non-termination of the animal experimented upon would be life threatening to human beings or other animals.

Costs of aftercare and/or rehabilitation of animals post-experimentation are to be part of research costs and should be scaled per animal in positive correlation with the level of sentience of the animals.

Principle 5

The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all.

Animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.

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

3.2.1 Need to avoid/minimize pain and suffering inflicted on experimental animals

Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anesthesia.

3.2.2 Proper care, handling and use of experimental animals

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

3.2.3 Agricultural production research

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

3.2.4 Powers of the Institutional Animals Ethics Committee (IAEC)

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

3.2.5 Inspection of animal house facilities

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

4. Procedures for approval of scientific experiments on animals

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

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

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

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

4.3 Function of CPCSEA

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

The main functions of CPCSEA are:

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

4.4 Functions of the Institutional Animals Ethics Committee (IAEC)
Every establishment constituted and operated in accordance with the

procedures specified by CPCSEA is required to constitute an Institutional Animals Ethics Committee (IAEC).

In terms of Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, every IAEC shall include a biological scientist, two scientists from different biological disciplines, a veterinarian involved in the care of animals, the scientist in charge of the animal facility of the establishment concerned, a scientist from outside the institute, a non-scientific socially aware member and a representative or nominee of the CPCSEA. A specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substances and deadly micro organisms.

IAEC may approve experiments on animals, up to the phylogenetic level of rodents (e.g. mice, rats and rabbits). However, IAEC is not empowered to clear research project proposals that involve experimentation on animals higher on the phylogenetic scale than rodents. In such cases, IAEC may consider proposals for scientific experiments involving animals above the sentience level of rodents, and forward its recommendations for consideration by CPCSEA.

4.5 Registration of establishments

In terms of Rule 3 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, no establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered, In terms of Rule 4 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, no establishment shall perform any experiment on animals unless it is registered with CPCSEA. Every such establishment shall stop performing experiments on animals or breeding of animals for use in experiments, if registration is refused to it by CPCSEA.

4.6 Approval of animal house facilities

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

4.7 Use of animals in experiments

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

minimum number of animals to give statistically valid results at 95% degree of confidence.

Replacement alternatives, not involving experiments on animals, should be given due and full consideration and sound justification must be provided, in case alternatives, though available, are not used.

4.8 Procurement of animals

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

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

4.9 Welfare of animals during use in experiments

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

4.10. Aftercare and rehabilitation of animals after use in scientific experiments

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall be responsible for the aftercare and rehabilitation of the animals after experimentation.

Costs of aftercare and rehabilitation of the animals after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals.

Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and

The establishment undertaking experiments or duly licensed and authorized animal welfare organizations under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

4.11. Situations Where euthanasia of animals is permissible

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

- (i) When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner; or
- (ii) If during the course of experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering; or
- (iii) Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

4.11 Suspension/revocation of registration of an establishment by CPCSEA

Rule 14 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, provides as follows:

- (a) The Committee, if it is satisfied with the report of the Member-Secretary or the authorized officer of the Committee (made to it as a result of any inspection or information received or otherwise) that-
 - (i) the rule made by it are not being complied with by an establishment or breeder; or
 - (ii) a violation of the directions of the Committee has been committed by any establishment or breeder and the Committee's directions to rectify such violation have not been complied within the period so specified,

The Committee may, by order in writing, suspend or revoke the registration of the establishment or breeder and / or direct the closure of the animal house facility for such a period as may be specified in the order:

Provided that no order under this clause shall be made without giving the establishment or breeder an opportunity of being heard in the matter.

Provided further that no order for suspension or revocation of registration, or closure of animal house facility shall be issued in a case of minor violation.

Explanation: For the purpose of this clause, “minor violation” means an act of commission or omission which does not have direct bearing on the health of an animal; which may not lead to adverse health effect or pain or suffering or death of an animal.

Note: All relevant Rules, Guidelines and minutes of the meetings of CPCSEA are available on the website of the Ministry of Environment and Forests:
www.envfor.nic.in.

APPENDIX

Relevant changes in Rules based on recommendations of the Consultative Group Based on the ethical principals so enunciated, the Consultative Group recommended changes in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended. These were further deliberated upon, and duly incorporated after the Report of the Consultative Group was accepted in toto by CPCSEA. The changes in the relevant Rules are summarized as follows:

1. Change in Rule 2 (e) in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

The definition of experiments has been widened to include the term “significant gains in the well-being of the people of the country”, as additional criteria justifying the use of animals in experiment.

2. Insertion of Rule 9 (bb) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This addition provides that preference be according to the use of the minimum number of animals, lowest in the phylogenetic scale, which provide for statistically valid results at 95% degree of confidence. Use of replacement/alternatives is encouraged and sound justification is required in case alternatives to use of animals are not used, when available.

3. Insertion of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This provision makes the personnel using animals in experiments responsible for their welfare after use in experimentation, including aftercare and rehabilitation and also makes it mandatory for the costs of aftercare and rehabilitation to be made part of the research costs, as a lump sum provision based on the statistically expected life span of the animals. Rehabilitation may be undertaken by the establishment or by a duly licensed and authorized animal welfare organization.

4. Insertion of Rule 9 (ff) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This provides for the specific parameters, which are to be adopted when considering euthanasia of any animal used in scientific experiments. These include impairment of the natural functions of the animal including independent locomotion, when the animal faces recurring pain and suffering, and when the non termination of the life of the experimental animal would be life threatening of humans or other animals.

5. Amendment of Rule 10 (b) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This amendment allows the establishment to procure animals from any other legal source in case of non-availability with registered breeders, with suitable documentation to establish legality of the procurement process.

6. Amendment of Rule 10 (e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended.

This provision allows the establishment to import genetically defined animals with the permission of DGFT, in case such animals are not available with registered breeders or other legal sources within the country. The condition of non-availability will not apply to genetically defined or laboratory bred rats and mice.

7. Amendment of Rule 12 in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

This Rule has been amended to allow establishments to undertake contract research as per the provisions of the PCA Act 1960 and the rules made thereunder.

8. Amendment of Rule 14 in the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended

The Rule has been amended to allow CPCSEA to take action against an establishment or breeder, based on the report of the Member Secretary or authorized officer, regarding any violations of the rules, or of directions of the Committee. In case of a major violation, CPCSEA may by written orders, suspend or revoke the registration of the establishment and / or order closure of the animal house facility, after giving the establishment or breeder an opportunity of being heard in the matter.

CPCSEA GUIDELINES FOR LABORATORY ANIMAL FACILITY - 2005

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

GOAL

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

VETERINARY CARE

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. Institutional requirements will determine the need for full-time or part-time or consultative veterinary services.

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 (**Annexure - 4**).

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

QUARANTINE, STABILIZATION AND SEPARATION

Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined. An effective quarantine minimizes the chance for introduction of pathogens into an established colony. The duration at quarantine in

small lab animals from one week to one month and large animals allowed up to 6 weeks (cat, dog, monkey, etc.)

Effective quarantine procedures should be used for non-human primates to help limit exposure of humans to zoonotic infections. The period varies from 2 to 3 months depending on the reaction of TB testing.

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.

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; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators shall be suitable alternatives.

In some instances, it shall be acceptable to house different species in the same room, for example, if two species have a similar pathogen status and are behaviorally compatible.

Separate set of personnel should be identified for taking care of these animals and other 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. As a rule, this should occur daily, but more-frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. It is imperative that appropriate methods be in place for disease surveillance and diagnosis (**Annexure 1 & 2**).

Postmortem examination and signs of illness, distress, or other deviations from normal health condition in animals should be reported promptly to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals in the colony. If an entire room of animals is known or believed to be exposed to an infectious agent (e.g. *Mycobacterium tuberculosis* in non-human primates), the group should be kept intact and isolated during the process of diagnosis, treatment, and control. Diagnostic clinical laboratory may be made available.

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 (**Annexure - 7**).

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 with appropriate Personnel Protective Equipment (PPE) e.g. showers, 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; however, institutional facilities should be used to decontaminate clothing exposed to potentially hazardous microbial agents or toxic substances. It is acceptable to use disposable gloves, masks, head covers, coats, coveralls and shoe covers. Personnel should change clothing as often as is necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility.

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

ANIMAL EXPERIMENTATION INVOLVING HAZARDOUS AGENTS

Institutions should have policies governing experimentation with hazardous agents. Institutional Bio-safety Committee whose members are knowledgeable about hazardous agents are in place in most of the higher-level education, research institutes and in many pharmaceutical industries for taking care of safety issues. This committee shall also examine the proposal on animal experiments involving hazardous agents in addition to its existing functions (**Annexure - 8**).

Since the use of animals in such studies requires special considerations, the procedures and the facilities to be used must be reviewed by both the Institutional Bio-safety committee and Institutional Animal Ethics Committee (IAEC).

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.

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

The following are important guidelines for the use of restraint equipments:

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

LOCATION OF ANIMAL FACILITIES TO LABORATORIES

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

- Laboratory animals are very sensitive to their living conditions. It is important that they shall be housed in an isolated building located as far away from human habitations as possible and not exposed to dust, smoke, noise, wild rodents, insects and birds. The building, cages and environment of animal rooms are the major factors, which affect the quality of animals.
- This separation can be accomplished by having the animal quarters in a separate building, wing, floor, or room. Careful planning should make it possible to place animal housing areas adjacent to or near laboratories, but separated from them by barriers such as entry locks, corridors, or floors.
- While planning an animal facility the space should be well divided for various activities. The animal rooms should occupy about 50-60% of the total constructed area and the remaining area should be utilized for services such as stores, washing, office and staff, machine rooms, quarantine and corridors. The environment of animal room (Macro-Environment) and animal cage (Microenvironment) are factors on which the production and experimental efficiency of the animal depends. Since animals are very sensitive to environmental changes, sharp fluctuations in temperature, humidity, light, sound and ventilation should be avoided. The recommended space requirements for animal rooms, for different species are given in (**Annexure - 3**).

FUNCTIONAL AREAS

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

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

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

- Specialized laboratories or
- Individual areas contiguous with or near animal housing areas for such activities as surgery, intensive care, necropsy, radiography, preparation of special diets,

experimental manipulation, treatment, and diagnostic laboratory procedures containment facilities or

- Equipment, if hazardous biological, physical, or chemical agents are to be used
- Receiving and storage areas for food, bedding
- Pharmaceuticals and biologics, and supplies
- Space for administration, supervision, and direction of the facility
- Showers, sinks, lockers and toilets for personnel
- An area for washing and sterilization equipment and supplies,
- An autoclave for equipment
- Food, and bedding; and separate areas
- For holding soiled and cleaned equipment
- An area for repairing cages and equipment
- An area to store wastes prior to incineration or removal

PHYSICAL FACILITIES

- (a) **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.
- (b) **Corridor(s)** should be wide enough to facilitate the movement of personnel as well as equipments and should be kept clean.
- (c) **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

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

Windows are not recommended for small animal facilities. However, where power failures are frequent and backup power is not available, they may be necessary to provide alternate source of light and ventilation. In primate rooms, windows can be provided.

FLOORS

Floors should be either monolithic or epoxy smooth, moisture proof, nonabsorbent, 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

Floor drains are not essential in all rooms used exclusively for housing rodents. Floor in such rooms can be maintained satisfactorily by wet vacuuming or mopping with appropriate disinfectants or cleaning compounds. Where floor drains are used, the floors should be sloped and drain taps kept filled with water or corrosion free mesh. To prevent high humidity, drainage must be adequate to allow rapid removal of water and drying of surfaces. At the inlet and outlets of the drains should be fitted with wire mesh guard to prevent wild rodent entry

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. 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 & intensive care and for treatment of animals.

ENVIRONMENT

(a) Temperature And Humidity Control

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

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

(b) Ventilation

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

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

(c) Power And Lighting

The electrical system should be safe and provide appropriate lighting and with sufficient number of power points lighting system be installed provide adequate illumination for people to work in the animal rooms and a lowered intensity of light for the animals.

Fluorescent lights are efficient and less than 400 lux is preferable for rodent facilities.

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

(d) Noise Control

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

ANIMAL HUSBANDRY

(a) Caging Or 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 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; **(Annexure – 3)**
- 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.

They should be constructed of sturdy, durable materials and designed to minimize cross-infection between adjoining units. Polypropylene, polycarbonate and stainless steel cages should be used to house small lab animals, Monkeys should be housed in cages made of steel or painted mild steel and for other animals such as sheep, horses, the details can be seen in **Annexure - 3**.

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.

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 conditions and an adequate protective and escape mechanism for submissive animals especially in monkeys by way of providing indoor portion of run.

Shelter should be accessible to all animals, with sufficient ventilation, and should be designed to prevent 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 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 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, particularly for canine, non-human primates, and other highly social mammals, because mixing of groups or introducing new members can alter behavioral and physiological functions.

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

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. e.g., artificial trees, ropes, bars, and perches are appropriate for non-human primates.

Cages are often used for short-term (up to 3 months) housing of dogs and may be necessary for postsurgical care, isolation of sick dogs, and metabolic studies.

Pens, runs, or other out-of-cage space provide more opportunity for exercise, and their use is encouraged when holding dogs for long periods.

FOOD

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; bio-availability of nutrients should be at par with the nutritional requirements of the animal. The animal feed should contain moisture, crude fibre, crude protein, essential vitamins, minerals, crude fat and carbohydrate for providing appropriate nutrition.

Laboratory animal diets should not be manufactured or stored in facilities used earlier for farm feeds or any products containing additives such as rodenticides, insecticides, hormones, antibiotics, fumigants, or other potential toxicants.

Areas in which diets are processed or stored should be kept clean and enclosed to prevent entry of insects or other animals.

Precautions should be taken if perishable items such as meats, fruits, and vegetables are fed, because these are potential sources of microbiological and chemical contamination and can also lead to variation in the amount of nutrients consumed.

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

Exposure to extremes of relative humidity, unsanitary conditions, light, oxygen, and insects hasten the deterioration of food.

Meats, fruits, vegetables, and other perishable items should be refrigerated if required to be stored. Unused, open food should be stored in vermin proof conditions to minimize contamination and to avoid potential spread of disease causing agents.

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

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. For larger animals, such as dogs, cats, and non - human primates, soiled litter material should be removed twice daily.

Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipments, such as feeders and watering devices, should be washed and sanitized frequently to keep them clean and contamination free. Generally this can be achieved by washing solid bottom rodent cages and accessories once or twice a week and cages, racks at least monthly.

Wire - bottom cages other than rodent cages should be washed at least every 2 weeks. It is good practice to have extra cages available at all times so that a systematic cage-washing schedule can be maintained. Cages can be disinfected by rinsing at a temperature of 82.2C (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. Equipments 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 equipments and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present. Routine sterilization of cages, feed and bedding is also essential besides care is taken to use clean materials from reliable sources. Where hazardous biological, chemical, or physical agents are used, a system of equipment monitoring might be appropriate.

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 off in a safe and sanitary manner. The most preferred method of waste disposal is incineration. Incinerators should be in compliance with all central, state, and local Public Health and Pollution Control Board regulations.

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

PEST CONTROL

Adaptation of Programs designed to prevent, control, or eliminate the presence of or infestations by pests are essential in an animal home environment.

EMERGENCY, WEEKEND AND HOLIDAY CARE

There should be an institutional policy to care animals 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 responsible persons 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.

RECORD KEEPING

It is essential that animal House should maintain following records:

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

STANDARD OPERATING PROCEDURES (SOPs) / Guidelines

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

A SOP should contain the following items:

- Name of the Author
- Title of the SOP
- Date of approval
- Reference of previous SOP on the same subject and date (Issue no and Date)
- Location and distribution of SOP's with sign of each recipient

- Objectives
- Detailed information of the instruments used in relation with animals with methodology (Model no., Serial no., Date of commissioning, etc)
- The name of the manufacturer of the reagents and the methodology of the analysis pertaining to animals
- Normal value of all parameters
- Hazard identification and risk assessment

PERSONNEL AND TRAINING

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 change over with lockers, wash basin, toilets and bathrooms to maintain personal hygiene. It is also important a regular medical check-up is arranged for the workers to ensure that they have not picked up any zoonotic infection and also that they are not acting as a source of transmission of infection to the animals. The animal house in-charge should ensure that persons working in animal house don't eat, drink, smoke in animal room and have all required vaccination, particularly against Tetanus and other zoonotic diseases.

Initial in-house training of staff at all levels is essential. A few weeks must be spent on the training of the newly recruited staff, teaching them the animal handling techniques, cleaning of cages and importance of hygiene, disinfection and sterilization. They should also be made familiar with the activities of normal healthy and sick animals so that they are able to spot the sick animal during their daily routine check up of cages (**Annexure - 7**).

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, mode of transport, containers, animal density in cages, food and water during transit, protection from transit infections, injuries and stress.

The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable, free movement and protection from possible injuries. 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 water during transit. The transport containers (cages or crates) should be of appropriate size and

only a permissible number of animals should only be accommodated in each container to avoid overcrowding and infighting (**Annexure - 4**)

ANAESTHESIA AND EUTHANASIA

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

It must also be ensured that the anaesthesia is given for the full duration of experiment and at no stage the animal is conscious to perceive pain during the procedure. If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irreparable injury, the animal should be humanely sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia (**Annexure - 5**).

In the event of a decision to sacrifice an animal or termination of an experiment or other wise an approved method of euthanasia should be adopted (**Annexure - 6**) and the investigator must ensure that the animal is clinically dead before it is sent for disposal. The data of all the animals, that have been euthanised, should be maintained.

Anaesthesia

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

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

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

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

Euthanasia

Euthanasia is resorted to events where an animal is required to be sacrificed or 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 have an initial depressive action on the central nervous system for immediate insensitivity to pain. The choice of a method will depend on the nature of study, the species of animal to be killed (**Annexure - 6**). 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.

LABORATORY ANIMAL ETHICS

All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view it is important that such considerations are taken care at the individual level, at institutional level and finally at the national level.

TRANSGENIC ANIMALS

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

MAINTENANCE

Housing, feeding, ventilation, lighting, sanitation and routine management practices for such animals are similar to those for the other animals of the species as given in guidelines. However, special care has to be taken with transgenic/gene knockout animals where the animals can become susceptible to diseases where special conditions of maintenance are required due to the altered metabolic activities. The

transgenic and knockout animals carry additional genes or lack genes compared to the wild population. To avoid the spread of the genes in wild population care should be taken to ensure that these are not inadvertently released in the wild to prevent cross breeding with other animals. The transgenic and knockout animals should be maintained in clean room environment or in animal isolators.

DISPOSAL

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

BREEDING AND GENETICS

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

Annexure – 1
HAEMATOLOGICAL DATA OF COMMON LABORATORY ANIMALS

	Mouse	Rat	Hamster	G. Ppig	Rabbit	Cat	Dog (Beagle)	Primate (Rhesus)
RBC(x10 ⁶ /mm ³)	7 - 12.5	7 - 10	6 - 10	4.5 - 7	4 - 7	5 - 10	5.5 - 8.5	3.56 -6.96
PCV(%)	39 - 49	36 - 48	36 - 55	37 - 48	36 - 48	30 - 45	37 - 55	26 - 48
Hb(g/dl)	10.2 - 16.6	11 - 18	10 - 16	11 - 15	10 - 15.5	8 - 15	12 - 18	8.8 - 16.5
WBC(X10 ³ /mm ³)	6 - 15	6 - 17	3 - 11	7 - 18	9 - 11	5.5 - 19.5	6 - 17	2.5 - 26.7
Neutrophils(%)	10 - 40	9 - 34	10 - 42	28 - 44	20 - 75*	35 - 75	60 - 70	5 - 88
Lymphocytes(%)	55 - 95	65 - 85	50 - 95	39 - 72	30 - 85	20 - 55	12 - 30	8 - 92
Eosinophils(%)	0 - 4	0 - 6	0 - 4.5	1 - 5	0 - 4	2 - 12	2 - 10	0 - 14
Monocytes(%)	0.1 - 3.5	0 - 5	0 - 3	3 - 12	1 - 4	1 - 4	3 - 10	0 - 11
Basophils(%)	0 - 0.3	0 - 1.5	0 - 1	0 - 3	2 - 7	rare	rare	0 - 6
Platelets(X10 ³ /mm ³)	160 - 410	500-1300	200-500	250-850	250-656	300-700	200-900	109-597

* Neutrophils often resemble eosinophils due to granules

(NOTE- The range of normal values may vary in a laboratory using specific species, strain or sub strain of these animals. Any major deviation on higher or lower side may be considered as a condition and not a disease per se)

Annexure – 2

BIOCHEMICAL DATA OF COMMON LABORATORY ANIMALS

	Mouse	Rat	Hamster	G.pig	Rabbit	Cat	Dog	Monkey
Protein (g/dl)	3.5 - 7.2	5.6 - 7.6	4.5 - 7.5	4.6 - 6.2	5.4 - 7.5	6 - 7.5	6 - 7.5	4.9 - 9.3
Albumin (g/dl)	2.5 - 4.8	2.8 - 4.8	2.6 - 4.1	2.1 - 3.9	2.7 - 4.6	2.5 - 4.0	3 - 4	2.8 - 5.2
Globulin (g/dl)	0.6	1.8 - 3.2	7 - 4.2	1.7 - 2.6	1.5 - 2.8	2.5 - 3.8	2.4 - 3.7	1.2 - 5.8
Glucose (mg/dl)	62 - 175	50 - 135	60 - 150	60 - 125	75 - 150	81 - 108	54 - 99	46 - 178
Urea nitrogen(mg/dl)	12 - 28	15 - 21	12 - 25	9 - 31.5	17 - 23.5	3.5 - 8.0	3.5 - 7.5	8 - 40
Creatinine (mg/dl)	0.3 - 1	0.2 - 0.8	0.91 - 0.99	0.6 - 2.2	0.8 - 1.8	<180 (n mol/l)	<120 (n mol/l)	0.1 - 2.8
Bilirubin (mg/dl)	0.1 - 0.9	0.2 - 0.55	0.25 - 0.6	0.3 - 0.9	0.25 - 0.74	<4.0 (m mol/l)	<5.0 (n mol/l)	0.1 - 2
Cholesterol (mg/dl)	26 - 82	40 - 130	25 - 135	20 - 43	35 - 53	2 - 4 (m mol/l)	4 - 7 (m mol/l)	108 - 263

The range of normal values may vary in a laboratory using specific species, strain or sub strain of these animals. Any major deviation on higher side may be considered as a condition and not a disease per se).

Annexure – 3A

Minimum floor area recommended for laboratory animals (based on their weight/size and behavioral activity)

Animal	Weight In grams	Floor area/ Animal (cm ²)		Cage height (cm ²)
Mouse	<10	38.7		12
	upto15	46		
	upto25	74		
	>25	96.7		
Rat	<100	109.6		14
	upto200	148.3		
	upto300	187.0		
	upto400	258.0		
	upto500	387.0		
	>500	≥451.5		
Hamster/Gerbil/ Mastomy/Cotton rat	>60	64.5		12
	upto 80	83.8		
	upto100	103.2		
	>100	122.5		
Guinea pig	<350	387.0		18
	>350	≥651.4		
		(Sq.ft)	Floor area (Sq.meter)	Height (inches)
Rabbit	<2000	1.5	0.135	14
	Upto 4000	3.0	0.27	14
	Upto 5400	4.0	0.36	14
	>5400	5.0	0.45	14
	Mother with Pubs	4.5	0.40	14

Annexure – 3B

Example for calculating the number of Mice to be kept per cage, based on floor area recommended for animal according to their weight (size) and size of the cage

Recommended floor Area per animal (Cm ²)	38.7	51.6	77.4	96.7
--	------	------	------	------

Weight of animals (Grams)	<10	upto15	upto25	>25
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Example I
Cage Size
24 x 14 cm
i.e. floor area of
336 cm²
maximum number
of animals

	9	7	4	3*
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Example II
Cage Size
32.5 x 21 cm
i.e floor area of
682.5 cm²
maximum number
of animals

	18	13	9	7
--	----	----	---	---

Note: Cage size, specially length and breadth may vary. However, the minimum area and cage height recommended for group housing has to be taken into consideration. Thus, the number of animals which can be housed in a particular cage (of different sizes) can be calculated on the basis of a) floor area of the cage, b) recommended floor area per animal and c) weight of animal.

* In case of breeding pairs, three adults (i.e. 1 male and 2 female) along with the pups from delivery up to weaning stage are permitted.

Annexure – 3C

Example for calculating the number of rats to be kept per cage, based on floor area recommended per animal according to their weight (size) and size of the cage

Recommended floor area per animal (cm ²)	109.6	148.3	187.0	258.0	387.0	>451.5
Weight of animal (Grams)	<100	upto 200	upto 300	upto 400	upto 500	>500
Example Cage size 32.5 x 21 cm i.e floor area of 682.5 cm ² maximum number of animals	6	5	4	3	2	1

Note: Cage size, specially length and breadth may vary. However the minimum floor area and cage height recommended for group housing has to be taken into consideration. Thus, the number of animal which can be housed in a particular cage (of different sizes) can be calculated on the basis of a) floor area of the cage, b) recommended floor area pre animal and c) weight of animal.

Annexure – 3D

Example for calculating the number of Hamster/ Gerbils/ Mastomys/Cotton rats to be kept per cage, based on floor area recommended per animal according to their weight (size) and size of the cage

Recommended floor area per animal (cm ²)	64.5	83.8	103.2	122.5
--	------	------	-------	-------

Weight of animal (grams)	<60	upto80	upto100	>100
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Example
Cage size
32.5 x 21 cm
i.e floor area of
682.5 cm²
maximum number
of animals

	11	8	7	6
--	----	---	---	---

Note: Cage size, specially length and breadth may vary. However the minimum floor area and cage height recommended for group housing has to be taken into consideration. Thus, the number of animal which can be housed in a particular cage (of different sizes) can be calculated on the basis of a) floor area of the cage, b) recommended floor area per animal and c) weight of animal.

Annexure - 3E

Minimum floor area and height recommended for monkeys (rhesus and bonnet) based on their weight (size) and behavioral activity (for langurs, the recommended space is in the foot note below)

Weight (in Kg)	Floor area		Height
	(cm) Ft ²	Cm ²	
Upto 1	1.6	1440	50
Upto 3	3.0	2700	72
Upto 10 - 12	4.3	3870	72
Upto 12 - 15	6.0	5400	72
Upto 15 - 25	8.0	7200	90

- Note: a) The height of the cage should be sufficient for the animals to stand erect with their feet on the floor, whereas the minimum height of the cage for langurs has to be 90 cm
- b) The floor area for langurs upto 6 kg weight, 5000 cm² and above 6 kg, 6000 - 9000 cm² is recommended. The height of the cage in either case remains the same, i.e. 90cm.
- c) If the experimental protocol demands individual caging for more than 6 months, animals should be provided with double the floor space mentioned above.
- d) All primate facilities should have one or more runs as big as possible with minimum floor space of 150sq.ft and height not less than 2 meters for free ranging activities.

Annexure - 3F

Recommended Space for Cats, Dogs and Birds

Animals	Weight, kg^a	Floor area/animal, ft^{2b}	Height in inches
Cat	<4	3.0	24
	<4	>4.0	24
Dog	<15	8.0	-
	Up to 30	12.0	-
	>30	>24.0	-
Pigeon	-	0.8	-
Chicken	<0.25	0.25	-
	Up to 0.5	0.50	-
	Up to 1.5	1.00	-
	Up to 3.0	2.00	-
	>3.0	>3.00	-

b To convert square feet to square meters Multiply with 0.09

Annexure - 3G

Recommended Space for Commonly Used Farm Animals

Animals/Enclosure	Weight kg ^a	Floor Area/Animal ft ² b	Height(ft.)
Sheep and Goats			8
	<25	10.0	
	Up to 50	15.0	
	>50	20.0	
2-5	<25	8.5	
	Up to 50	12.5	
	>50	17.0	
>5	<25	7.5	
	Up to 50	11.3	
	>50	15.0	
Swine			8
	Up to 25	12.0	
	Up to 50	15.0	
	Up to 100	24.0	
	Up to 200	48.0	
	>200	>60.0	
2-5	<25	6.0	
	Up to 50	10.0	
	Up to 100	20.0	
	Up to 200	40.0	
	>200	>52.0	
>5	<25	6.0	
	Up to 50	9.0	
	Up to 100	18.0	
	Up to 200	36.0	
	>200	>48.0	

Animals/Enclosure	Weight. Kg^a	Floor Area/Animal, ft²^b	Height (ft)
Cattle			8
1	<75	24.0	
	Up to 200	48.0	
	Up to 350	72.0	
	Up to 500	96.0	
	Up to 650	124.0	
	>650	>144.0	
2 -5	<75	20.0	
	Up to 200	40.0	
	Up to 350	60.0	
	Up to 500	80.0	
	Up to 650	105.0	
	>650	>120.0	
>5	<75	18.0	
	Up to 200	36.0	
	Up to 350	54.0	
	Up to 500	72.0	
	Up to 650	93.0	
	>650	>108.0	
Horses	144.0	10	
Ponies		8	
1 - 4	72.0		
>4/pen	<200	60.0	
	>200	>72.0	

^aTo convert kilograms to pounds. Multiply with 2.2

^b To convert square feet to square meters. Multiply with 0.09

Larger animals might require more space to meet performance Stan

ANNEXURE – 4

SPECIFICATIONS FOR TRANSPORT OF LABORATORY ANIMALS BY ROAD, RAIL AND AIR

	Mouse	Rat	Hamster	G. pig	Rabbit	Cat	Dog	Primate
Maximum No. of Animals per cage	25	25	25	12	2	1 or 2	1 or 2	1
Material Used in Transport box	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal	Metal	Bamboo / wood / metal
Space per Animal (Cm. Sq.)	20 - 25	80 - 100	80 - 100	160 - 180	1000 - 1200	1400 - 1500	3000	2000 - 4000
Minimum height of box (cm)	12	14	12	15	30	40	50	48

ANNEXURE – 5

COMMONLY USED ANAESTHETIC AGENTS FOR LABORATORY ANIMALS

Drugs (mg/kg)	Mouse	Rat	Hamster	Guinea pig	Rabbit	Cat	Dog	Primate
KTEAMINE Hcl	22 - 24 i/m	22 - 24 i/m	-	22 - 24 i/m	22 - 24 i/m	30 i/m	30 i/m	15 - 40
PENTOBAR- BITONE	35 i/v	25 i/v	35 i/v	30 i/v	30 i/v	25 i/v	20 - 30 i/v	35 i/v
SODIUM	50 i/p	50 i/p	-	40 i/p	40 i/p	-	-	-
THIOPENT- ONE	25 i/v	20 i/v	20 i/v	20 i/v	20 i/v	25 i/v	25 i/v	25 i/v
SODIUM	50 i/p	40 i/p	40 i/p	55 i/p				60 i/p
URETHANE	-	0.75 i/p	-	1.5 i/p	1.0 i/p, i/v	1.25 i/v 1.50 i/p	1.00 i/v	1.0 i/v

ATROPINE: Dose 0.02 – 0.05 mg/kg for all species by *s/c* or *i/m* or *i/v* routes used to reduce salivary and bronchial secretions and protect heart from vagal inhibition, given prior to anaesthesia.

i/m = intramuscular, *i/v* = intravenous, *i/p* = intraperitoneal, *s/c* = subcutaneous

ANNEXURE – 6
EUTHANASIA OF LABORATORY ANIMALS
(A – Methods Acceptable NR – Not Recommended)

Species	Mouse	Rat	Hamster	Guinea pig	Rabbit	Cat	Dog	Primate
a) PHYSICAL METHODS								
Electrocution	NR	NR	NR	NR	NR	NR	NR	NR
Exsanguination	NR	A	A	A	A	A	NR	NR
Decapitation (for analysis of stress)	A	A	A	NR	NR	NR	NR	NR
Cervical dislocation	A	A	A	NR	NR	NR	NR	NR
b) INHALATION OF GASES								
Carbon Monoxide	A	A	A	A	A	A	A	A
Carbon Dioxide	A	A	A	A	A	A	NR	NR
Carbon Dioxide plus Chloroform	A	A	A	A	A	A	NR	NR
Helothane	A	A	A	A	A	A	A	A
c) DRUG ADMINISTRATION								
Barbiturate Overdose (route)	A(IP)	A(IP)	A(IP)	A(IP)	A(IV,IP)	A(IV,IP)	A(IV,IP)	A(IV,IP)
Chloral hydrate Overdose (route)	NR	NR	NR	NR	A(IV)	A(IV)	A(IV)	A(IV)
Ketamine Overdose (route)	A(IM/P)	A(IM/IP)	A(IM/IP)	A(IM/IP)	A(IM/IV)	A(IM/IV)	A(IM/IV)	A(IM/IV)
Sodium Pentothol [Overdose (route)]	IP	IP	IP	IP	IV	IV	IV	IV

Methods Not Acceptable for any species of animals
intrapertitoneal

IP =

a) PHYSICAL METHODS:

(i) Decompression (ii) Stunning

b) INHALATION OF GASES

(i) Nitrogen Flushing (ii) Argon Flushing

c) DRUG ADMINISTRATION

(i) Curariform drugs (ii) Nicotine Sulphate (iii) Magnesium Sulphate (iv) Potassium Chloride (v) Strychnine (vi) Paraquat (vii) Dichlorvos (viii) Air Embosium

IV = Intravenous

IM = Intramuscular

Annexure - 7

QUALIFICATIONS & KNOWLEDGE REQUIRED FOR LABORATORY ATTENDANT

Basic Education: 10th standard

Introduction - Definition of plants and animals - types of animals - animals without back bones (invertebrates) and those with back bones (chordates/vertebrates) - animals that live in water (aquatic), air (aenar), land (terrestrial) - wild animals and domesticated animals - poisonous and non-poisonous animals - laboratory bred and non-laboratory bred animals - diurnal and nocturnal animals (suitable and relevant Indian examples to be given).

Animals rooms - animals chambers/cages - sizes of animal chambers general dimensions for monkey and rat cages stocking density - need for light (LD cycles), air water and feed - cleaning animal chambers, animal runs, aquana and animal rooms - frequency of feeding - frequency of cleaning.

Handling of animals - precautions while handling animals - common injuries and ailments in animals - litters - weaning - maintenance - record keeping.

Personal hygiene - need to use apron, gloves, mask handling of detergents and other cleaning substances - zoonoses - need of safety handling - antidotes for specific poisons if handling poisonous animals like venomous snakes - first aid.

Emergency situations: escaping animals - use of fire extinguishers - emergency lamps - sirens.

Annexure – 8

Institutional Biosafety Committee (IBSC)

Institutional Biosafety Committee (IBSC) is to be constituted in all centers engaged in genetic engineering research and production activities. The Committee will constitute the following.

- (i) Head of the institution or his nominee
- (ii) 3 or more scientists engaged in DNA work or molecular biology with an outside expert in the relevant discipline.
- (iii) A member with medical qualification-Biosafety officer (in case of work with pathogenic agents/large scale used.)
- (iv) One member nominated by DBT

The Institutional Biosafety Committee shall be the point for interaction within institution for implementation of the guidelines. Any research project which is likely to have biohazard potential (as envisaged by the guidelines) during the execution stage or which involve the production of either micro-organisms or biologically active molecules that might cause biohazard should be notified to ISBC. ISBC will allow genetic engineering activity on classified organisms only at places where such work should be performed as per guidelines. Provision of suitable safe storage facility of donor, vectors, recipients and other materials involved in experimental work should be made and may be subjected to inspection on accountability.

The biosafety functions and activity include the following:

- (a). Registration of Biosafety Committee membership composition with RCGM and submission of report.
ISBC will provide half yearly reports on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any. A computerized Central Registry for collation of periodic reports on approved projects will be setup with RCGM to monitor compliance on safeguards as stipulated in the guidelines.
- (b). Review and clearance of project proposals falling under restricted category that meets the requirements under the guidelines.
IBSC would make efforts to issue clearance certificates quickly on receiving the research proposals from investigators.
- (c). Tailoring biosafety program to the level of risk assessment
- (d). Training of personnel on bio safety
- (e). Instituting health monitoring program for laboratory personnel Complete medical check up of personnel working in projects involving work with potentially dangerous microorganism should be done prior to starting such projects. Follow up medical check ups including pathological test should be done periodically, at annually for scientific workers involved in such projects. Their medical record should be accessible to the RCGM. It will provide half yearly reports on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any.
- (f). 3 Adopting emergency plans.

THE PREVENTION OF CRUELTY TO ANIMAL ACT, 1960
(59 of 1960)

As amended by Central Act 26 of 1982
ARRANGEMENT OF SECTIONS

Section No.

CHAPTER I - PRELIMINARY

1. Short title, extent and commencement.
2. Definitions.
3. Duties of persons having charge of animals.

CHAPTER II - ANIMAL WELFARE BOARD OF INDIA

4. Establishment of Animal Welfare Board of India.
5. Constitution of the Board.
- 5A. Reconstitution of the Board.
6. Term of office and conditions of service of Members of the Board.
7. Secretary and other employees of the Board.
8. Funds of the Board.
9. Functions of the Board.
10. Power of Board to make regulations.

CHAPTER III - CRUELTY TO ANIMALS GENERALLY

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LIST OF ABBEREVATIONS USED

- Ins. Inserted
S. Section
Subs. Substituted

THE PREVENTION OF CRUELTY TO ANIMALS ACT, 1960
(59 OF 1960)
26th December, 1960)
AN ACT

to prevent the infliction of unnecessary pain or suffering on animals and for that purpose to amend the law relating to the prevention of cruelty to animals.

Be it enacted by Parliament in the Eleventh year of the Republic of India as follows:-

CHAPTER I

PRELIMINARY

- | | |
|---|--|
| Short title, extent and commencement | 1. (1) This Act may be called the Prevention of Cruelty to Animals Act, 1960.
(2) It extends to the whole of India except the State of Jammu and Kashmir.
(3) It shall come into force on such date as the Central Government may, by notification in the official Gazette, appoint, and different dates may be appointed for different States and for the different provisions contained in this Act |
| Definitions | 2. In this Act, unless the context otherwise requires, -
(a) “animal: means any creature other than a human being;
(b) “Board” means the Board established under Section 4, and as reconstituted from time to time under Section 5A }
(c) “captive animal” means any animal (not being a domestic animal) which is in captivity or confinement, whether permanent or temporary, or which is subjected to any appliance of contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed;
(d) “domestic animal” means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of man or which, although it neither has been nor is intended to be so tamed, is or has become in fact wholly or partly tamed. |

*See Annexure for notifications Under Section 1 (3)

*Subs. by Act. 26 of 1982 which came into force on 30th July 1982.

- (e) “local authority” means a municipal committee, district board or other authority for the time being invested by law with the control and administration of any matters within a specified local area;
- (f) “owner”, used with reference to an animal, includes not only the owner but also any other person for the time being in possession or custody of the animal, whether with or without the consent of the owner.
- (g) “phooka” or “doom dev” includes any process of introducing air or any substance into the female organ of a milch animal with the object of drawing off from the animal any secretion of milk:
- (h) “prescribed” means prescribed by Rules made under this Act:
- (I) “street” includes any way, road, lane, square, court, alley, passage or open space, whether a thoroughfare or not to which the public have access.

Duties of Persons having charge of animals (3)

It shall be the duty of every person having the care or charge of any animal to take all reasonable measures to ensure the well-being of such animal and to prevent the infliction upon such animal of unnecessary pain or suffering.

CHAPTER II

* (ANIMAL WELFARE BOARD OF INDIA)

Establishment of Animal Welfare Board of India (4)

(1) For the promotion of animal welfare generally and for the purpose of protecting animals from being subjected to unnecessary pain or suffering, in particular, there shall be established by the Central Government, as soon as may be after the commencement of this Act, a Board to be called the ** (Animal Board of India.)

(2) The Board shall be a body corporate having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property and may by its name sue and be sued.

Constitution of the Board (5)

(1) The Board shall consist of the following persons, namely:-
(a) the Inspector General of Forest, Government of India, ex-officio;
(b) the Animal Husbandry Commissioner to the Government of India ex-officio;

* Subs. by Act 26 of 1982: S.3, for the words “ Animal Welfare Board”

** Sub-ibid, S.4 for the words “ Animal Welfare Board”

- *(ba) two persons to represent respectively the Ministries of the Central Government dealing with Home Affairs and Education, to be appointed by the Central Government;
- (bb) one person to represent the Indian Board for Wild Life, to be appointed by the Central Government;
- (bc) three persons who, in the opinion of the Central Government, are or have been actively engaged in animal welfare work and are well-known humanitarians, to be nominated by the Central Government;)
- (C) one person to represent such association of veterinary practitioners as in the opinion of the Central Government ought to be represented on the Board, to be elected by that association in the prescribed manner;
- (d) two persons to represent practitioners of modern and indigenous systems of medicine, to be nominated by the Central Government;
- **[(e) one person to represent each of such two municipal corporations as in the opinion of the Central Government ought to be represented on the Board, to be elected by each .of the said corporations in the prescribed manner;)
- (f) one person to represent each of such three organisations actively interested in animal welfare as in the opinion of the Central Government ought to be represented on the Board, to be chosen by each of the said organisations in the prescribed manner;
- (g) one person to represent each of such three societies dealing with prevention of cruelty to animal as in the opinion of the Central Government ought to be represented on the Board, to be chosen in the prescribed manner;
- (h) three persons to be nominated by the Central Government;
- (I) six Members of Parliament, four to be elected by the House of the People (Lok Sabha) and two by the Council of States (Rajya Sabha).
- (2) Any of the persons referred to in clause 9a) or ..* [clause (b) or clause (ba) or clause (bb) of sub-section (1) may depute' any other person to attend any of the meetings of. the Board.

* inserted by Act 26 of 1982; S. 5 (a) (i)

** Subs. - ibid S. 5 (a) (ii) for the original clause.

*** Subs. by Act 26 of 1982: S.5 (b), for the word, brackets and letter "clause (b)

*[(3) The Central Government shall nominate one of the members of the Board to be its Chairman and another member of the Board to be its Vice-Chairman.]

@ [5.A (1) In order that the Chairman and other members of the Board hold office till the same date and that their terms of office come to an end on the same date, the Central Government may, by notification in the Official Gazette, reconstitute, as soon as may be after the Prevention of Cruelty to Animals (Amendment) Act, 1982 comes into force, the Board.

(2) The Board as reconstituted under sub-section (1) shall be reconstituted from time to time on the expiration of every third year, from the date of its reconstitution under sub-section (1).

(3) There shall be included amongst the members of the Board reconstituted under sub-section (1), all persons who immediately before the date on which such reconstitution is to take effect, are Members of the Board but such persons shall hold office only for the unexpired portion of the term for which they would have held office if such reconstitution had not been made and the vacancies arising as a result of their ceasing to be Members of the Board shall be filled up as casual vacancies for the remaining period of the term of the Board as so reconstituted:

Provided that nothing in this sub-section shall apply in relation to any person who ceases to be member of the Board by virtue of the amendment made in sub-section (1) of section 5 by sub-clause (ii) of clause (a) of section 5 of the Prevention of Cruelty to Animals (Amendment) Act, 1982).

Terms of Office and conditions of service of members of the Board.

****6. (1) The term for which the Board may be reconstituted under section 5A shall be three years from the date of the reconstitution and the Chairman and other Members of the Board as so reconstituted shall hold office till the expiry of the term for which the Board has been so reconstituted.**

(2) Notwithstanding anything contained in sub-section (1):

(a) the term of office of an ex-officio Member shall continue so long as he holds the office by virtue of which he is such a Member;

* Subs. *ibid*, 5.5 (c) for the original clause.

@ *ins. ibid*, 5.6.

** Subs., by Act 26 of 1982, 5.7, for the original Section.

- (b) the term of office of a Member elected or chosen under clause (c), clause (e), clause (g), clause (h) or clause (i) of section 5 to represent anybody of persons shall come to an end as soon as he ceases to be a Member of the body which elected him or in respect of which he was, chosen;
 - (c) the term of office of a Member appointed, nominated, elected or chosen to fill a casual vacancy shall continue for the remainder of the term of office of the Member in whose place he is appointed, nominated, elected or chosen;
 - (d) the Central Government may, at any time, remove for reasons to be recorded in writing a member from office after giving him a reasonable opportunity of showing cause against the proposed removal and any vacancy caused by such removal shall be treated as casual vacancy for the purpose of clause (C).
- (3) The members of the Board shall receive such allowance, if any, as the Board may, subject to the previous approval of the Central Government, provided by regulations made in this behalf,
- (4) No act done or proceeding taken by the Board shall be questioned on the ground merely of the existence of any vacancy in, or defect in the constitution of the Board and in particular, and without prejudice to the generality of the foregoing, during the period intervening between the expiry of the term for which the Board has been reconstituted under section SA and its further reconstitution under that section, the ex-officio members of the Board shall discharge all the powers and function of the Board.)

Secretary and
other employees
of the Board

7 (1)The Central Government shall appoint 'xxxxx the Secretary of the Board.

(2)Subject to such rules as may be made by the Central Government in this behalf, the Board may appoint such number of other officers and employees as may be necessary for the exercise of its powers and the discharge of its functions and may determine the terms and conditions of service of such officers and other employees by regulations made by it with the previous approval of the Central Government.

Funds of the
Board

(8) The funds of the Board shall consist of grants made to it from time to time by the Government and of contributions, subscriptions, bequests, gifts and the like made to it by any local authority or by any other person.

* The words "one of its officers to be" omitted by Act 26 of 1982,

(9) The functions of the Board shall be.

- (a) to keep the law in force in India for the prevention of cruelty to animals under constant study and advise the Government on the amendments to be undertaken in any such law from time to time;
- (b) to advise the Central Government on the making of rules under this Act with a view to preventing unnecessary pain or suffering to animals generally, and more particularly when they are being transported from one place to another or when they are used as performing animals or when they are kept in captivity or confinement;
- (c) to advise the Government or any local authority or other person on improvements in the design of vehicles so as to lessen the burden on draught animals;
- (d) to take all such steps as the Board may think fit for '(amelioration of animals) by encouraging or providing for, the construction of sheds. water-troughs and the like and by providing for veterinary assistance to animals:
- (e) to advise the Government or any local authority or other person in the design of slaughter-houses or the maintenance of slaughter houses or in connection with slaughter of animals so that unnecessary pain or suffering, whether physical or mental, is eliminated in the pre-slaughter stages as far as possible, and animals are killed; wherever necessary, in as humane a manner as possible;
- (f) to take all such steps as the Board may think fit to ensure that unwanted animals are destroyed by local authorities, whenever it is necessary to do so, either instantaneously or after being rendered insensible to pain or suffering.
- (g) to encourage by the grant of financial assistance or otherwise, *(the formation or establishment of pinjrapoles, rescue homes, animal shelters, sanctuaries and the like) where animals and birds may find a shelter when they have become old and useless or when they need .protection:

*Subs, by Act 26 of 1982, S.9 (a) for the word "ameliorating the condition of beasts of burden

**Subs, ibid, S, 9 (b) for the words "the formation of pinjrapoles, sanctuaries and the like"

- (h) to co-operate with, and co-ordinate the work of, associations or bodies established for the purpose of preventing unnecessary pain or suffering to animals or for the protection of animals and birds;
- (I) to give financial and other assistance to animal welfare organisations functioning in any local area. or to encourage the formation of animal welfare organisations in any local area which shall work under the general supervision and guidance of the Board;
- (j) to advise the Government on matters relating to the medical care and attention which may be provided in animal hospital, and to give financial and other assistance to animal hospitals whenever the Board thinks it necessary to do so;
- (k) to impart education in relation to the humane treatment of animals and to encourage the formation of public opinion against the infliction of unnecessary pain or suffering to animals and for the promotion of animal welfare by means of lectures, books, posters, cinematographic exhibitions and the like;
- (l) to advise the Government on any matter connected with animal welfare or the prevention of infliction of unnecessary pain or suffering on animals.

Power of the Board to make regulations.

10. The Board may, subject to the previous approval of the Central Government, make such regulations as it may think fit for the administration of its affairs and for carrying out its functions.

**CHAPTER III
CRUELTY TO ANIMALS GENERALLY**

11. (1) If any person

- (a) beats, kicks, over-rides, over-drives, over-loads, tortures or otherwise treats any animal so as to subject it to unnecessary pain or suffering or causes, or being the owner permits, any animal to be so treated; or
- (b) *(employs in any work or labour or for any purpose any animal which, by reason of its age or any disease) infirmity, wound, sore or other cause, is unfit to be so employed or, being the owner, permits any such unfit animal to be employed; or
- (c) wilfully and unreasonably administers any injurious drug or injurious substance to **(any animal) or wilfully and unreasonably causes or attempts to cause any such drug or substance to be taken by ***(any animal); or
- (d) conveys or carries, whether in or upon any vehicle or not, any animal in such a manner or position as to subject it to unnecessary pain or suffering; or
- (e) keeps or confines any animal in any cage or other receptacle which does not measure sufficiently in height, length and breadth to permit the animal a reasonable opportunity for movement; or
- (f) keeps for an unreasonable time any animal chained or tethered upon an unreasonably short or unreasonably heavy chain or cord; or
- (g) being the owner, neglects to exercise or cause to be exercised reasonably any dog habitually chained up or kept in close confinement; or
- (h) being the owner of (any animal) fails to provide such animal with sufficient food, drink or shelter; or
- (I) without reasonable cause, abandons any animal in circumstances which tender it likely that it will suffer pain by reason of starvation thirst; or

*Subs. by Act 26 of 1982, S. 10 (a) (i) for the words "employs in any work or labour any animal which, by reason of any disease";

**Subs. ibid S.10 (a) (ii) for the words "any domestic or captive animal".

***Subs. ibid S. 10 (a) (ii) for the words "any captive animal".

- (j) wilfully permits any animal, of which he is the owner, to go at large in any street, while the animal is affected with contagious or infectious disease or, without reasonable excuse permits any diseased or disabled animal, of which he is the owner, to die in any street; or
- (k) offers for sale or without reasonable cause, has in his possession any animal which is suffering pain by reason of mutilation, starvation, thirst, overcrowding or other ill-treatment; or
- * (1) mutilates any animal or kills any animal (including stray dogs) by using the method of strychnine injections in the heart or in any other unnecessarily cruel manner or;
- ** (m) solely with a view to providing entertainment
- (i) confines or causes to be confined any animal (including tying of an animal as a bait in a tiger or other sanctuary) so as to make it an object or prey for any other animal; or
- (n) ***[xxxx] organises, keeps uses or acts in the management or, any place for animal fighting or for the purpose of baiting any animal or permits or offers any place to be so used or receives money for the admission of any other person to any place kept or used for any such purposes; or
- (o) promotes or takes part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting:

he shall be punishable ****(in the case of a first offence, with fine which shall not be less than ten rupees but which may extend to fifty rupees and in the case of a second or subsequent offence committed within three years of the previous offence, with fine which shall not be less than twenty-five rupees but which may extend, to one hundred rupees or with imprisonment for a term which may extend, to three months, or with both.)

(2) For the purposes of section (1) an owner shall be deemed to have committed an offence if he has failed to exercise reasonable care and supervision with a view to the prevention of such offence;

**Subs. by Act 26 of 1982, S. 10 (a) (iv) for the original clause.

**Subs. ibid. S. 10 (a) (v) for the original clause.

***The words "for the purposes of his business" omitted by Act 26 of 1982, S. 10 (a) (vi)

****Subs. ibid S. 10 (a) (vii) for the portion beginning with the words "in the case of a first offence" and ending with the words "or with both".

Provided that where an owner is convicted permitting cruelty by reason only of having failed to exercise such care and supervision, he shall not be liable to imprisonment without the option of a fine.

- (3) Nothing in this section shall apply to
 - (a) the dehorning of cattle, or the castration or branding or noseroping of any animal in the prescribed manner, or
 - (b) the destruction of stray dogs in lethal chambers *[by such other I methods as may be prescribed] or
 - (c) the extermination or destruction of any animal under the authority of any law for the time being in force; or
 - (d) any matter dealt with in Chapter IV; or
 - (e) the commission or omission of any act in the course of the! destruction or the preparation .tor destruction of any animal as food for mankind unless such destruction or preparation was accompanied by the infliction of unnecessary pain or suffering.

Penalty for Practising phooka or doom dev.

12. If any persons upon any cow or other milch animal the operation called phooka or **[doom dev or any other operation (including injection of any substance) to improve lactation which is injurious to the health of the animal] or permits such operation being performed upon any such animal in his possession or under his control, he shall be punishable with fine' which may extend to one thousand rupees, or with imprisonment for a term which may extend to two years, or with both, and the animal on which the operation was performed shall be forfeited to the Government.

Destructions or suffering animals

13. (1) Where the owner of an animal is convicted of an offence under section 11, it shall be lawful for the court, if 'the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animals to any suitable person for that purpose, and the person to whom such animal is so assigned shall as soon as possible, destroy such animal or cause such animal to be destroyed in his presence without unnecessary suffering: and any reasonable expense incurred in destroying the animal may be ordered by the court, if the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animal to any reasonable expense incurred in destroying the animal may be ordered by the court to be recovered from the owner as if it were a fine:

*Subs. by Act 26 of 1982, S. 10 (b), for the words "by the other methods with a minimum of suffering"

** Subs. ibid S. 11, for the words, "doom dev"

Provided that unless the owner assents there to, no order shall be made under this section except upon the evidence of a veterinary officer in charge of the area.

- (2) When any magistrate, commissioner of police or district superintendent of police has reason to believe that an offence under section 11 has been committed in respect of any animal, he may direct the immediate destruction of the animal, if in his opinion, it would be cruel to keep the animal alive.
- (3) Any police officer above the rank of a constable or any person authorised by the State Government in this behalf who finds any animal so diseased or so severely injured or in such a physical condition that in his opinion it cannot be removed without cruelty, may, if the owner is absent or refuses his consent to the destruction of the animal, forth with summon the veterinary officer in charge of the area in which the animal is found, and if the veterinary officer certifies that the animal is mortally injured or so severely injured or in such a physical condition that it would be cruel to keep it alive, the police officer or the person authorised, as the case may be, may, after obtaining orders from a magistrate, destroy the animal injured or cause it to be destroyed; *(in such manner as may be prescribed)
- (4) No appeal shall lie from any order of a magistrate for the destruction of an animal.

CHAPTER IV

EXPERIMENTATION OF ANIMALS

Experiments on animals

Nothing contained in this Act shall render unlawful the performance of experiments (including) experiments involving operations) on animals for the purpose of advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or for prolonging life or alleviating suffering or for combating any disease, whether of human beings, animals or plants.

Committee for control and supervision of experiments on animals

15. (1) If at any time, on the advice of the Board, the Central Government is of opinion that it is necessary so to do for the purpose of controlling and supervising experiments on animals it may be notification in the Official Gazette

*Ins.by Act 26 of 1982, S.12

Constitute a Committee consisting of such number of officials and non-officials, as it may think fit to appoint thereto.

- (2) The Central Government shall nominate one of the Members of the Committee to be its Chairman.
- (3) The Committee shall have power to regulate its own Procedure in relation to the performance of its duties.
- (4) The funds of the Committee shall consist of grants made to it from time to time by the Government and of contributions, donations, subscriptions, bequests, gifts and the like made to it by any person.

Sub-committee *[15A.(1) **The Committee may constitute as many sub-committees as it thinks fit for exercising any power or discharging any duty of the Committee or for inquiring into or reporting and advising on any matter which the Committee may refer.**

- (2) A sub-committee shall consist exclusively of the Members of the Committee.]

Staff of the committee

16. **Subject to the control of the Central Government, the Committee may appoint such number of officers and other employees as may be necessary to enable it to exercise its powers and perform its duties and may determine title remuneration and other terms and conditions of service of such officers and other employees.**

Duties of the Committee and power of the committee to make rules relating to experiments on animals.

17. (1) **It shall be the duty of the Committee to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them, and for the purpose it may, by notification in the Gazette of India and subject to the condition of previous publication, make such rules as it may think fit in relation to the conduct of such experiments.**

**[(1 A) In particular, and without prejudice to the generality to the foregoing power, such rules may provide for the following matters namely:

- (a) the registration of persons or institutions carrying on experiments on animals;
- (b) the reports and other information which shall be forwarded to the Committee by persons and institutions carrying on experiments on animals.]
- (2) In particular, and without prejudice to the generality of the foregoing power, rules made by the Committee shall be designed to secure the following objects, namely:

*Ins. by Act 26 of 1982, S. 13.

**Ins. by Act 26 of 1982, S. 14.

- (a) that in cases where experiments are performed in any institution, the responsibility therefore is placed on the person in charge of the institution and that, in cases where experiments are performed outside an institution by individuals, the individuals, are performed outside an institution by individuals, the individuals, are qualified in that behalf and the experiments are performed on their full responsibility;
- (b) that experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power .to prevent the animals feeling pain;
- (c) that animals which, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;
- (d) that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
- (e) that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, frogs and rats;
- (f) that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- (g) that animals intended for the performance of experiments are properly looked after both before and after experiments;
- (h) that suitable records are maintained with respect to experiments performed on animals
- (3) In making any rules under this section, the Committee shall be guided by such directions as the Central Government (consistently with the objects for which the Committee is set up) may give to it, and the Central Government is hereby authorised to give such direction.
- (4) All rules made by the Committee shall be binding on all individuals performing experiments outside institutions and on persons incharge of institutions in which experiments are performed.

Power of entry and inspection

- 18. **For the purpose of ensuring that the rules made by it are being complied with the Committee may authorise any of its officers or any other person in writing to inspect any institution or place where experiments are being carried on and report to it as a result of such inspection, and any officer or person so authorised may**

- (a) enter at any time considered reasonable by him and inspect any institution or place in which experiments on animals are being carried on; and
- (b) require any person to produce any record kept by him with respect to experiments on animals.
- Power of Prohibit experiments on animals**
- 19. If the Committee is satisfied, on the report of any officer or other person made to it as a result of any inspection under section 18 or otherwise, that the rules made by it under section 17 are not being animals, the Committee may, after giving an opportunity to the person or institution carrying on experiments on animals; the Committee may, after giving an opportunity to the person or institution of being heard in the matter, by order, prohibit the person or institution from carrying on any such experiments either for a specified period or indefinitely, or may allow the person or institution to carry on such experiments subject to such special conditions as the Committee may think fit to impose.**
- Penalties**
- 20. If any person**
- (a) contravenes any order made by the Committee under section 19; or
- (b) commits a breach of any condition imposed by the Committee under that section:
- he shall be punishable with fine which may extend to two hundred rupees, and, when the contravention or breach of condition has taken place in any institution the person incharge of the institution shall be deemed to be guilty of the offence and shall be punishable accordingly.

CHAPTER V PERFORMING ANIMALS

- "Exhibit and "Train" defined**
- 21. In this Chapter, "exhibit" means exhibit or any entertainment to which the public are admitted through sale of tickets, and "train" means train for the purpose of any such exhibition, and the expressions "exhibitor" and "trainer" have respectively the corresponding meanings.**
- Restriction on exhibition training of performing animals**
- 22. No person shall exhibit or train**
- (i) any performing animal unless he is registered in accordance with the provisions of this Chapter;

Procedure of registration

(ii) as a performing animal, any animal which the Central Government may, by notification in the official gazette, specify as an animal which shall not be exhibited or trained as a performing animal.

23 (1) Every person desirous of exhibiting or training any performing animal shall, on making an application in the prescribed form to the prescribed authority and on payment of the prescribed fee, be registered under this Act unless he is a person who, by reason of an order made by the court under this Chapter, is not entitled to be so registered.

(2) An application for registration under this Chapter shall contain such particulars as to the animals and as to the general nature of the performances in which the animals are to be exhibited or for which they are to be trained as may be prescribed, and the particulars so given shall be entered in the register maintained by the prescribed authority.

(3) The prescribed authority shall give to every person whose name appears on the register kept by them, a certificate of registration in the prescribed form containing the particulars entered in the register.

(4) Every register kept under this Chapter shall at all reasonable times be open for inspection on payment of the prescribed fee, and any person shall, on payment of the prescribed fee, be entitled to obtain copies thereof or make extracts therefrom.

(5) Any person whose name is entered in the register shall, subject to the provisions of any order made under this Act by any court, be entitled, on making an application for the purpose, to have the particulars entered in the register with respect to him varied, and where any such particulars are so varied, the existing certificate shall be cancelled and a new certificate issued.

Power of court to prohibit or restrict exhibition and training of performing animals

24. (1) Where it is proved to the satisfaction of any magistrate on a complaint made by a police officer or an officer authorised in writing by the prescribed authority referred to in section 23, that the training or exhibition of any performing animals has been accompanied by unnecessary pain or suffering and should be prohibited or allowed only subject to conditions, the court may make an order against the person in respect of whom the complaint is made, prohibiting the training or exhibition or imposing such conditions in relation thereto, as may be specified by the order.

- (2) Any court by which an order is made under this section, shall cause a copy of the order to be sent, as soon as may be after the order is made, to the prescribed authority by which the person against whom the order is made is registered. and shall cause the particulars of the order to be endorsed upon the certificate held by the person, and that person shall produce his certificate on being so required by the court for the purposes of endorsement, and the prescribed authority to which a copy of an order is sent under this section shall enter the particulars of the order in that register;

Power to enter premises

25.(1) Any person authorised in writing by the prescribed authority referred to in section 23 and any police officer not below the rank of a sub-inspector may

- (a) enter at all reasonable times and inspect any premises in which any performing animals are being trained or exhibited or kept for training or exhibition, and any such animals found therein; and
- (b) require any person who, he has reason to believe is a trainer or exhibitor of performing animals to produce his certificate of registration,
- (2) No person or police officer referred to in sub section (1) shall be entitled under this section to go on or behind the stage during a public performance of performing animals.

Offences

26. If any person

- (a) not being registered under this chapter, exhibits or trains any performing animal; or
- (b) being registered under the Act, exhibits or trains any performing animal with respect to which or in a manner with respect to which, he is not registered; or
- (c) exhibits or trains as a performing animal, any animal which is not to be used for the purpose by reason of a notification issued under clause (ii) of section 22; or
- (d) obstructs or wilfully delays any person or police officer referred to in section 25 in the exercise of powers under this Act as to entry and inspection; or
- (e) conceals any animal with a view to avoiding such inspection: or
- (f) being a person registered under the Act, on being duly required in pursuance of this Act to produce his certificate under this Act, fails without reasonable excuse so to do; or

- (g) applies to be registered under this Act when not entitled to be so registered,

He shall be punishable on conviction with fine which may extend to five hundred rupees or with imprisonment which may extend to three months, or with both.

Exemptions

27. Nothing contained in this Chapter shall apply to

- (a) the training of animals for bonafide military or police purpose or the exhibition of any animals so trained; or
(b) any animals kept in any zoological garden or by any society or association which has for its principal object the exhibition of animals for educational or scientific purposes.

**CHAPTER VI
MISCELLANEOUS**

Saving as respects manner of killing prescribed by religion

28. Nothing contained in this Act shall render it an offence to kill any animal in a manner required by the religion of any community.

Power of court to deprive person convicted of ownership animal

- 29.** (1) If the owner of any animal is found guilty of any offence under this Act, the court upon his conviction thereof, may, if it thinks fit, in addition to any other punishment make an order that the animal with respect to which the offence was committed shall be forfeited to Government and may, further, make such order as to the disposal of the animal as it thinks fit under the circumstances.
- (2) No order under sub section (1) shall be made unless it is shown by evidence as to a -previous conviction under this Act or as to the character of the owner or otherwise as to the treatment of the animal that the animal if left with the owner, is likely to be exposed to further cruelty.
- (3) without prejudice to the provision contained in sub-section (1), the court may also order that a person convicted of an offence under this Act shall, either permanently or during such period as is fixed by the order, be prohibited from having the custody of any animal of any kind whatsoever, or as the court thinks fit of any animal of any kind or species specified in the order.
- (4) No order under sub-section (3) shall be made unless
- (a) it is shown by evidence as to a previous conviction or as to the character of the said person or otherwise as to the treatment of the animal in relation to which he has been convicted that an animal in the custody of the said person is likely to be exposed to cruelty;

- (b) it is stated in the complaint upon which the conviction was made that it is the intention of the complaint upon the conviction of the accused to request that an order be made as aforesaid and
 - (c) the offence for which the conviction was made was committed in an area in which under the law for the time being in force a licence is necessary for the keeping of any such animal as that in respect of which the conviction was made.
- (5) Notwithstanding anything to the contrary contained in any law for the time being in force, any person in respect of whom an order is made under sub-section (3) shall have no right to the custody of any animal contrary to the provisions of the order, and if he contravenes the provisions of any order, he shall be punishable with fine which may extend to one hundred rupees, or with imprisonment for a term which may extend to three months, or with both.
- (6) Any court which has made an order under sub-section (3) may at any time, either on its own motion or on application made to it in this behalf, rescind or modify such order.

Presumption as to guilt in certain cases

30. If any person is charged with the offences of killing a goat, cow or its progeny contrary to the provisions of clause (1) of sub-section (1) or section 11, and it is proved that such person had in his possession, at the time the offence is alleged to have been committed, the skin of any such animal as is referred to in this section with any part of the skin of the head attached thereto, it shall be presumed until the contrary is proved that such animal was killed in a cruel manner.

Cognizability of Offences

31. Notwithstanding anything contained in the Code or Criminal procedure, 1898, (5 of 1898) an offence punishable under clause (1) or clause (n) or clause, (0) of sub-section (1) of section 11 or under section 12 shall be a cognizable offence within the meaning of that code.

Powers of search and seizure

32. (1) If a police officer not below the rank of sub-inspector, or any person authorised by the State Government in this behalf has reason to believe that an offence under clause (I) of sub-section (1) of section 11 in respect of any such animal as is referred to in section 30 is being, or that any person has in his possession the skin of any such animal with any part of the skin of the head attached thereto, he may enter and search such place or any place in which he has reason to believe any such skin to be, and may seize such skin or any article or thing used or intended to be used in the commission of such offence.

- (2) If a police officer not below the rank of sub-inspector, or any person authorised by the State Government in this behalf, has reason to believe that phooka or '(doom dev or any other operation of the nature referred to in section 12) has just been or is being, performed on any animal within the limits of his jurisdiction, he may enter any place in which he has reason to believe such animal to be, and may seize the animal and produce it for examination by the veterinary officer incharge of the area in which the animal is seized.
- Search Warrants** 33. (1) If a magistrate of the first or second class or a presidency magistrate or a commissioner of police or district superintendent of police, upon information in writing; and after such inquiry as he thinks necessary, has reason to believe that an offence under this Act is being, or is about to be, or has been committed in any place, he may either himself enter and search or by his warrant authorise any police officer not below the rank of sub-inspector to enter and search the place.
- (2) The provisions of the Code of Criminal Procedure, 1898, relating to searches shall so far as those provision can be made applicable, apply to searches under this Act.
- General Power of seizure for examination** 34. Any police officer above the rank of a constable or any person authorised by the State Government in this behalf, who has reason to believe that an offence against this Act has been or is being, committed in respect of any animal, may, if in his opinion the circumstances so require, seize the animal and produce the same for examination by the nearest magistrate or by such veterinary officer as may be prescribed; and such police officer or authorised person may, when seizing the animal, require the person in charge thereof to accompany it to the place of examination.
- Treatment and care of animals.** 35. (1) The State Government, may by general or special order appoint infirmaries for the treatment and care of animals in respect of which offences against this Act have been committed, and may authorise the detention therein of any animal pending its production before a magistrate.
- (2) The magistrate before whom a prosecution for an offence against this Act has been instituted may direct that the

*Subs. by Act 26 of 1982 S. 15 for the words "doom dev".

animals concerned shall be treated and cared for in an infirmary, until it is fit to perform its usual work or is otherwise fit for discharge, or that it shall be sent to a pinjrapole, or if the veterinary officer in charge of the area in which the animal is found or such a verterinary officer as may be authorised in this behalf by rules made under this Act certifies that it is incurable or cannot be removed without cruelty, that it shall be destroyed.

(3) An animal sent for care and treatment to an infirmary shall not, unless the magistrate directs that it shall be sent to a pinjrapole or that it shall be destroyed, be released from such place except upon a certificate of its fitness for discharge issued by the verterinary officer in charge of the area in which the infirmary is situated or such other veterinary officer as may be authorised in this behalf by rules made under this Act.

(4) The cost of transporting the animal to an infirmary or pinjrapole and of its maintenance and treatment in an infirmary, shall be payable by the district magistrate, or, in presidency-towns, by the commissioner of police;

Provided that when the magistrate so orders on account of the poverty of the owner of the animal, no charge shall be payable for the treatment of the animal.

(5) Any amount payable by an owner of an animal under subsection (4) may be recovered in the same manner as an arrear of land revenue,

(6) If the owner refuses or neglects to remove the animal within such time as a magistrate may specify, the magistrate may direct that the animal be sold and that the proceeds of the same be applied to the payment of such cost.

(7) The surplus, if any, of the proceeds of such sale shall, on application made by the owner within two months from the date of the sale be paid to him.

Limitation of Prosecutions.

36. A prosecution for an offence against this Act shall not be instituted after the expiration of three months from the date of the commission of the offence.

Delegation of Powers

37. The Central Government may, by notification in the official Gazette, direct that all or any of the powers exercisable by it under this Act, may, subject to such conditions as it may think fit to impose, be also exercisable by any State Government.

Power to make rules

38. (1) The Central Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to carry out the purposes of this Act.

- (2) In particular, and without prejudice to the generality of the foregoing power, the Central Government may make rules providing for all or any of the following matters, namely :-
- (a) the *(xxxx) conditions of service of members of the Board, the allowances payable to them and the manner in which they may exercise their powers and discharge their functions.
 - **[(aa) the manner in which the persons to represent municipal corporation are to be elected under clause (e) of sub-section (1) of section 5:)]
 - (b) the maximum load (including any load occasioned by the weight of passengers) to be carried or drawn by any animal ;
 - (c) the conditions to be observed for preventing the overcrowding of animals.
 - (d) the period during which, and the hours between which, any class of animals shall not be used for drought purposes :
 - (e) prohibiting the use of any bit or harness involving cruelty to animals.
 - ***[(ea) the other methods of destruction of stray dogs referred to in clause (b) of sub-section (3) of section 11;
 - (eb) the methods by which any animal which cannot be removed without cruelty may be destroyed under sub-section (3) of section 13,]
 - (f) requiring persons carrying on the business of a farrier to be licensed and registered by such authority as may be prescribed and levying a fee for the purpose;
 - (g) the precautions to be taken in the capture of animals for purposes of sale, export or for any other purpose, and the different appliances or devices that may alone be used for the purpose; and the licensing of such capture and the levying of fees for such licences;
 - (h) the precautions to be taken in the transport of animals whether by rail, road, inland waterway, sea or air and the manner in which and the cages or other receptacles in which they may be so transported;
 - (i) requiring person owning or in charge of premises in which animals are kept or milked to register such premises, to comply.

*The words "terms and" omitted by Act 26 of 1982, S. 16 (a) (i).

**Ins ibid S. 16 (a) (ii).

***Ins by Act 26 of 1982 S. 16 (a) (iii)

with such conditions as may be laid down in relation to the boundary walls or surroundings of such premises, to permit their inspection for the purpose of ascertaining whether any offence under this Act is being, or has been committed therein, and to expose in such premises copies of section 12 in a language or languages commonly understood in the locality;

(j) the form in which applications for registration under Chapter V may be made, the particulars to be contained therein the fees payable for such registration and the authorities to whom such applications may be made;

*[(ja) the fees which may be charged by the Committee constituted under section 15 for the registration of persons or institutions carrying on experiments on animals or for any other purpose;]

(k) the purposes to which fines realised under the Act may be applied, including such purposes as the maintenance of infirmaries, pinjrapole and veterinary hospitals;

(l) any other matter which has to be, or may be prescribed.

(3) If any person contravenes, or abets the contravention of, any rules made under this section, he shall be punishable with fine which may extend to one hundred rupees, or with imprisonment for a term which may extend to three months, or with both. **[xxxx]

Rules and Regulation to be laid before Parliament

***[38a. Every rule made by the Central Government or by the Committee constituted under section 15 and every regulation made by the Board shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty day which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation, as the case may be, should not be made the rule or regulation shall there after have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of any thing previously done under that rule or regulation.]

Persons authorised under Sec. 34 to be public servants.

39. Every person authorised by the State Government under section 34 shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal code.

*Ins. by Act 26 of 1982. S. 16 (a) (iv)

**Sub-section (4) of the Pincipal Act ommitted by Act 26 of 1982. S. 16(b)

***Ins. ibid S. 17.

indemnify	40	No suit, prosecution or other legal proceeding shall lie against any person who is, or who is deemed to be a public servant within the meaning of section 21 of the Indian Penal Code in respect of anything in good faith done or intended to be done under this Act.
Repeal of Act 11 of 1890	41	Where in pursuance of a notification under subsection (3) of section 1 any provision of this Act comes into force in any State, any provision of the Prevention of Cruelty to animals Act, 1890, which corresponds to the provision so coming into force, shall thereupon stand repealed.

ANNEXURE

Notifications under section 1 (3) of the Act bringing it into force in specified States and Union Territories.

1. (a) Chapters I and III came into force in the States of Assam, Andhra Pradesh, Bihar, Gujarat, Kerala, Chennai (Tamil Nadu), Maharashtra, Madhya Pradesh, Mysore (Karnataka), Orissa, Uttar Pradesh and West Bengal and the Union Territories or Delhi, Manipur and Tripura on the 1st September, 1961, vide Notification No. 9-2/61 L.D. dated 25th August, 1951/Bhadra, 1883 of Government of India. Ministry of Food and Agriculture (Department of Agriculture).
- (b) Chapter IV come into force in the States of Assam, Andhra Pradesh Bihar, Gujarat, Kerala, Chennai (Tamil Nadu), Maharashtra, Madhya Pradesh, Mysore (Karnataka), Orissa, Rajasthan, Uttar Pradesh and West Bengal and in the Union Territories of Delhi, Himachal Pradesh, Manipur and Tripura on the 15 July, 1963, vide Notification No. 19-12/63-LD Dated 11th July 1963/20th Asadha, 1885 (S.E.) of Government of India, Ministry of Food and Agriculture (Department of Agriculture).
- (c) Capters III and IV came into force in the States of Assam Andhra Pradesh, Bihar, Gujarat, Kerala, Chennai (Tamil Nadu), Maharashtra Madhya Pradesh, Mysore (Karnataka), Orissa, Uttar Pradesh and West Bengal and the Union Territories of Delhi, Himachal Pradesh, Manipur and Tripura on the 20th November, 1963 /7th Kartika 1885 (S.E.) of Government of India, Ministry of Food and Agriculture (Department of Agriculture)
- (d) Chapters III and IV came into force in West Bengal on the 1st June 1975. vide Notification No. 21-2/74-LDI. dated 28th May, 1975 of Government of India, Ministry of Agriculture and Irrigation (Department of Agriculture)
- (e) The whole Act came into force in the State of Punjab and the Union Territory of andaman and Nicobar Islands on the 1st april, 1961 vide Notification No. 9-2/61-LD of the Ministry of Food and Agriculture.
- (f) Chapters I and II came into force in the then Union Territory of Himachal Pradesh on the 2nd October, 1961 vide Notification No. 9-2/61 LD of the Ministry of Food and Agriculture.
- (g) Chapters I and II came into force on the 26th January, 1962 in the State of Rajasthan vide Notification No. 9-2/61-LD. of the Ministry of Food and Agriculture.
- (h) Chapters V came into force in all the States and Union Territories (except Jammu & Kashmir) on 24th May 1977 Vide Notification No. 14-22/76-LDI dated 24th May 1977 of Government of India, Ministry of Agriculture and Irrigation (Department of Agriculture).

MINISTRY OF SOCIAL JUSTICE & EMPOWERMENT

NOTIFICATION

New Delhi, the 15th December, 1998

S.O. 1074.—Whereas the draft Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 were published, as required by sub section (1) of Section 17 of, the Prevention of Cruelty to Animals Act, 1960 (59 of 1960) under the notification of the Government of India, Ministry of environment and Forests number S.O. 789(E) dated, the e September, 1998 in the Gazette of India, Extraordinary , Part II, section 31 Sub-section (ii) inviting objections and suggestion from all the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which copies of the Gazette, containing the said notification are made available to the public;

And, whereas the said Gazette was made available to the public on 8th September, 1998.

And whereas the objections/suggestions received in respect of the said draft rules, have been duly considered-by the Committee for control and supervision of experiments on animals;

Now, therefore, in exercise of the powers conferred by sub-section (1) (1A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 196 (59 of 1960), the Committee for control and supervision of experiments on animals hereby makes the following rules, namely:

1. Short Title and commencement. - (1) These rules may be called the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions. - In these rules, unless the context otherwise requires -

- (a) "Act" means the Prevention of Cruelty to Animals Act, 1960 (59 of 1960);
- b. "breeder" means a person including an institution, which breeds animals for the purpose of transfer to other authorised institution for performing experiments;
- c. "Committee" means the Committee under section 15 of the Act for control and supervision of experiments on animals;
- (d) "establishment means any individual, company, firm, corporation, institution other than schools up to higher secondary level, which performs experiments on animals;
- (e) "experiment" means any programme/project involving experiments on an animal /animals for the purpose of advancement by new discovery of physiological knowledge which will be useful for saving or prolonging life or

alleviating suffering or for combating any disease whether on human beings or animals;

- (f) "Institutional Animals Ethics Committee" means a body comprising of a group of persons recognised and registered by the Committee for the purpose of control and supervision of experiments on animal performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee;
- (g) "contract Research" means any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, company, firm, corporation or institution for any consideration;
- (h) "collaborative research" means any research undertaken between two or more research institutions on an equal footing which does not involve any financial or monetary considerations and is undertaken solely for the purpose of advancement of scientific research and human welfare;
- (i) "specified format" means the form specified for the purpose by the Committee from time to time.

3. Breeding of animals –

- (a) No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered.
- (b) Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall, apply for registration within sixty days from the date of commencement of these rules and, stop breeding of animals if registration is subsequently refused to it by the Committee.

4. Registration of establishments. –

- (a) No establishment shall perform any experiment on animals unless it is registered.
- (b) Every establishment performing experiments on animals, shall, apply for registration within sixty days from the date of commencement of these rules and, stop performing experiments on animals if registration is subsequently refused to it by the Committee.

5. Application for registration. –

- (a) The application for registration by a breeder under sub-rule (b) of rule 3 and an establishment under sub-rule (b) of rule 4 shall be made in the specified format to the Member- Secretary or any other officer authorised in this regard by the Committee.
- (b) The Member-Secretary or the authorised officer of the Committee, may for deciding the issue of registration, ask for information relating to premises

where the experiments are to be conducted, animal housing facilities, details of breeding of animals and its trade, other infrastructure including availability of manpower trained in handling animals and for verification of facts mentioned in the application for registration, and if satisfied, shall register such establishment or the breeder.

- (c) A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with the conditions as may be specified, at the time of registration, by the Member-Secretary of the Committee or any officer authorised in this regard by the Committee.

6. Details of the experiments conducted. –

- (a) Every registered establishment shall maintain a register as per the specified format and keep complete particulars about the kind of animal to be used for conducting any experiment, the health of the animal, the nature of experiment to be performed, and the reasons necessitating the performance of such an experiment on particular species.
- (b) The Member-Secretary or the officer authorised by the Committee in this behalf may examine the register so maintained, and if, he is not satisfied irrespective -of the -opportunity given for improvement, he may bring the same to the notice of the Committee seeking directions in this regard.

7. Stocking of animals.— The animals shall be stocked by the breeder and the establishment in the following manner:-

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

8. Permission of the Committee required for conducting experiments. –

- (a) Every registered establishment before acquiring an animal or conducting any experiment on an animal/animals shall apply for permission of the Committee

or the Institutional Animals Ethics Committee recognised for the purpose by the Committee along with the details contained in the specified format to the Member Secretary of the Committee or the Institutional Animals Ethics Committee, as the case may be.

- (b) The Member Secretary of the Committee or the Institutional Animals Ethics Committee, shall cause the application for permission to be brought before the Committee/Institutional Animals Ethics Committee as the case may be, and the Committee/ Institutional Animals Ethics Committee after scrutiny of the application, if satisfied, may grant permission to the establishment stating the name of the species and the number of animals that can be acquired for carrying out the experiments.
- (c) The Committee or Institutional Animals Ethics Committee, as the case may be, may, while granting permission for conducting experiments on animals, put conditions as it may deem fit to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.
- (d) The Committee may require the establishments and Institutional Animals Ethics Committees and persons carrying on experiments on animals to forward to the Committee such information as it may require, on completion of experiments for which the permission has been granted.

9. Performance of experiments.- In conducting experiments on animals, regard shall be had to the following conditions, namely:

- (a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
- (b) experiments shall be performed with due care and humanity;
- (c) animals intended for the performance of experiments are properly looked both before and after experiments;
- (d) experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic to prevent the animal feeling pain and it shall remain so throughout the experiment. Anesthesia shall be administered by a Veterinary Surgeon trained in methods of anesthesia or a Scientist/technician so trained for this purpose and who shall remain present near the animal till the completion of the experiment;
- (e) animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anesthesia;

- (f) when there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment;
 - (g) the experiment shall not be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions;
 - (h) experiments shall not be performed by way of an illustration;
 - (i) experiments shall not be performed as a public demonstration;
 - (j) the substance known as Urari or Curari or any such paralyser shall not be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness;
 - (k) no experiment the result of which is already conclusively known, shall be repeated without previous justification;
 - (l) there shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain;
 - (m) dogs held for experimental purposes shall not be debarked.
 - (n) where experiments are performed in any institution, the responsibility therefor is placed on the person in charge of the institution and in cases where experiments are performed outside an institution by an individual qualified in that behalf, the experiments, are performed on his responsibility.
- 10. Transfer and acquisition of animals for experiment.** - (a) A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these' rules.
- (b) An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment.
 - (c) Every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment.
 - (d) The animals used for experimentation in a production/ breed improvement programme may be given out by the breeder' institution for domestic use.
 - (e) No animal shall be imported by a breeder or an establishment which is available in the country.
 - (f) A breeder or establishment shall comply, with the directions given by the Committee for the purpose of controlling and supervising experiments on animals.

- 11. Records.** - (a) Every, establishment/Institutional Animals Ethics Committee shall maintain a record of the animals under its control and custody in the specified format.
- (b) Every establishment/Institutional Animals Ethics Committee shall furnish such information, as the Committee may from time to time require in the specified format.
- (c) All laboratories shall inform the exact number/ species of animals to the Member Secretary or any officer authorised in this regard by the Committee as per the specified format.
- 12. Contract animal experiments.-** No establishment shall contract or undertake to perform contract research or experiments on contract basis on behalf of any other establishment or research or educational Institution, This shall not apply to collaborative research between academic institutions.
- 13. Composition of Institutional Animals Ethics Committee.** - Every Institutional Animals Ethics committee shall include a biological scientist, two scientists from different biological disciplines, a veterinarian involved in the care of animal, the scientist in charge of animals facility of the establishment concerned, a scientist from outside the institute, a non scientific socially aware member and a representative or nominee of the specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.
- 14. Power to suspend or revoke registration. –**
- (a) If the Committee is satisfied, on the report of the Member-Secretary of the authorised officer of the Committee made to it as a result of any inspection or information received otherwise that the rules made by it are not being complied with by any establishment or breeder or an Institutional Animals Ethics Committee, the Committee may, after giving a reasonable opportunity to the establishment or breeder or Institutional Animals Ethics Committee of being heard in the matter, revoke the registration of such establishment or breeder or Institutional Animals Ethics Committee either for a specified period or indefinitely, or may allow the establishment of- breeder or Institutional Animals Ethics Committee to carry on subject to such special conditions as the Committee may impose.
- (b) The Committee may, pending the final determination, if, it is of the opinion that an establishment or breeder has prima facie failed to comply with the provisions of these Riles, suspend the registration of such establishment or the breeder.
- (c) The Committee may in the event of revocation or suspension of registration of an establishment or breeder, issue such directions as it, deems fit for the care and protection of the animals which are under the custody or control of such establishment or the breeder.

- (d) That in the event of suspension or revocation of a license, such establishment or breeder shall forthwith on the communication of the order cease to perform any experiment on, any animal or acquire or transfer any animal.

{F. No. 7-5/98-AW]
ASHOK PAL SINGH, Member Secretary
Committee for the Purpose of Control &

Supervision of Experiments on Animals

MINISTRY OF SOCIAL JUSTICE AND EMPOWERMENT

NOTIFICATION

New Delhi, the 15th February, 2001

S.O. 134(E).—Whereas certain draft rules to amend the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 were published, as required by sub-section (1) of section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960) under the notification of the Government of India in the Ministry of Social Justice and Empowerment number S.O. 168(E) dated the 18th February, 2000 inviting objections and suggestions from all the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which copies the Gazette containing the said notification are made available to the public;

And whereas the said Gazette was made available to the public on 24th February, 2000;

And whereas the objections/suggestions received in respect of the said draft rules, have been duly considered by the Committee for control, and supervision of experiments on animals;

Now, therefore, in exercise of the powers conferred by sub-sections (1), (1A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), the Committee for control and supervision of experiments on animals hereby makes the following rules to amend the Breeding of and Experiments on Animals (Control and Supervision) rules, 1998, namely:-

1. (1) These rules may be called the Breeding of and Experiments on animals (Control and Supervision) Amendment Rules, 2001.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (hereinafter referred to as the said rules), in rule 2, for the existing clause (e), the following clause shall be substituted, namely:

(e) "experiment" means any programme/project involving use of an animal/animals for the acquisition of knowledge of a biological, psychological, ethological, physical or chemical nature; and includes the use of animal in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of, saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals.

3. In the said rules, in rule 5, for sub-rule (c) the following sub-rules shall be substituted, namely:-

"(c) A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with the conditions as may be specified at the time of registration by the Committee.

(d) The Committee or any other-officer authorized In this regard by the Committee shall take decision on the registration within three months of making the application.

(e) if any modification of facilities are required before registration, the details needed shall be communicated by the Committee."

(4) In the said rules, for rule 6, the following rule shall be substituted, namely:-

"6. Detail; of the experiments conducted:- (a) Every registered establishment shall- maintain a register of particulars about the animals used from: day to day for conducting experiments, with the number of animals, the species, the age, gender and other relevant particulars

"(b) "The Committee or any other officer authorized by the Committee may examine the register so maintained and if the Committee is not satisfied even after opportunities given for Improvement, It may take such action as may be appropriate under these rules".

(5) In the said rules, in rule 7, after the existing condition (f), the following conditions shall be inserted, namely:-

"(g) - detailed specifications for housing, feeding and maintenance of various species to be used In animal experimentation as notified by the Committee, shall be adhered to by the registered establishment.

(h) In the Interim period fill such detailed specifications are notified, the breeders and establishments shall comply with the Indian National Science Academy Guidelines."

(6) In the said rules, in rule 9, - (i) for the existing condition (a), the following condition shall be substituted, namely:-

"(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree holders In Medicine or Veterinary Science, Post Graduate and above in life Sciences/Pharmaceutical Sciences or any other natural sciences, Degree or Diploma holders in Pharmacy, Diploma or Certificate In Laboratory Animal Techniques Sciences from a recognized Institution as Identified by Committee for the Purpose of Control and Supervision of Experiments on Animals for the purpose and under the responsibility of the person performing the experiment,";

(ii) for the -existing, condition (g), the following condition shall be substituted, namely:

(g) the experiments shall not be performed for the sole purpose of attaining or retaining manual skill except In schools, colleges and programmes duly scrutinized and permitted in registered establishments by the Committee;";

(iii) in the existing condition for the words, "the substance known as urari or curare or any such paralyisan shall not be used", the words "**no paralyzing agent, Including but not limited to curare, shall be used**" shall be substituted.

7. In the said rules, in rule 10,-

(i) for sub-rule (b), the following sub-rules shall be substituted, namely:-

"(b) A breeder or establishment shall not acquire -any animal by sale or otherwise except from a registered breeder or establishment.

(bb) For the acquisition of laboratory bred experimental rats and mice species of genetically defined strains not available within the country, the registered breeders or establishments shall apply for permission to the Institutional Animal Ethics Committee recognized by the Committee for the Purpose of Control and Supervision of Experiments on Animals."

(ii) for sub-rule (e), the following-sub-rule shall be substituted, namely:-

"(e) No animal shall be Imported by a registered breeder or establishment, except genetically defined or laboratory bred experimental rats an! d mice of genetically defined strains, which is available in the country."

8. In the said rules, for rule 12, the following rule shall be substituted, namely:-

"12. Contract animal experiments. - No establishment shall contract or undertake to perform contract research or

experiments on contract basis on behalf of any other establishment or research or educational Institution, except with prior permission of the committee:

Provided that no such restriction shall apply to collaborative research between academic Institutions."

[F. No. 7-5/98-AW (Vol. II)]

A. K. JOSHI, Member Secy.

(Committee for the Purpose of Control and Supervision of Experiments on Animals)

Note:—The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide S.O. No. 809, dated 15th December, 1998.

MINISTRY OF ENVIRONMENT AND FORESTS

NOTIFICATION

New Delhi, the 23rd October, 2006.

S.O. 1818 (E). - Whereas certain draft rules to amend the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 were published, as required by sub-sections(1), (1A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), under the notification of the Government of India in the Ministry of Environment and Forests number S.O.42(E) dated 10th January, 2006 inviting suggestions from all the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which copies of the Gazette containing the said notification are made available to the public;

And whereas the said Gazette was made available to the public on 10th January, 2006;

And whereas the objections/suggestion received in respect of the said draft rules, have been duly considered;

Now, therefore, in exercise of the powers conferred by sub-section (1), (1A) and (2) of Section 17 of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960), the Committee for the purpose of control and supervision of experiments on animals hereby makes the following rules to amend the Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998, namely:-

1. (1) These rules may be called the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006.
- (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (hereinafter referred to as the said rules), in rule 2, for clause (e), the following clause shall be substituted, namely:-

'(e) "Experiment" means any programme or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical or chemical nature; and includes the use of animal(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering or significant gains in well being for people of the country or for combating any disease whether of human beings or animals;'

3. In rule 9 of the said rules, -

(1) after clause (b), the following clause shall be inserted, namely:-

"(bb) animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure and the experiment should be designed using minimum number of animals to give statistically valid results at 95% degree of confidence:

Provided that replacement alternatives not involving experiments on animals should be given due and full consideration and sound justification must be provided in case alternatives, though available, are not used;" ;

(2) after clause (c), the following clause shall be inserted, namely:

"(cc) (i) personnel using experimental animal(s) shall be responsible for the welfare of animal(s) during their use in experiments;

(ii) investigators shall be responsible for the aftercare and rehabilitation of animal(s) after experimentation, and shall not euthanise animal(s) except in situations as defined in clause (ff);

(iii) costs of aftercare and rehabilitation of animal(s) after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animal(s);

(iv) rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and

(v) the establishment undertaking experiments or duly licensed and authorised animal welfare organization under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals;”;

(3) after clause (f), the following clause shall be inserted, namely:-

“(ff) the following parameters shall be adopted for application of euthanasia, namely:-

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

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

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

4. In rule 10 of the said rules, -

(1) for clause (b), the following clause shall be substituted, namely:-

“(b) (i) an establishment shall acquire animal(s) for experiments from registered breeders only;

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

(iii) in case the animal is procured from the alternate legal sources, the same shall be procured after taking written permission from the authority competent under the law for the time being in force, to give such permission; and

(iv) the establishment procuring such animal shall maintain a record in this regard and shall produce the same before the Committee, whenever required;” ;

(2) for clause (e), the following clause shall be substituted, namely:-

“(e) In case an animal is not available from a registered breeder or from alternate legal sources within the country, genetically defined animals may be imported with permission of Directorate General of Foreign Trade:

Provided that the condition of non-availability within the country shall not apply for laboratory bred rats and mice of genetically defined strains;”.

5. For rule 12 of the said rules, the following rule shall be substituted, namely:-

“12. Contract animal experiments. - Registered establishments may undertake contract research on behalf of any other agency in accordance with the Prevention of Cruelty to Animals Act, 1960 (59 of 1960) and the rules made thereunder.”.

6. In rule 14 of the said rules, for clause (a), the following clause shall be substituted, namely:-

“(a) The Committee, if it is satisfied with the report of the Member-Secretary or the authorized officer of the Committee (made to it as a result of any inspection or information received or otherwise) that -

(i) the rules made by it are not being complied with by an establishment or breeder; or

(ii) a violation of the directions of the Committee has been committed by any establishment or breeder and the Committee’s directions to rectify such violation have not been complied within the period so specified,

the Committee may, by order in writing, suspend or revoke the registration of the establishment or breeder and/or direct closure of the animal house facility for such a period as may be specified in the order:

Provided that no order under this clause shall be made without giving the establishment or breeder any opportunity of being heard in the matter:

Provided further that no order for suspension or revocation of registration, or closure of animal house facility shall be issued in a case of minor violation.

Explanation:- for the purposes of this clause, "minor violation" means an act of commission or omission which does not have direct bearing on the health of an animal which may not lead to adverse health effect or pain or suffering or death of an animal."

(F.No.25/04/2005-AWD)

(Somya T. Dave)
Member Secretary,
Committee for the Purpose of Control and Supervision of Experiments on Animals

Note:- The principal rules were published in the Gazette of India, Extraordinary, vide number S.O. 1074 dated 15th December, 1998 and subsequently amended vide number S.O.134(E) dated 15th February, 2001.

**{ TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY,
PART II, SECTION 3, SUB-SECTION (ii) }**

GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT AND FORESTS
Notification

New Delhi the 19th October, 2006

S.O. 1817(E). - In exercise of the powers conferred by section 15 of the prevention of Cruelty to Animals Act, 1960, (59 of 1960), the Central Government, on the advice of the Board, and being satisfied that it is necessary for the purpose of controlling and supervising experiments on animals, hereby constitutes a Committee consisting of following persons as its members, with effect from the date of publication of this notification in the Official Gazette, namely:-

1.	Additional Secretary, Incharge of Animal Welfare, Government of India, Ministry of Environment and Forests, New Delhi.	Chairperson / Member
2.	Joint Secretary (Animal Welfare), Ministry of Environment and Forests, New Delhi.	Vice- Chairperson/ Member
3.	Dr. (Mrs.) Vasantha Muthuswamy, Senior Deputy Director General & Chief, Division of BMS, Traditional Medicines & Bioethics, Indian Council of Medical Research, Ansari Nagar, New Delhi-110 029.	Member
4.	Dr. P. Balakrishna Murthy, Director, International Institute of Biotechnology and Toxicology (IIBAT), 12, Harleys Raod, Kilpauk, Chennai-600 010.	Member
5.	Dr. D. Swarup Head, Division of Medicine, Indian Veterinary Research Institute, Izatnagar-243 122, (Uttar Pradesh)	Member

6.	Dr. K. Nachimuthu, Director of Research, Tamilnadu Veterinary and Animal Sciences University Madhavaram Milk Colony Chennai-600 051	Member
7.	Prof. Anup Kumar Nayak, Wildlife Institute of India Post Bag # 18, Chandrabani, Dehradun - 248 001, Uttranchal.	Member
8.	Dr. Kodavalla Venkaiah, Head & Asst. Director, Bio-Statistics Deptt., National Institute of Nutrition, Jamai-Osmania (PO), Hyderabad - 500 007.	Member
9.	Dr. V.K. Vinayak, (Retd. Senior Advisor), Department of Biotechnology, B-1, E-12, Mohan Co- operative Industrial Estate, Mathura Road, New Delhi-110 044.	Member
10.	Prof. A. Jagannadha Rao (Retd.) Department of Bio-Chemistry and Molecular Reproduction, Development & Genetics, Indian Institute of Science, Bangalore-560 012	Member
11.	Dr. Shashi Motilal, Professor (Philosophy), University of Delhi, 7, Vaishali Apartments, IIT/Delhi, Hauz Khas, New Delhi-110 016	Member
12.	Dr. T.P.R. Bharadwaj, Senior Consultant, Haematologist, Apollo Hospitals, 21, Greams Lane, Off. Greams Road, Chennai-600 006	Member
13.	Director (Animal Welfare), Ministry of Environment & Forests, New Delhi.	Member Secretary

2. The Central Government hereby nominates Additional Secretary, incharge of Animal Welfare, Ministry of Environment and Forests and Member to be the Chairperson of the Committee as per sub-section (2) of section 15 of the said Act.
3. Joint Secretary (Animal Welfare), Ministry of Environment and Forests and Member will be Vice Chairperson of the Committee.
4. The term of the Committee shall, unless sooner dissolved, be four years from the date of its constitution.
5. The Committee constituted earlier vide Gazette Notification No. S.O. 32(E) dated 10th January, 2003 amended subsequently vide Notification Numbers S.O.599(E) dated 26.05.2003; S.O.955(E) dated 21.8.2003; S.O.69(E) dated 15.01.2004; S.O.85(E) dated 25.1.2005; S.O.1491(E) dated 17.10.2005 and S.O. 933 (E) dated 21.6.2006 stands dissolved from the date of publication of this notification in the Official Gazette.

(Desh Deepak Verma)
Joint Secretary
[F.No.25/34/2004-AWD]

Note: The earlier notification constituting the committee for the Purpose of Control and Supervision of Experiments on Animals was published in the Gazette of India, Extraordinary vide No. S.O.32(E) dated 10.1.2003 and was subsequently amended vide notification numbers S.O. 599(E) dated 26.05.2003; S.O.955(E) dated 21.8.2003; S.O.69(E) dated 15.01.2004; S.O. 85(E) dated 25.1.2005; S.O.1491(E) dated 17.10.2005 and S.O. 933(E) dated 21.6.2006

***Application for Registration of Breeder/Establishment/Educational Institutions / Shelters**

1. Name and address of establishment

with Tel. No., Fax No. & E-mail.

- a) Number & date of registration as per company act / council or any other act
- b) Name of the Sister organization and Address & Reference number
- c) Premises is Rented / leased / self owned.

2. Name of the Head of the organization with Address & Contact number.

3. Objectives of the organization

4. Purpose of Registration

5. Procurement of animal

Name of the supplier & Address Registration Number Mode of transportation

6. Availability of animals and their housing facilities (please attach layout plan of AHF)

Name & breed of animals Number Sex Age

7. Place and facilities to conduct animal experimentation

- a) Location of Animal House Facility (In the same premises or outside premises).

8. Trained staff for animal experimentation

Name Designation Qualification Experience

9. Post experimental facilities for Animals

{In case of rehabilitation, registration number of shelter to which animal will be rehabilitate }

10. Details regarding Animal Breeding

- a. Breeding for experimentation
- b. Breeding for trade or business

11. Institutional Animal Ethics Committee (as per Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended)

a) Date of constitution of IAEC

b)

Name of member & age (DOB)	Designation	Qualification	Experience	Organization to which they belong	Resume Consent of member
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c) Minutes of IAEC in which the proposal of registration with CPCSEA is approved, with signature of all the members.

12. Information regarding ongoing research proposals with animal experimentation and dates of approval of CPCSEA / other agencies (including sister organization)

13. Mode of transportation of animals.

Verification:

I, (name and designation of authorised officer), do hereby verify that the contents of the above paragraphs 1 to 12 are true to the best of my knowledge and nothing relevant material has been concealed therein.

Signature

Name and designation of head of the organization / Chairman, IAEC

Seal

Date:

Place:

*The filled in Registration Form A having above information / details / supporting documents should be sent to the Member Secretary, CPCSEA, Ministry of Environment & Forests, 8th floor, Jeevan Prakash Building, 25, Kasturba Gandhi Marg, New Delhi-110 001

CHECK-LIST

(To be submitted for consideration of CPCSEA)

Title of the protocol	
Name and address of the Institute submitting proposal, with Ref No. if any	
CPCSEA Registration No. and valid upto	
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
Type of research work	<ol style="list-style-type: none"> 1. Academic Research 2. In-house R&D 3. Drug Development & Research 4. Preclinical toxicity study 5. Multicenter research collaborative study 6. Education 7. Contract Research
Name & Address of CPCSEA Nominee and Link Nominee and date of appointment	
[Date of change of Nominee (if any)]	
Composition of IAEC as per approved guidelines and the names and addresses of the establishment / members to which they represent	
whether detailed signed minutes of IAEC by members including nominee attached with the protocol.	
Recommendations of IAEC	
Recommendation of Institutional Bio Safety Committee (IBSC)	
Recommendations of Review Committee on Genetic Manipulation (RCGM)	
The date of last inspection of Animal House Facility and approval details conveyed by CPCSEA.	
Name of the PI with designation, qualification and work experience with animals.	
Name of the Co-PI with designation, qualification and work experience with Large Animals.	
Source of procurement of animals, types, number, age & sex.	
Information regarding import / export of animals / material before and after experimentation.	
A signed declaration by PI 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, CPCSEA

Form B (per rule 8(a))*

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

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

Part A

1. **Name and address of 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 on which the experiment is to commence and duration of experiment.**
7. **Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)**

Signature

Name and Designation of
Investigator

Date:

Place:

*The filled in Form B having above information / details / supporting documents (1 original + 14 copies and 1 soft copy in CD) should be sent to: -

The Member Secretary,
CPCSEA, Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001

PART B

Protocol from for research proposals to be submitted to the committee / Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

- 1. Project / Dissertation / Thesis Title:**

- 2. Principal Investigator / Research Scholar / Research Guide / Advisor:**
 - a. Name
 - b. Designation
 - c. Dept / Div/ Lab
 - d. Telephone No.
 - e. Experience

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

Co-guides

 - a. Name
 - b. Address
 - c. Experience

- 4. Funding source with complete address (Please attach the proof)**

- 5. Duration of the project**
 - a. Number of months
 - b. Date of initiation (Proposed)
 - c. Date of completion (Proposed)

- 6. Detailed study plan may be given (Not more than one page)**

7. Animals required

- a. Species / Common name
- b. Age/ weight/ size
- c. Gender
- d. Number to be used (Year-wise breakups and total figures needed to be given)
- e. Number of days each animal will be housed.
- f. Proposed source of animals.

8. Rationale for animal usage

- a. Why is animals usage necessary for these studies?
- b. Why are the particular species selected required?
- c. Why is the estimated number of animals essential?
- d. Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.
- e. If yes, why new experiment is required?
- f. Have similar experiments been made by any other organization agency ? If so, their results in your knowledge.

9. Description the procedures to be used.

List and describe all invasive and potentially stress full non-invasive procedures that animals will be subjected to in the course of the experiments.

Furnish details of injections schedule

Substances	:
Doses	:
Sites	:
Volumes	:
Blood withdrawal	
Volumes	:
Sites	:
Radiation (dosage and schedules)	:

10. Please provide brief descriptions of similar studies from invitro / invivo (from other animal models) on same / similar test component or line of research. If, enough information is available, justify the proposed reasons.

11. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification.

12. Will survival surgery be done?

If Yes, the following to be described.

- a. List and description of all such surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of operators
- c. Description of post-operative care
- d. Justification in major survival surgery is to be performed more than once on a single individual animals.

13. Methods of disposal post-experimentation

a. Euthanasia (Specific method):

b. Method of carcass disposal :

c. Rehabilitation :

14. Animal transportation methods if extra-institutional transport is envisaged.

15. 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)

- (a) Radionuclides
- (b) Microorganisms / Biological infectious Agents
- (c) Hazardous chemicals or drugs
- (d) Recombinant DNA
- (e) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.

INVESTIGATOR'S DECLARATION.

1. I certify that I have determined that the research proposal herein 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 11, 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 significant changes in this study.
5. Certified 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 (to be named)).
6. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
7. I shall maintain all the records as per format (Form D)
8. I certify that, I will not initiate the study unless approval from CPCSEA received in writing. Further, I certify that I will follow the recommendations of CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted.

Signature

Name of Investigator

Date:

CERTIFICATE

This is certify that the project title
.....
has been approved by the IAEC.

Name of Chairman/ Member Secretary IAEC: Name of CPCSEA nominee:

Signature with date

Chairman/ Member Secretary of IAEC:

CPCSEA nominee:

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

FORM C

Record of Animals bred / acquired: (to be maintained by the Breeder/Establishment)

Date of entry	No. of Animals (Specify species, sex and age)	No. of Animals acquired (Specify date of acquisition species, sex and age)	Name, Address and date & from whom acquired	No. of animals transferred (specify date, species, sex and voucher/bill no.)	Name, address and registration No. of the Establishment to whom transferred	Signature
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FORM D

Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator)

Date of entry	No. of animals acquired (specify species, sex and age)	Name, address and registration No. of the breeder from whom acquired with voucher/bill no.	Date and particulars of order of grant of permission by the committee	Date/period of experiment	Name and address of the person authorizing the experiment	Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied with (Signature)
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CHECK LIST FOR INSPECTION OF ESTABLISHMENT /INSTITUTE

1.	Name and address of the Institute/Establishment (with contact no. Fax no. and mobile)	
	<p>(a) No. and Date of registration as per Company Act/Council or any other Act.</p> <p>(b) Whether the premises of the Institute/Establishment is on rent/lease or self owned (specify)</p> <p>(c) Name of the Sister concern (if any), where animal experiments are being carried out.</p> <p>(d) Location of the Animal House Facility (whether inside the premises or away from the premises) (Enclosed annexure I)</p>	
2.	Name of the Head of the organization & address with contact details	
3.	Objective(s) of the organization	
4.	Purpose for Registration with CPCSEA	
5.	<p>Type of work to be taken:</p> <p>(a) Research</p> <p>(b) Education</p> <p>(c) Breeding</p> <p>(d) Trade</p>	
6.	If Research, specify whether Basic/contract/collaborative/regulatory research	
7.	If Education, Name of the Certificate/Diploma/Degree	
8.	Composition of the IAEC in details having, Name/Designation/Qualification/Discipline and organization to which the members belong.	

9.	Enclose copy of detailed minutes of last IAEC meeting of the establishment/institute.	
10.	Overall assessment.	
11.	<p>Recommendation:</p> <p>(1) Recommended for approval (without any stipulations)</p> <p>(2) Recommended for re-inspection (Please specify here)</p> <p>(3) Recommended for rejection with specific grounds (Please specify here)</p>	

(Name & Signature of the Inspecting Authority)

INSPECTION REPORT OF ANIMAL HOUSE FACILITY

(a) Details of animals, Species wise, Kept at the time of Inspection in the Animal House

Details of Animals	Species	Number	Sex	Age

- (b) Veterinary Care of animals :
- (c) Health status of animals :
- (d) Animal Procurement :
- (e) Quarantine, Stabilization and Separation :
- (f) Physical Facilities :
- (i) Building materials :
- (ii) Corridor(s) :
- (iii) Utilities :
- (iv) Doors of Animal Room :
- (v) Exterior windows :
- (vi) Floors :

- (vii) Drainage :
- (viii) Walls and ceilings :
- (ix) Storage areas :
- (x) Facilities for sanitizing equipment and supplies :
- (xi) Experimental Area :
- (xii) Environment :
- (xiii) Temperature and Humidity control :
- (xiv) Ventilation :
- (xv) Power and lighting :
- (xvi) Noise control :
- (g) Animal Husbandry :

(i) Caging or housing system	
(ii) Sheltered or outdoor housing	
(iii) Social environment	

- (h) Food :
- (i) Bedding :
- (j) Water :
- (k) Sanitation and Cleanliness :
- (l) Waste Disposal :

- (m) Pest Control :
- (n) Emergency, weekend and holiday care :
- (o) Record Keeping :
- (p) Personnel and Training :
- (q) No. of technical Staff, supporting staff, details of the training of the supporting staff :
- (r) Transport of laboratory animals :
- (s) Anaesthesia and Euthanasia :
- (t) Laboratory animal ethics :
- (u) Transgenic animals :
- (v) Maintenance :
- (w) Disposal :
- (x) Details of rehabilitation facilities :
- (y) Overall assessment
- (z) Recommendation (_____)

1. Recommended for approval (without any stipulations).

2. Recommended for approval with suggestions for improvement
(please specify here)

3. Recommended for fulfillment of stipulated conditions before consideration for approval
(please specify here)

4. Recommended for rejection with specific grounds
(please specify here)

Member's Signature

Member's Signature

Member's Signature

**THE RECOMMENDATIONS OF THE SUB-COMMITTEE ON
REHABILITATION OF ANIMALS AFTER EXPERIMENTATION SET UP
BY CPCSEA**

- (i) The cost of aftercare and/or rehabilitation of animals post-experimentation are to be part of research costs and should be scaled per animal in positive correlation with the level of sentience of the animals.
- (ii) ******The average costs of rehabilitation and aftercare of different species of animals were thereafter worked out based on the actual average expenses incurred by various institutions. The Sub Committee was of the view that the following minimum amounts may be necessary for maintenance of animals after experimentation (for feed and husbandry but not including infrastructure and other overheads). *However, this may be reviewed once in two years, if required. The rehabilitation of small animals is not necessary.*

<u>Species</u>	<u>Minimum cost per day per animal (In Rs.)</u>
Dogs/Cats	20
Sheep/Goats	15
Cattle	25
Horse	25
Monkey	25

In the context of amended Rule 9 (cc) which provides for provision of a lump sum amount as costs for rehabilitation and care of such animals to cover its entire statistical expected life span, the Sub Committee discussions indicated that provision of a lump sum amount, payable to an AWO, would not cover the possibility that the animal may not actually live for its statistically expected lifespan. Accordingly payments at intervals, as also annual confirmation regarding the well being of the animal may be required.

Rule 9(cc) of the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules 2006 also provides for the AWOs to be under the control of the Committee. However, given the administrative structure of CPCSEA and the fact that proper scrutiny and registration of AWOs is already being done by AWBI, prior to release of grants, the Sub Committee was of the view that AWOs should be shortlisted from amongst those AWOs already registered with AWBI, on the basis of a well defined selection criteria.

- (iii) Since the basic responsibility for rehabilitation of the animals after experimentation was of the concerned establishment, Government may contribute financial support for rehabilitation of animals by NGOs or other institutions only under available animal welfare schemes.
- (iv) Breeding of animals, post-experimentation should not be allowed.

- (v) For animals recommended for euthanasia post-experimentation, the relevant criteria could be that:
 - (a) the animal is not able to perform its natural functions and left in pain & suffering.
 - (b) the animal has been exposed to contagious/infectious diseases of zoonotic importance.
 - (c) the animal has been exposed to radioisotope experiments.

In other cases, animals would have to be rehabilitated by the concerned institute unless they are fit for transfer to NGOs **or other institutions**.

Thus the Sub Committee was of the view that the possibility of the same animal being diverted for further use in scientific experimentation by another institution, should also be considered, as this would avoid use of additional animals. This could be operationalised by a scientific method of identifying each animal, and by putting in place a mechanism whereby details of experimental animals available with institutions, could be made available to other institutions for examining their suitability for further use. *The IAEC of the concerned institution will consider the issue as per existing norms and guidelines and forwarded its recommendation to the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) for consideration.*

- (vi) A format for maintaining health records of experimental animals has been devised, which will facilitate transfer of animals among institutions as well as to NGOs (**Annexure-I**).
- (vii) ICMR agreed to develop a web solution for facilitating exchange of details of animals available post-experimentation.

Regarding the ethical aspect of reuse of an animal, this is permitted in many countries, though sometimes with conditions eg not subjecting the animal more than once, to experiments involving severe pain, distress or suffering.

- (viii) A checklist for selection of NGOs for rehabilitation of experimental animals was also prepared (**Annexure-II**). *The agencies/NGOs and their Animal House Facilities must be registered with Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and should satisfy the conditions laid down by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) in this regard. The permanent identification marks eg tattooing must be done before rehabilitation of animals.* Further, once an institute handed over an animal to an NGO, it would be the responsibility of the NGO to ensure the well being of the animals, with annual inspection by the concerned institution. In case, it is necessary to transfer an animal out of the charge of the NGO, the concerned institute will be responsible for ensuring the continued well being of the animal.

- (ix) Since the concerned institute is otherwise required to look after or maintain animals post-experimentation, they would reach an agreement directly with the concerned NGO regarding any reimbursement for handling the animals, apart from any assistance that NGO may obtain directly from AWBI/any other source. Modalities for transfer of experimental animals would be handled directly between concerned institute/NGO and no guidelines would be required to be formulated except stipulating that all existing animal laws would be followed.
- (x) As regards the generic guidelines in respect of small animals, the mandate for examining proposals relating to small animals is with the IAECs.

** the animals which are presently out of experimentation and need instant rehabilitation prior to the notification of the Rehabilitation guidelines, will be provided a lump-sum amount by the establishments on the basis of types of animals, their health status and remaining lifespan of such animals, to the agencies. For the animals which are in experimentation and will be rehabilitated after their use by the establishment, the payment for maintenance of such animals will be made annually till the survival of the animals by the concerned organization, on the basis of demand made by the rehabilitating agency.

Experimental Animal Health Records

Instructions and guidelines

It is expected that all registered animal houses (for breeding or for conducting experiments) should adopt an institutional policy for animal welfare and implement the code of practice at different stages of animals under their custody. One of the most important aspects of this is to compilation and maintenance of accurate records relating to animal admissions, treatment, health, experimentation and rehabilitation. Records pertaining to these aspects provide valuable information and facilitate inspection at all times.

The following forms will help in achieving the objectives in line with the policy.

1. Items that are marked (*) in the forms are optional. However if information is available it should be presented
2. These forms are to be filled up only by designated persons and signed by appropriate authority
3. As an archival policy of the institute these forms should be available in the animal facilities for at least 10 years for inspection and data preservation.
4. Copies of the data pertaining to large animals at different phases need to be submitted to CPCSEA office mainly information on acquiring source, completion of experiment and number of animal saved
5. As per the current CPCSEA regulations permissions for experimentation in large animals is obtained from the central sub committee with recommendation routed through IAEC of the institute and it is important to mention the reference number of the approval in these forms.
6. Date of initiation and date of termination mentioned in the form is as per IAEC approval.

Following forms are compulsory for rehabilitation

1. **Pre Experimentation details of Animal for Transfer to Rehabilitation**
Form is for maintaining records of animal's origin, treatment and tests performed during quarantine by the acquiring institution prior to experimentation signed by a veterinarian.
2. **Experimentation details**
Form is for maintaining records pertaining to animal experimentation to know the kind of material handled during experimentation and protocols followed signed by principal investigator.
3. **Post Experimentation Details of Animal & Suitability Certification**
Form is for maintaining records of animals after performance of experimentation for its continuation either for next experiment or for rehabilitation signed by veterinarian.
4. **Transfer Certificate for Rehabilitation**
Form is for certifying suitability for rehabilitation authorized by a veterinarian

Following forms should be maintained for supportive information

1. Tuberculin Testing
2. X – Ray
3. Body Weight
4. Parasitology
5. Microbiology
6. Treatment
7. Surgery
8. Research and Experimentation
9. Blood drawn
10. Hematology
11. Menstrual cycle

Forms such as Postmortem details and Histopathology are essential to be maintained for all animals that have been sacrificed in experiments and died during rehabilitation. In addition, institutions are required to maintain records pertaining to regular transfers within the institution for any experimentation or for any rehabilitation program.

A unique identification number is followed in all these forms for uniformity in every institution. The number to be placed in the appropriate box based on the following:

I Species:

- 01 Dog
- 02 Monkey
- 03 Cat
- 04 Sheep
- 05 Goat
- 06 Cattle
- 07 Horse
- 08 Any other

II Sex

- M Male
- F Female

III Year of Birth

- 1997 97
- 2001 01

IV Institutional Number Starts with CPCSEA

- Registration no.:
- 0159
 - 00401

V Individual number as per the institution

- 002
- 009
- 019

Example

6	M	01	159	009
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Pre Experimentation details of Animal for Transfer to Rehabilitation

1. Name of the organization currently holding the animal/s

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2. Details of the Animals

a. Animal No:				b. DOB	
c. Animals procured / Trapped from:				d. Date of procurement / trapping	
e. Supplier / Source				f. Colony bred / Wild caught	
g. Dam Number				h. Sire Number	
i. Color		j. Date of Induction		k. Body Weight and Date	

3. Physical Examination on arrival

a. Fore Limbs			b. Hind limbs		
c. * Dental Formula: I		C	PM	M	d. Teeth condition
e. Eyes			f. Nostrils		
g. Mouth lesions if any					
h. External Body Coat			i. Abdominal palpation		
j. Lymph nodes					
k. Chest auscultation			l. Body Temperature		
m. Any injuries physical deformities					
n. Clinical Symptoms if any					
o. Health condition					

4. Quarantine period

a. Introduced on	b. Released from quarantine on
------------------	--------------------------------

5. Microscopic examination for parasites

a. Fecal Examination for Endo parasites
b. Any Ectoparasites
c. Parasites on Blood smear examination

6. Any Treatment given during Quarantine

Date	Clinical Symptoms	Diagnosis	Treatment	Recovered on

7. Tuberculin Testing as per the animal:

Date	Source /Batch of Antigen	Result at each Observation		
		First	Second	Third

8. * Chest X ray

a. Date	
b. Report contents	

9. Transferred to which Experiment

--

Signature
Name
Designation

Experimentation details
[Separate sheet for each experiment]

1. Animal No <table border="1" style="width: 100%;"><tr><td style="width: 15%; height: 20px;"></td><td style="width: 15%; height: 20px;"></td><td style="width: 15%; height: 20px;"></td><td style="width: 15%; height: 20px;"></td><td style="width: 15%; height: 20px;"></td></tr></table>						2. Body weight / Date

3 Details of the Experiments:

a. Title/s of the project
b. Principal Investigator
c. Details of the protocol
4. Age and weight range at the time of Initiation of the experiment
5. Experimental Endpoint Criteria
6. Date of Termination of experiment as per IAEC approval
7. Infectious agent used if any give details
8. Radioisotope used if any give details

Signature of the Principal Investigator
Name
Designation

Post Experimentation Details of Animal & Suitability Certification

1. Name of Organization currently possessing the animal			
2. Animal No			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3. Title of the experiment			
4. Investigator/s			
5. Duration under experimentation			
6. Experimental Procedure			
7. Body Weight & Date			
8. Details of Experiment/ procedures:			
9. Number of times anesthetized		10. Number of times blood withdrawn	
11. Infectious organisms involved			
12. Radioactive substance used			
13. Is the animal suffering from any Zoonotic disease?			
14. Physical abnormalities if any furnish details			
15. Any clinical symptoms			
16. Any attention of a veterinarian required during rehabilitation and how long			
17. Special nutritional requirements if any during rehabilitation			
18. Present condition of the animal for rehabilitation. [Mark √]			
Excellent [Answers to 11-17 are No]	<input type="checkbox"/>	It can be Retained	<input type="checkbox"/>
Good [Answer to 11-16 are No]	<input type="checkbox"/>	It can be given for Experimentation	<input type="checkbox"/>
Satisfactory [Answers to 11-15 are No]	<input type="checkbox"/>	Fit for transfer to NGO for Rehab	<input type="checkbox"/>
Poor [Answers 11-14 are Yes]	<input type="checkbox"/>	Can be sent for Euthanasia	<input type="checkbox"/>

Signature of Veterinarian
Name
Designation

Transfer Certificate for Rehabilitation

[To be filled in for every animal separately]

1. Animal No <table border="1" style="width: 100%; height: 20px; margin-top: 5px;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> </tr> </table>							2. Body weight / Date
3. Name & CPCSEA No. of Organization handing over the animal/s							
4. Name & CPCSEA No (if any) of the Organization taking over the animal/s							
5. CPCSEA Registration No of the Rehabilitation unit:							
6. In case of Emergencies Contact person/s details							
Name Telephone No(s) Fax:	Name Telephone No(s) Fax:						
7. Person handing over the animal Signature Name Designation Date	8. Person under taking over the animal Signature Name Designation Date						

Tuberculin Testing

Animal No										
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>										
Date	Source & Batch number	Result of readings			Remarks					
		First	Second	Third						

Signature of Veterinarian
 Name
 Designation

X - Ray

Animal No										
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>										
Date	Organ / Site	Radiological Findings								

Signature of Radiologist
 Name
 Designation

Blood Drawn

Animal No									
Date	Quantity	If any anesthetic used & Quantity	Purpose	Name of the Person drawn the blood					

Signature of Animal Technician
 Name
 Designation

Body Weight

Animal No										
Date	Weight									

Signature of Animal Technician
 Name
 Designation

Microbiology

Animal No					<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Test	Material	Organisms found	Remarks					

Signature of Veterinarian/ Microbiologist
Name
Designation

Parasitology

Animal No				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Ectoparasites	Endoparasites	Remarks					

Signature of Veterinarian/ Parasitologist
Name
Designation

Treatment

Animal No									
Date	Clinical Symptoms	Diagnosis	Treatment	Remarks					

Signature of Veterinarian
 Name
 Designation

Hematology

Animal No														
Date	RBC Millions/cc	WBC Cells/cc	PCV	HB g%	Differential Leukocyte Count					ESR				
					N	L	M	B	E					

Signature of Pathologist / Veterinarian
 Name
 Designation

Surgery

Animal No									
<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table>									
Date	Type of Surgery	Purpose	Treatment	Remarks					

Signature of Veterinarian
Name
Designation

Post Mortem Report

1. Animal No <table border="1" style="width: 100%; height: 20px; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> </tr> </table>							2. Source .3. Date of Induction
4. Was the animal Sacrificed / Died naturally							
5. Condition of Carcass	6. Date of Death						
7. History of Animal							

8 External Examination

a. Head	b. Body	c. Limbs
---------	---------	----------

9. Discharges if any

a. Mouth	b. Eyes	c. Ears	d. Nose	e. Anus	f. Vagina/Penis
g. Lesions in the Buccal Cavity		h. Teeth		i. Tongue	

10. Internal Examination

a. Lesions in Brain:	b. Lesions in Sinuses:
c. Lungs:	d. Heart:
e. Liver:	f. Pancreas:
g. Spleen :	h. Kidney/ Ureter:
i. Mesenteric Lymph nodes:	j. Stomach
k. Intestine	l. Cecum:
m. Colon:	n. Rectum
o. Uterus	p. Ovaries / Testes

11. Material Collected for Laboratory as deemed necessary by pathologist conducting PM

Samples for Microbiology	Findings
Samples for Parasitology	
Samples for Histopathology	

12. Important Findings:

--

13. Cause of Death

--

Signature of Pathologist / Veterinarian
 Name
 Designation

Histopathology

1. Animal No			<input type="text"/>				
<i>Date</i>	<i>Material</i>	<i>Findings</i>					

Signature: Pathologist / Veterinarian

Name:

Designation:

Rehabilitation

Animal should be examined and assessed accurately by a person who is knowledgeable in particular requirements of that species by a veterinarian or by an experienced rehabilitator process with primary objective of animal welfare.

The criteria may vary however following are a few conditions that preclude animal from rehabilitation and animals may require prompt euthanasia

1. Where the animal is found to be suffering from significant pain, distress, trauma or disease that cannot be relieved.
2. Where the animal would not survive without extended treatment or surgery, and is unlikely to recover sufficiently to return to the normal life.

Following conditions also preclude successful rehabilitation:

1. Loss of limbs or function of limbs
2. Permanent vital sensory loss (hearing, sight, smell, feeding)
3. Untreatable infectious disease
4. Permanent damage to the nervous system
5. Inability to adjust to temporary captivity
6. Chronic ill health
7. Abnormal behavioral patterns

11. Describe facilities for euthanasia, if required.

For office use

Name of observer (s) :

Date of visit (DAY/MONTH/YEAR):

Start time:

End time:

Duration

Region:

State:

Shelter name and address:

1. Whether all physical facilities match the particulars/ specifications given in the application.
2. Whether adequate veterinary / care available.
3. Remarks comments.
4. Recommendation

Date:

Signature:

Minimum space requirements for specific animals:

(in Sq. Ft.)

Dogs/ Cats	Goat or Sheep	Cattle	Monkey	Horse
8-14	10	Calf 24 Full Grown 48	8 (Minimum height 10 feet)	60

Minimum ratio of animals to attendants for specific animals:

Dogs / Cats	Goat or Sheep	Cattle	Monkey	Horse
10:2	15:1	10:1	6:1	4:1

ROLE OF NOMINEE

Nominee should be familiar with the CPCSEA guidelines, the concept of 3 Rs and other animal welfare issues. He/She must keep liaison with CPCSEA and also browse the MoEF website for any update of information or draft guidelines or rules and regulation, placed for comment. He/She should be familiar with animal experimentation procedures, husbandry conditions, supplies, humane way of dealing with animals, handling procedures etc and other requirements as published in the CPCSEA/INSA guidelines for GLP methods. He/she must learn/be familiar with alternatives, reduction and refinement procedure available in biomedical research studies/programmes.

Nominee attached to educational institution should be through with the syllabus prescribed by the University/college for a particular course. Nominee attached with research institutions should learn about the over all goal/mandate of the institute and keep himself/herself abreast with the current and past work done by the institute in animal studies and thus be able to link the new studies proposed. Nominees attached with institutions undertaking regulatory toxicology work should read and be familiar with various guidelines for registration of products such a pesticide, drugs and pharma, biotechnology and etc. For any clarifications on the protocols, methods, either they should see more details with the investigator when the agenda is circulated or seek comments from CPCSEA.

Nominee must read the proposal attached with Agenda thoroughly and come prepared to attend the IAEC meeting. He/she should aim for humane/ethical issues and compliance to GLP principles, avoid repetitions of animal studies, expected out come and it's impact, number and sex of animals used, source, health status, alternatives, reduction without loosing scientific conclusions etc.

Nominee should not to indulge in arguments and heated debate but understand the merit of a study based on above principles.

Nominee is expected to sign the necessary forms of each protocol and maintain a copy/list in his/her records.

In case of proposals dealing with large animal, nominees should note that IAEC is only a recommending authority for such studies. Nominee should ascertain the capability of institution to perform studies on large animals and make sure his/her recommendations find place in the minutes attached to CPCSEA.

Nominees should forward a copy of the minutes to CPCSEA office within 15 days from the date of meeting/inspection of animal house.

If no meetings are held for 6 months in a row because of lack of projects or due to other reasons, nominee should notify to CPCSEA about “no meetings” after confirmation/verification with the organization.

Nominee should visit animal house atleast once in a calendar year and submit the report in the prescribed form to CPCSEA office within a month from the date of inspection. Follow up may be taken up and reports also submitted to CPCSEA with ATR.

If nominee requires assistance of any other expert to review a protocol he/she can do so by consulting CPCSEA.

The nominee would be paid sitting fee and reimbursement of travel expenditure by the establishment / institute as decided by CPCSEA, from time to time.

Nominee not supposed to do

1. Nominee is not allowed to print visiting cards, letter pad with his/her name with Government of India official seal as IAEC nominee.
2. Nominee is not permitted to make any campaign/publicity about his/her role and solicit any sponsorship from any organization falling under his/her jurisdiction.
3. Nominee should not sign the minutes of the meeting/Forms/Register without attending the meeting in person.
4. Further, nominees should not allow any tele/audio conference with a non-participating member during the IAEC meeting.
5. Nominee should not allow any outside member to attend the IAEC meeting.
6. The nominees must keep themselves away from the media and press and will not disclose the confidential information related to the CPCSEA.

CPCSEA NOMINEE APPLICATION FORM*

NAME OF THE APPLICANT :

SEX/ DATE OF BIRTH :

QUALIFICATION :

PROFESSION :

COMMUNICATION ADDRESS :

TELEPHONE :

FAX :

MOBILE :

E-MAIL :

PHOTO

**Experience if any, in animal welfare activities
And the animal welfare organization/s
With which associated :**

DECLARATION

1. I am fully aware of my duties and responsibilities as CPCSEA nominee representing the Institutional Animal Ethics Committees (IAEC's)
2. I will carry out my responsibilities in accordance with the rules and regulations of CPCSEA and as per the instructions received from CPCSEA.
3. I will not use the name of CPCSEA on personal letter heads or other communications.
4. I will not misuse the name and purpose of CPCSEA for any assistance or gain.
5. I will not disclose any confidential information of the institution / CPCSEA.
6. I am aware that my nomination can be cancelled by CPCSEA, without assigning any reason.

Date

Signature of Applicant

*The filled in application Form alongwith above information / details / supporting documents should be sent to :-

The Member Secretary,
CPCSEA, Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001

**ONE PAGE CV FOR MEMBERS OF THE INSTITUTIONAL
ANIMAL ETHICS COMMITTEE**

Last Name	First Name	Middle Initial
Date of Birth (mm/dd/yy):		Sex
Professional Mailing Address (Include institution name)		
Telephone (Office):		Mobile Number:
Telephone (Residence):		E-Mail:
Academic Qualifications (Most current qualification first)		
Degree/Certificate	Year	Institution, Country
Professional Experience		
Month and Year	Title	Institution/Company, Country
Signature:		Date:
(Signature Required)		