



**Ministry of Environment, Forest and Climate Change
Government of India**

cpcsea.nic.in

COMPENDIUM OF CPCSEA 2018



**COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF
EXPERIMENTS ON ANIMALS (CPCSEA)**

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Additional Secretary
&
Chairman (CPCSEA)



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पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST &
CLIMATE CHANGE


MESSAGE

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory Committee set up under Prevention of Cruelty to Animals Act 1960, has been functioning since 1991 to ensure that animals are not subjected to unnecessary pains or suffering *before, during or after* performance of experiments on them. In course of its work, it has issued various guidelines and established procedures for effective compliance with provisions of the Act.

The Secretariat of the CPCSEA has published its guidelines from time to time with a view to guide its work. The present compendium of 2018 is another milestone in this direction.

In this manual, an attempt has been made to compile various guidelines issued by the CPCSEA for experimentation on animals, with welfare and well-being of animals as the utmost concern. The main aim of these instructions is to ensure humane and ethical treatment of animals, while carrying out legitimate scientific research/studies involving experiments on animals.

I fervently hope that this compendium of essential documents of CPCSEA would act as a standard reference document and provide comprehensive information about its extant guidelines.


(Anil Kumar Jain)



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मंजु पाण्डे

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Joint Secretary
Government of India

Ministry of Environment, Forest & Climate Change

MESSAGE

This compendium of rules and guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been designed to bring out homogeny in the understanding of the guidelines of CPCSEA and working of Institutional Animal Ethics Committees (IAECs) 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 hope that this would be a useful document for the Nominees of CPCSEA, IAEC members, principal investigators and researchers.


(Manju Pandey)



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Member Secretary (CPCSEA)
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FOREWORD

On behalf of Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), I extend my best wishes to the users of this manual.

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 strictly adhere to the Rules and Guidelines laid down by CPCSEA.

This document is a step to apprise the researchers dealing with the laboratory animals working in the field of Biomedical, Pharmaceutical, Veterinary Science etc. about the various provisions which have to be kept in mind while conducting legitimate scientific work while keeping intact the welfare of laboratory animals.

I appreciate the efforts of Members of CPCSEA and the team CPCSEA in bringing out this publication of compendium.

(S. Gowri Shankar)

with best wishes.



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

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

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

- (a) Every experiment shall be performed by or under the supervision of a person duly qualified in that behalf, that is, Degree holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
- (b) That experiments are performed with due care and humanity and as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals from feeling pain;
- (c) That animals who, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily medically allowed to death while still under influence of anaesthetic;
- (d) That experiments on animals are avoided wherever it is possible to do so.
- (e) That experiments on larger animals are avoided when it is possible to achieve the same results by experiments on small laboratory animals like guinea-pigs, rabbits, mice, rats etc;
- (f) That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- (g) That animals intended for the performance of experiments are properly looked after before, during and after experiments;
- (h) That suitable records are maintained with respect to experiments performed on animals

3. Functions of IAEC

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

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

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

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

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

4. Composition of IAEC

Institutional Animals Ethics committee shall include eight members as follows:

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

- i. One biological scientist
- ii. Two scientists from different biological disciplines
- iii. One veterinarian involved in the care of animal
- iv. One scientist in charge of animal facility of the establishment concerned

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

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

B. Nominees from the CPCSEA:

- i. Main Nominee (01)
- ii. Link Nominee *
- iii. Scientist from outside the Institute (01)
- iv. Socially Aware Nominee (01)

****Link Nominee shall substitute the main nominee in case main nominee conveys his unavailability in writing to the chairperson of the IAEC in advance as per described procedure.***

The CPCSEA shall endeavour that nominees appointed by CPCSEA in any private establishment should not be from the establishments which is having the same objectives as to the establishment where the nominees are being nominated, so as to avoid the conflict of interest between the establishments.

In addition to the above IAEC members, a specialist may be co-opted of the relevant field while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.

5. The minimum qualification for the IAEC Members is as below:

- i. B.V.Sc. or
- ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or
- iv. M. Pharm. with experience in animal handling and animal research, or
- v. MD/ MS with research experience in laboratory animal handling.

6. The qualification for Nominee(s) of CPCSEA is as under:

I. The minimum qualification for Nominee should be:

- i. B.V.Sc. or
- ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii. M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research. or
- iv. M. Pharm. with experience in animal handling and animal research, or
- v. MD/ MS with research experience in laboratory animal handling.

II. The minimum qualification for Socially Aware nominee should be at least Graduate from any subject. Preference will be given to those with a background in Biological Sciences.

7. Upper age limit for the Nominees of CPCSEA:

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

****Link Nominee shall substitute the main nominee in case main nominee conveys his unavailability in writing to the chairperson of the IAEC in advance as per described procedure.***

The CPCSEA shall endeavour that nominees appointed by CPCSEA in any private establishment should not be from the establishments which is having the same objectives as to the establishment where the nominees are being nominated, so as to avoid the conflict of interest between the establishments.

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- ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii. M.Sc. (Life Sciences/Biological Sciences/ Biochemistry/ Biotechnology) with experience in animal handling and animal research or
- iv. M. Pharm. with experience in animal handling and animal research or
- v. M.D. (Microbiology and Pharmacology) with experience in animal handling and animal research.

6. The qualification for Nominee(s) of CPCSEA is as under:

I. The minimum qualification for Nominee should be:

- i) B.V.Sc. or
- ii) M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
- iii) M.Sc. (Life Sciences Biological Sciences/ Biochemistry/ Biotechnology) with experience in animal handling and animal research. or
- iv) M. Pharm. with experience in animal handling and animal research or
- v) M.D. (Microbiology and Pharmacology) with experience in animal handling and animal research.

II. The minimum qualification for Socially Aware nominee should be at least Graduate from any subject. Preference will be given to those with a background in Biological Sciences.

7. Upper age limit for the Nominees of CPCSEA:

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

8. Authority under which IAEC is constituted and duration:

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

9. IAEC requirements:

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

10. Quorum requirements:

The minimum of six members shall be required to form quorum of the IAEC meetings. All decisions shall be required to be undertaken in the meetings of IAEC and not by the method of circulation of project proposals. Presence of main nominee of CPCSEA nominee is a must. It shall be a must for the establishment to invite all nominees of IAEC for attending the meeting and the meeting notice shall invariably be issued by Registered Post atleast 15 days before the date of the meeting. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairperson of IAEC. Socially aware member's presence is *compulsory* in all cases referred to CPCSEA and their presence is mandatory atleast in one meeting of IAEC of the establishment in a calendar year. It shall be the duty of establishment to inform to CPCSEA about the continuous absence of nominees of CPCSEA in a calendar year.

11. Conduct of business:

The Chairperson of the IAEC shall be responsible for conducting atleast two meeting of IAEC in a calendar year with the help of the Member Secretary of IAEC. If for reasons beyond control, the Chairperson is not available, or has conflict of interest an *ad-hoc* Chairperson will be elected from amongst the present members, who will conduct the business of the meeting. The Member Secretary of IAEC 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 Chairperson after NOC from all members 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.

12. Participation by Investigators / experts in IAEC.

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

13. 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 as per 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.

14. 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 so.
- 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 point's should be recorded in the minutes. CPCSEA shall consider only those decisions which are arrived with consensus. In case consensus is not arrived and the case merits special attention of CPCSEA, such cases may be forwarded to CPCSEA with approval of the chairman of the IAEC of the establishment alongwith the detailed reason for forwarding the matter to CPCSEA and points of consideration for CPCSEA.
- d. Researchers will be invited to offer clarifications, if needed.
- e. Independent consultants/Experts will be invited to offer their opinion on specific Research proposals, if needed.

- f. The decisions of the IAEC will be minuted and Chairperson's approval shall be taken in writing with signature of all the IAEC members present.

15. Decision-making of IAEC of the Establishment:

- a. Members will discuss all the related issues concerning the welfare of animals 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 informed to the chairperson prior to the review of the application and the same should be recorded in the minutes.
- c. Decisions of IAEC shall be valid where the quorum of IAEC is complete.
- d. Only members of IAEC can vote for the decision. The experts / investigators / invitees may only offer their opinions.
- e. In case of research protocols on small animals, the IAEC of the establishment shall be empowered to grant approval for experiment on animals considering the welfare of the animals. For carrying out the experiment on **large animals**, approval of CPCSEA is a must and IAEC may only recommend the research protocol for consideration of CPCSEA. Specific suggestions for modifications in the research protocol and reasons for rejection should be clearly indicated.
- f. In cases of conditional decisions on research protocol, suggestions for subsequent review and the procedure for having the application reviewed may be specified clearly.
- g. Modified proposals may be reviewed by an expedited review through identified members.
- h. Procedures for appeal by the researchers should be clearly defined by the respective IAEC.

16. Communicating the decision

- a. Decisions of the IAEC will be communicated by the Member Secretary in writing to CPCSEA within 15 days of conduct of the meeting.
- b. Suggestions for modifications in research protocols, if any, should be delt by IAEC but minuted and sent to CPCSEA.
- c. Reasons of rejection of the research protocol should be informed to the researchers in writing.
- d. The schedule / plan of ongoing review by the IAEC should be communicated to the PI.

17. Follow up procedures

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

- be intimated to IAEC.
- d. Protocol deviation, if any, should be informed with adequate justifications to IAEC and in case of large animals, it should be intimated to CPCSEA immediately for consideration of CPCSEA. The procedural deviations in research protocol shall be treated as a fresh research protocol by CPCSEA.
 - e. Any new information related to the study should be communicated to IAEC immediately.
 - f. Premature termination of study should be notified to the IAEC with reasons along with summary of the data obtained so far.
 - g. Change of investigators / sites should be informed and approval of IAEC should be undertaken first.

18. Record keeping and Archiving:

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

19. Updating IAEC members:

- a. All relevant new guidelines and amendments to the Rules and Act pertaining to CPCSEA 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 the area.

20. 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 30 days.

21. Reimbursement to CPCSEA representative

CPCSEA representative(s) on the IAEC or authorized person(s) sent for inspection of the establishment(s) or otherwise by CPCSEA for any other purpose are required to be paid Rs. 2000/- each as sitting fees/visiting fee per day (or as revised from time to time) along with the reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

22. Fees Payable to CPCSEA:

S.No.	Purpose	Code	Fee to be charged	
			Small	Large
1	Registration for the purpose of <i>Research for education</i>	Re	Rs. 10,000.00	Rs. 10,000.00
2	Registration for the purpose of <i>Research for commercial</i>	Rc	Rs. 10,000.00	Rs. 10,000.00
3	Registration for the purpose of <i>Research</i>	R	Rs. 10,000.00	Rs. 10,000.00
4	Registration for the purpose of <i>Non-Research Commercial</i> (i.e. Production of Hyperimmune Plasma and Serum)	NRc	-	Rs. 10,000.00
5	Registration for <i>Breeding for in-house use</i>	Bi	Rs. 15,000.00	Rs. 25,000.00
6	Registration for <i>Breeding for the purpose of Trade</i>	Bt	Rs. 25,000.00	Rs. 25,000.00
7	Renewal for the purpose of <i>Research for education</i>	Re	Rs. 2,500.00*	Rs. 2,500.00*
8	Renewal for the purpose of <i>Research for commercial</i>	Rc	Rs. 2,500.00*	Rs. 2,500.00*
9	Renewal for the purpose of <i>Research</i>	R	Rs. 2,500.00*	Rs. 2,500.00*
10	Renewal for the purpose of <i>Non-Research Commercial</i> (i.e. Production of Hyperimmune Plasma and Serum)	NRc	-	Rs. 2,500.00*
11	Renewal for <i>Breeding for in-house use</i>	Bi	Rs. 2,500.00*	Rs. 2,500.00*
12	Renewal for <i>Breeding for the purpose of Trade</i>	Bt	Rs. 2,500.00*	Rs. 2,500.00*
13	Revision of IAEC	-	Rs. 1,000.00	
14	Protocol on Large Animals (educational) where the Joint Director (Research) or Dean (Research) or competent authority equivalent to Joint Director (Research) or Dean (Research) would certify that the particular protocol under this category is a thesis project (per protocol)	-	Rs. 1,000.00	
15	Protocol on Large Animals (educational other than thesis project) (per protocol)	-	Rs. 5,000.00	
16	Protocol on Large Animals (non-educational) (per protocol)	-	Rs. 5,000.00	

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

Note:

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

23. All communications must be addressed to:

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

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

11. Treating animals cruelly.
12. Penalty for practising phooka or doom dev.
13. Destruction of suffering animals.

CHAPTER IV - EXPERIMENTATION OF ANIMALS

14. Experiments on animals.
15. Committee for control and supervision of experiments on animals.
- 15A. Sub-Committee.
16. Staff of the Committee.
17. Duties of the Committee and power of the Committee of the Committee to make rules relating to experiments on animals.
18. Power of entry and inspections.
19. Power to prohibit experiments on animals.
20. Penalties.

CHAPTER V-PERFORMING ANIMALS

21. "Exhibit" and "train" defined.
22. Restriction on exhibition and training of performing animals.
23. Procedure for registration.
24. Power of court to prohibit or restrict exhibition and training of performing animals.
25. Power to enter premises.
26. Offences.
27. Exemptions.

CHAPTER VI-MISCELLANEOUS

28. Saving as respects manner of killing prescribed by religion.
29. Power of court to deprive person convicted of ownership of animal.
30. Presumptions as to guilt in certain cases.
31. Cognoscibility of offences.
32. Powers of search and seizure.
33. Search Warrants.
34. General Power of seizure for examination.
35. Treatment and care of animals.
36. Limitation of prosecutions.
37. Delegation of powers.
38. Power to make rules.
- 38A Rules and regulations to be laid before Parliament.
39. Persons authorised under section 34 to be public servants.
40. Indemnity
41. Repeal of Act 11 of 1890.

LIST OF ABBREVIATIONS 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;

*[9b) “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.

- (1) The Board shall consist of the following persons, namely:-

**Constitution of
the Board**

5. (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 5A 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
employees
of the Board**

- 7 (1) The Central Government shall appoint *xxxxx the Secretary other 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,

Functions of the Board

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 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 for 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 of 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

14 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 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.

***[I(1A) 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 of 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.
- 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-

**Power of entry
and inspection**

		<ul style="list-style-type: none"> (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	19.19.	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.	<p>If any person -</p> <ul style="list-style-type: none"> (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: <p>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.</p>
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 and training of performing animals	22.	<p>No person shall exhibit or train -</p> <ul style="list-style-type: none"> (i) any performing animal unless he is registered in accordance with the provisions of this Chapter;

- (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.

Procedure of registration

- 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 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 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 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 veterinary 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 veterinary 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 sub-section (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]

***[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.]

**Rules and
Regulation to be
laid before
Parliament**

- 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.

**Persons
authorised under
Sec. 34 to be public
servants.**

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

**Sub-section (4) of the Principal Act omitted 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 of 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 came 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) Chapters 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. Anaesthesia shall be administered by a Veterinary Surgeon trained in methods of anaesthesia or a Scientist/technician so trained for this purpose and who shall remain present near the animal till the completion of the experiment;
- (e) animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anaesthesia;
- (f) when there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment;
- (g) the experiment shall not be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions;
- (h) experiments shall not be performed by way of an illustration;
- (i) experiments shall not be performed as a public demonstration;

- (j) the substance known as Urari or Curari or any such 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's 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 Rules, 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 sold 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 and 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.

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 s 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 to, 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 establishments 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 anaesthesia.

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 anaesthesia.

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.

The establishment involved in breeding of animals and birds for laboratory purpose has to be registered however, the establishments breeding the farm animals and poultry for slaughter purpose shall not be liable for registration with 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.

4.12. 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 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 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.

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 *intoto* 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 there under.

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 - 2015

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

1. GOAL

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

2. VETERINARY CARE

- a. Adequate veterinary care must be provided and is the responsibility of a veterinarian or a person who has training or experience in laboratory animal sciences and medicine.
- b. Daily observation of animals can be accomplished by someone other than a veterinarian; however, a mechanism of direct and frequent communication should be adopted so that timely and accurate information on problems in animal health, behaviour, and well being is conveyed to the attending veterinarian.
- c. The veterinarian can also help the establishment in designing appropriate policies and procedures for ancillary aspects of veterinary care, such as use of appropriate methods to prevent and control diseases (e.g. vaccination and other prophylaxis, disease monitoring and surveillance, quarantine and isolation), operative and post-operative care, diagnosis and treatment of diseases as well as injuries. reviewing protocols and proposals, animal husbandry and animal welfare; monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation. Institutional requirements will determine the need for full-time or part-time or consultative veterinary services.

3. ANIMAL PROCUREMENT

- a. All animals (like cattle, buffalo, sheep, goat, pigs, equine etc.) must be acquired lawfully as per the CPCSEA guidelines. Small animals and dogs can be procured from registered breeders. Large animals can be procured from farm, farmers or as per guidance of wild life department, as is done in case of macaques. Cats can be bred for their use. Rodents can be imported from abroad after necessary licence from Director General of Foreign trade (DGFT) is obtained for import.
- b. A health surveillance program for screening incoming animals should be carried out before purchase to assess animal quality. Methods of transportation should also be taken into account (**Annexure - 4**).
- c. Each consignment of animals should be inspected for compliance with procurement specifications, and the animals should be quarantined and stabilized according to procedures appropriate for the species and circumstances.

4. QUARANTINE, STABILIZATION AND SEPARATION

- a. Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined. An effective quarantine minimizes the chance for introduction of pathogens into an established colony. The duration at quarantine in small lab animals is from one week to one month and large animals allowed up to 6 weeks (cat, dog, monkey, etc). However, duration of quarantine can be increased depending on type of infection / suspected infection noticed in the animals.
- b. Effective quarantine procedures should be used for non-human primates to help limit exposure of humans to zoonotic infections. The period varies from 2 to 3 months depending on the reaction of TB testing. Any macaque found positive for TB for at least two times and shows signs of weight loss or ill health should be euthanized as is practiced internationally to prevent spreading of TB to workers and other macaques.
- c. Regardless of the duration of quarantine, newly received animals should be given a period for physiologic, psychologic and nutritional stabilization before their use. The length of time stabilization will depend on the type and duration of animal transportation, the species involved and the intended use of the animals.
- d. Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioural changes due to interspecies conflict.
- e. Such separation is usually accomplished by housing different species in separate rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators can be used as suitable alternatives.
- f. In some instances, it shall be acceptable to house different species in the same room, for example, if two species have a similar pathogenic status and are behaviourally compatible. Separate set of personnel should be identified for taking care of these infected (sick) animals and other workers should be restricted from entering in to the facilities unless otherwise required and after handling these animals they should not be handling any other animals in the facilities

5. SURVEILLANCE, DIAGNOSIS, TREATMENT AND CONTROL OF DISEASE

- (a) All animals should be observed for signs of illness, injury, or abnormal behaviour by animal house staff. As a rule, this should occur daily, but more-frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. It is imperative that appropriate methods be in place for disease surveillance and diagnosis (**Annexure 1 & 2**).
- (b) Post-mortem examination and signs of illness, distress, or other deviations from normal health condition in animals should be reported promptly to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals in the colony. If an entire room of animals is known or believed to be exposed to an infectious agent (e.g. *Mycobacterium tuberculosis* in non-human primates), the group should be kept intact and isolated during the process of diagnosis, treatment, and control. Animals suffering from contagious diseases like Tuberculosis etc. must be euthanized as is practiced internationally to prevent its spread to other animals and often animal handlers.

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

6. ANIMAL CARE AND TECHNICAL PERSONNEL

- (a) Animal care programs require technical and husbandry support. Institutions should employ people trained in laboratory animal science or provide for both formal and on-the-job training to ensure effective implementation of the program (**Annexure-7**).

7. PERSONAL HYGIENE

- (a) It is essential that the animal care staff maintain a high standard of personal cleanliness. Facilities and supplies for meeting this obligation should be provided with appropriate Personnel Protective Equipment (PPE) e.g. showers, change of uniforms, footwear etc.
- (b) Clothing suitable for use in the animal facility should be supplied and laundered by the institution. A commercial laundering service is acceptable in many situations; however, institutional facilities should be used to decontaminate clothing exposed to potentially hazardous microbial agents or toxic substances. It is acceptable to use disposable gloves, masks, head covers, coats, coveralls and shoe covers. Personnel should change clothing as often as is necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal facility.
- (c) Washing and showering facilities appropriate to the program should be available. Personnel should not be permitted to eat, drink, smoke or apply cosmetics and perfumes in animal rooms. They should finish the work with animals as early as possible and sit somewhere else, outside and not in the animal rooms / areas. A separate area or room should be made available for these purposes.

8. ANIMAL EXPERIMENTATION INVOLVING HAZARDOUS AGENTS

- (a) Institutions should have policies governing experimentation with hazardous agents. Institutional Bio-safety Committee whose members are knowledgeable about hazardous agents are in place in most of the higher-level education, research institutes and in many pharmaceutical industries for taking care of safety issues. This committee shall also examine the proposal on animal experiments involving hazardous agents in addition to its existing functions (**Annexure - 8**).
- (b) Since the use of animals in such studies requires special considerations, the procedures and the facilities to be used must be reviewed by both the Institutional Bio-safety committee and Institutional Animal Ethics Committee (IAEC). Disposing of tissues and fluids from such used animals must also be appropriately governed as per the laid in practices of the institution / bio-safety regulation.

9. MULTIPLE SURGICAL PROCEDURES ON SINGLE ANIMAL

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

10. DURATIONS OF EXPERIMENTS

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

11. PHYSICAL RESTRAINT

- (a) Brief physical restraint of animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or with devices be suitable in size and design for the animal being held and operated properly to minimize stress and avoid injury to the animal.
- (b) Prolonged restraint of any animal, including the chairing of non-human primates, should be avoided unless essential to the research objectives. Less restrictive systems, such as the tether system or the pole and collar system should be used when compatible with research objectives.
- (c) Following points should be considered during handling and restraining animals:-
 - i. Animals should be handled by competent individuals trained in methods that cause minimal distress and injury (for example, a person with a publication to his/her credit and post/experience in relevant techniques for handling animals is preferable).
 - ii. The use of restraint devices is sometimes essential for the welfare of the animal and safety of the handler. Restraint devices should be used to the minimum
 - iii. extent, for the minimum period required to accomplish the purpose of the experiment and be appropriate for the animal.
 - iv. Tranquilisers or anaesthetics may initially be used to aid restraint but they may prolong recovery from the procedure. When these agents have been used, recovery of the animals should be closely monitored.
- (d) **The following are important guidelines for the use of restraint equipments:**
 - i. Restraint devices cannot be used simply as a convenience in handling or managing animals. The period of restraint should be the minimum required to accomplish the research objectives. Animals to be placed in restraint devices should be given training to adapt to the equipment, prior to initiation of the experimentation.
 - ii. Provision should be made for observation of the animal at appropriate intervals. Veterinary care should be provided if symptoms or illness associated with restraint are observed. The presence of illness, or severe behavioural change should be dealt with by temporary or permanent removal of the animal from restraint related protocol.

12. 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)**.

13. FUNCTIONAL AREAS

- (a) The size and nature of a facility will determine whether areas for separate service functions are possible or necessary. Sufficient animal area required to:
 - Ensure separation of species or isolation of individual projects when necessary;
 - Receive, quarantine, and isolate animals; and
 - Provide for animal housing.
- (b) In facilities that are small, maintain few animals or maintain animals under special conditions (e.g., facilities exclusively used for housing germfree colonies or animals in runs and pens) some functional areas listed below could be unnecessary or included in a multipurpose area. Professional judgement must be exercised when developing a practical system for animal care.
 - Specialized laboratories or
 - Individual areas contiguous with or near animal housing areas for such activities as surgery, intensive care, necropsy, radiography, preparation of special diets, experimental manipulation, treatment, and diagnostic laboratory procedures containment facilities or
 - Equipment, if hazardous biological, physical, or chemical agents are to be used
 - Receiving and storage areas for food, bedding
 - Pharmaceuticals and biologics, and supplies
 - Space for administration, supervision, and direction of the facility
 - Showers, sinks, lockers and toilets for personnel
 - An area for washing and sterilization equipment and supplies,
 - An autoclave for equipment
 - Food, and bedding; and separate areas
 - For holding soiled and cleaned equipment
 - An area for repairing cages and equipment
 - An area to store wastes prior to incineration or removal

14. PHYSICAL FACILITIES

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

- (a) Housing facility should be compatible with the needs of the species to be housed.
- (b) Housing Facilities should be designed and operated to facilitate control of environmental factors to exclude vermin and limit contamination associated with the housing of animals, delivery of food, water, bedding, and the entry of people and other animals.
- (c) Housing Facilities should be maintained in good repair. Walls and floors should be constructed of durable materials with surfaces that can be cleaned and disinfected readily.
- (d) Housing Facilities should be kept clean and tidy and operated to achieve maximum possible hygiene.
- (e) There should be a pest control programme to monitor and control vermin.
- (f) There should be adequate and appropriate storage areas for food, bedding and equipment.
- (g) Deodorants designed to mask animal odours should not be used in Housing Facilities as they may expose animals to volatile compounds which can alter metabolic processes. In addition, deodorants must not be used as a substitute for good cage and equipment cleaning practices and good ventilation.
- (h) Cleaning practices should be monitored on a regular basis to ensure effective hygiene and sanitation. This may include visual inspection, monitoring water temperatures and microbiological testing of surfaces after cleaning.
- (i) There should be proper water supply and drainage.
- (j) There should be adequate contingency plans to cover such emergencies as flooding and fire, or the breakdown of lighting, heating, cooling or ventilation.
- (k) In the interest of disease prevention and general animal welfare, access to the Housing Facilities by unauthorised persons should be restricted

- I. **Building Materials** should be selected to facilitate efficient and hygienic operation of animal facilities. Durable, moisture-proof, fire-resistant, seamless materials are most desirable for interior surfaces including vermin and pest resistance.
- II. **Corridor(s)** should be wide enough to facilitate the movement of personnel as well as equipments and should be kept clean.
- III. **Utilities** such as water lines, drain pipes, and electrical connections should preferably be accessible through service panels or shafts in corridors outside the animal rooms.
- IV. **Animal Room Doors**

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

V. **Exterior Windows**

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

VI. **Floors**

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

They should be capable of supporting racks, equipment, and stored items without becoming gouged, cracked, or pitted, with minimum number of joints.

VII. **Drains**

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

VIII. **Walls & Ceilings**

Walls should be free of cracks, unsealed utility penetrations, or imperfect junctions with doors, ceilings, floors and corners.

Surface materials should be capable of withstanding scrubbing with detergents, disinfectants and the impact of water under high pressure. Materials used for construction of roof should cater needs of local climatic condition to provide comfort to the animals.

IX. **Storage Areas**

Separate storage areas should be designed for feed, bedding, cages and materials not in use.

Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal tissue waste.

X. Facilities For Sanitizing Equipment And Supplies

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

XI. Experimental Area

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

15. 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 open enclosures of large animals.

(b) Ventilation

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

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

(c) Power And Lighting

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

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

(d) Noise Control

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

16. ANIMAL HUSBANDRY

i. Caging of Housing System

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

The housing system should:

- Provide space that is adequate, permit freedom of movement and normal postural adjustments, and have a resting place appropriate to the species;
(Annexure – 3)
 - Provide a comfortable environment
 - Provide an escape proof enclosure that confines animal safely
 - Provide easy access to food and water;
 - Provide adequate ventilation
 - Meet the biological needs of the animals, e.g., maintenance of body temperature, urination, defecation, and reproduction;
 - Keep the animals dry and clean, consistent with species requirements ;
 - Facilitate research while maintaining good health of the animals.
- (b) They should be constructed of sturdy, durable materials and designed to minimize cross-infection between adjoining units. Polypropylene, polycarbonate and stainless steel cages should be used to house small lab animals, Monkeys should be housed in cages made of steel or painted mild steel and for other animals such as sheep, horses, the details can be seen in **Annexure - 3**.
- (c) To simplify servicing and sanitation, cages should have smooth, impervious surfaces that neither attract nor retain dirt and a minimum number of ledges, angles, and corners in which dirt or water can accumulate. The design should allow inspection of cage occupants without disturbing them. Feeding and watering devices should be easily accessible for filling, changing, cleaning and servicing.
- (d) Cages, runs and pens must be kept in good condition to prevent injuries to animals, promote physical comfort, and facilitate sanitation and servicing. Particular attention must be given to eliminate sharp edges and broken wires, keeping cage floors in good condition. International guidelines can be referred from time to time to improve caging facilities.

ii. Sheltered or Outdoor Housing

- (a) When animals are maintained in outdoor runs, pens, or other large enclosures, there must be protection from extremes in temperature or other harsh 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 have sufficient ventilation, and should be designed to prevent accumulation of waste materials and excessive moisture.
- (b) Houses, dens, boxes, shelves, perches, and other furnishings should be constructed in a manner and made of materials that allow cleaning or replacement in accordance with generally accepted husbandry practices when the furnishings are soiled or worn out.
- (c) Ground-level surfaces of outdoor housing facilities can be cemented or covered with absorbent bedding, sand, gravel, grass, or similar material that can be removed or replaced when that is

needed to ensure appropriate sanitation. Accumulation of animal waste and stagnant water should be avoided by, for example, using contoured or drained surface. Other surfaces should be able to withstand the elements and be easily maintained.

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

17. SOCIAL ENVIRONMENT

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

18. ACTIVITY

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

19. FOOD

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

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

20. BEDDING

- (a) Bedding should be absorbent, free from toxic chemicals or other substances that cause irritation, injure animals or personnel, and of a type not readily eaten by animals. Bedding should be used in amounts sufficient to keep animals dry between cage changes without coming into contact with watering tubes.
- (b) Bedding should be removed and replaced periodically with fresh materials as often as necessary to keep the animals clean and dry. The frequency is a matter of professional judgement of animal care personnel in consultation with the investigation depending on the number of animals and size of cages. In general it is ideal to change the bedding twice a week or whenever requires.
- (c) The desirable criteria for rodent contact bedding is ammonia binding, sterilizable, deleterious products not formed as a result of sterilization, easily stored, non - desiccating to the animal, uncontaminated, unlikely to be chewed or mouthed, non - toxic, non - malodorous, nestable, disposable by incineration, readily available, remains stable during use, manifests batch uniformity, optimizes normal animal behaviour, non - deleterious to cage - washers, non - injurious and non - hazardous to personnel, non - nutritious and non - palatable.
- (d) Nesting materials for newly delivered pups should be provided wherever needed (e.g. Paper

cuttings, tissue paper, cotton etc.).

21. WATER

- (a) Animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their requirements. Periodic monitoring of microbial contamination in water is necessary.
- (b) Watering devices, such as drinking nozzles and automatic waterers should be examined routinely to ensure their proper operation. Sometimes it is necessary to train animals to drink water from automatic watering devices.
- (c) Animals should receive appropriate, uncontaminated and nutritionally adequate food according to accepted requirements for the species. The food should be in sufficient quantity and of appropriate composition to maintain normal growth of immature animals, normal weight of adult animals or provide for the requirements of pregnancy or lactation.
- (d) When animals are fed in groups, there should be sufficient trough space or feeding points to cater to the number and size of animals that eat together at one time so as to avoid undesirable competition for food, especially if feed is restricted.
- (e) Uneaten perishable food should be removed promptly unless contrary to the eating habits or needs of the species. Any alteration to dietary regimes should be gradual.

22. SANITATION AND CLEANLINESS

- (a) Sanitation is an essential activity in an animal facility. Animal rooms, corridors, storage spaces, and other areas should be properly cleaned with appropriate detergents and disinfectants as often as necessary to keep them free of dirt, debris, and harmful agents of contamination.
- (b) Cleaning utensils, such as mops, pails, and brooms, should not be transported between animal rooms.
- (c) Where animal waste is removed by hosing or flushing, this should be done at least twice a day. Animals should be kept dry during such procedures. For larger animals, such as dogs, cats, and non - human primates, soiled litter material should be removed twice daily.
- (d) Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipments, such as feeders and watering devices, should be washed and sanitized frequently to keep them clean and contamination free. Generally this can be achieved by washing solid bottom rodent cages and accessories once or twice a week and cages, racks at least monthly.
- (e) Wire - bottom cages other than rodent cages should be washed at least every 2 weeks. It is good practice to have extra cages available at all times so that a systematic cage-washing schedule can be maintained. Cages can be disinfected by rinsing at a temperature of 82.2C (180°F) or higher for a period long enough to ensure the destruction of vegetative pathogenic organisms.
- (f) Disinfection can also be accomplished with appropriate chemicals. Equipments should be rinsed free of chemicals prior to use. Periodic microbiologic monitoring is useful to determine the efficacy of disinfection or sterilization procedures.
- (g) Rabbits and some rodents, such as guinea pigs, mice and hamsters, produce urine with high concentration of proteins ammonia and minerals. Minerals and organic compounds in the urine from these animals often adhere to cage surfaces and necessitate treatment with acid solutions

before washing.

- (h) Water bottles, sipper nozzles stoppers, and other watering equipment should be washed and then sanitized by rinsing with water of at least 82.2°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.
- (i) Some means for sterilizing equipments and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present. Routine sterilization of cages, feed and bedding is also essential besides care is taken to use clean materials from reliable sources. Where hazardous biological, chemical, or physical agents are used, a system of equipment monitoring might be appropriate.
- (j) Deodorants or chemical agents other than germicidal agents should not be used to mask animal odours. Such products are not a substitute for good sanitation.

23. ASSESSING THE EFFECTIVENESS OF SANITATION

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

24. WASTE DISPOSAL

- (a) Wastes should be removed regularly and frequently. All waste should be collected and disposed off in a safe and sanitary manner. The most preferred method of waste disposal is incineration. Incinerators should be in compliance with all central, state, and local Public Health and Pollution Control Board regulations.
- (b) Waste containers containing animal tissues, carcasses, and hazardous wastes should be lined with leak - proof, disposable liners. If wastes must be stored before removal, the waste storage area should be separated from other storage facilities and free of flies, cockroaches, rodents, and other vermin. Cold storage might be necessary to prevent decomposition of biological wastes. Hazardous wastes should be rendered safe by disinfection, decontamination, or other appropriate means before they are disposed off from an animal facility.

25. PEST CONTROL

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

26. 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 near telephone. A disaster plan that takes into account both personnel and animals should be prepared as part of the overall safety plan for the animal facility.

27. RECORD KEEPING

It is essential that animal House should maintain following records:

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

28. STANDARD OPERATING PROCEDURES (SOPs) / Guidelines

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

A SOP should contain the following items:

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

29. PERSONNEL AND TRAINING

- (a) The selection of animal facility staff, particularly the staff working in animal rooms or involved in transportation, is a critical component in the management of an animal facility.
- (b) The staff must be provided with all required protective clothing (face masks, head covers,

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

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

30. TRANSPORT OF LABORATORY ANIMALS

- (a) The transport of animals from one place to another is very important and must be undertaken with care. The main considerations for transport of animals are, mode of transport, containers, animal density in cages, food and water during transit, protection from transit infections, injuries and stress.
- (b) The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable movement and protection from possible injuries. Sometimes injuries can be avoided by reducing space but parallelly decreasing time of transportation. The food and water should be provided in suitable containers or in suitable form so as to ensure that they get adequate food and more particularly fluid during transit. The transport containers (cages or crates) should be of appropriate size and only a permissible number of animals should be accommodated in each container to avoid overcrowding and infighting (**Annexure - 4**)

31. ANAESTHESIA AND EUTHANASIA

- (a) The investigators should ensure that the procedures, which are considered painful, are conducted under appropriate anaesthesia as recommended for each species of animals.
- (b) It must also be ensured that the anaesthesia is given for the full duration of experiment and at no stage the animal is conscious to perceive pain during the procedure. If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irreparable injury, the animal should be humanely sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia (**Annexure - 5**).
- (c) In the event of a decision to sacrifice an animal or termination of an experiment or otherwise an approved method of euthanasia should be adopted (**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.

I. Anaesthesia:-

- (a) Unless contrary to the achievement of the results of study, sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment. Anaesthetic agents generally affect cardiovascular, respiratory and thermo-regulatory mechanism in addition to central nervous system.
- (b) Before using actual anaesthetics the animals are prepared for anaesthesia by overnight fasting and using pre-anaesthetics, which block parasympathetic stimulation of cardio-pulmonary system and reduce salivary secretion. Atropine is most commonly used anti-cholinergic agent. Local or general anaesthesia may be used, depending on the type of surgical procedure.
- (c) Local anaesthetics are used to block the nerve supply to a limited area and are used only for minor and rapid procedures. This should be carried out under an expert supervision for regional infiltration of surgical site, nerve blocks and for epidural and spinal anaesthesia.
- (d) A number of general anaesthetic agents are used in the form of inhalants. General anaesthetics are also used in the form of intravenous or intra-muscular injections such as barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side - effects such as excess salivation, convulsions, excitement and disorientation should be suitably prevented and controlled. The animal should remain under veterinary care till it completely recovers from anaesthesia and postoperative stress.

II. Euthanasia

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

32. LABORATORY ANIMAL ETHICS

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

33. TRANSGENIC ANIMALS

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

34. 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.

35. 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.

36. BREEDING AND GENETICS

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

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 ⁶)	6 - 15	6 - 17	3 - 11	7 - 18	9 - 11	5.5 - 19.5	6 - 17	2.5 - 26.7
Neutrophil	10 - 40	9 - 34	10 – 42	28 - 44	20 - 75*	35 - 75	60 - 70	5 - 88
Lymphocyte	55 – 95	65 – 85	50 - 95	39 - 72	30 - 85	20 - 55	12 – 30	8 - 92
Eosinophil	0 - 4	0 - 6	0 - 4.5	1 - 5	0 - 4	2 - 12	2 - 10	0 - 14
Monocyte	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(X ¹⁰ ⁹)	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		
	upto15	46		
	upto25	74		
	>25	96.7		12
Rat	<100	109.6		
	upto200	148.3		
	upto300	187.0		
	upto400	258.0		
	upto500	387.0		
	>500	>=451.5		14
Hamster/Gerbil/ Mastomy/Cotton rat	>60	64.5		
	upto 80	83.8		
	upto100	103.2		
	>100	122.5		12
Guinea pig	<350	387.0		
	>350	>=651.4		18
		Floor area		Height
		(Sq.ft)	(Sq.meter)	(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 Pups	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
Example I Cage Size 24 x 14 cm i.e. floor area of 336 cm ² maximum number of animals	9	7	4	3*
Example II Cage Size 32.5 x 21 cm i.e floor area of 682.5 cm ² 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 per 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
Example Cage size 32.5 x 21 cm i.e floor area of 682.5 cm ² 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 (in Cm)
	(in Ft ²)	(in 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	<25	10.0	8
	Up to 50	15.0	
	>50	20.0	
	<25	8.5	
	Up to 50	12.5	
	>50	17.0	
2-5	<25	7.5	
	Up to 50	11.3	
	>50	15.0	
Swine	Up to 25	12.0	8
	Up to 50	15.0	
	Up to 100	24.0	
	Up to 200	48.0	
	>200	>60.0	
	<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 (ft ² b)	Height (ft)
Cattle/buffalo			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

Cattle, Buffalo, Equine, Sheep, Goat and Pigs may be procured (transported) as per the Transport of Animals (Amendment) Rules, 2009
(Refer: [www.awbi.org/awbi-pdf/Transport of Animals \(Amendment\) Rules, 2009.pdf](http://www.awbi.org/awbi-pdf/Transport%20of%20Animals%20(Amendment)%20Rules,%202009.pdf))

ANNEXURE – 5

COMMONLY USED ANAESTHETIC AGENTS FOR LABORATORY ANIMALS

Drugs (mg/kg)	Mouse	Rat	Hamster	Guinea pig	Rabbit	Cat	Dog	Primate	Cattle/ Buffalo	Equine
KETAMINE HCl	87mg/kg IP once (in combination with xylazine)	87mg/kg IP once (in combination with xylazine)	200 mg/kg IP once (in combination with xylazine)	40 mg/kg IM, 60 mg/kg IP once (in combination with xylazine)	24-35mg/kg IM	22-33mg/kg IM	11 to 22 mg/kg IM.	5- 15mg/kg	2 to 2.2mg/kg IV	2.2 - 2.75 mg/kg IV
PENTOBAR- BITONE SODIUM	35 IV 40-70mg/kg IP	30-40 mg/kg IV 40-60mg/kg IP	70-90mg/kg IP	30mg/kg IV 40mg/kg IP	30-40mg/kg IV 40mg/kg IP	25-35 mg/kg IV	10 – 33mg/kg IV	20-30mg/kg IV	5.5-15.4 mg/kg IV	15- 18mg/kg IV
THIOPENT- ONE SODIUM	25mg/kg IV 50mg/kg IP	20-40mg/kg IV 40mg/kg IP	20 mg/kg IV 40mg/kg I/P	20 mg/kg IV 55 mg/kg IP	20 mg/kg IV	13.2- 26.4mg/kg IV	13.2-29 mg/kg IV	15-20mg/kg IV	5.5- 15.4mg/kg IV	6- 15.4mg/kg IV
URETHANE	1000mg/kg IP*	1000mg/kg IP*	1500mg/kg IP*	1500mg/kg IP*	1000mg/kg IP*	750mg/kg IV*, 1500mg/kg IP*	1000 mg/kg IP*	-	-	-

*(prolonged anaesthesia: terminal procedures only)

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

Anesthesia for Laboratory Animals:

For mice ketamine is used alone intramuscularly. Usually I/M is not recommended in Mice due small muscle mass, and may cause lameness in mice. Also Injection may cause discomfort and local tissue irritation. Ketamine is rarely administered alone due to its poor muscle relaxation. Ketamine has been used in combination with various other anesthetic drugs, but it is most commonly combined with Xylazine or Medetomidine.

The Drugs/dose and route of administration is as follows:-

Drug (mg/Kg)	Mouse	Rat	Rabbit	Hamster	G.Pigs	Cat	Dog	Primate
Ketamine+Xylazine	80mg+10mg i/p	75+10mg i/p	35-40 +5-10mg i/m	200+10 mg/i/p	40+5 mg i/p	20 +1mg i/m	5+1.5 mg i/m	10+0.5mg i/m

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
Halothane		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

* Cervical dislocation is not allowed in rats weighing more than 200gms.

IP = Intra Peritoneal, IV= Intra Venous, IM = Intra Muscular

**METHODS NOT ACCEPTABLE FOR EUTHANASIA OF ANY
SPECIES OF ANIMAL:-**

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 Embolism

For Cattle, Equine, Swine, Sheep & Goat, Thiopentone Sodium is given three times the anaesthetic dose for that species.

Equines

Sedation with acepromazine I/M / xylazine I/M followed by Thiopentone sodium I/V or Potassium chloride 10% solution I/V.

Livestock

Sedation with xylazine I/M and ketamine I/V followed by 10% potassium chloride/Thiopentone sodium

Swine

For swine restraining with Gallamine I/M, followed by sedation with xylazine, followed by Potassium chloride/Thiopentone sodium I/V.

NOTE

Potassium chloride 10% solution must be given intravenously at a very fast pace after proper sedation of the animal.

Barbiturates (Thiopentone) at three times the anaesthetic dose can be administered for euthanasia.

Annexure - 7

QUALIFICATIONS & KNOWLEDGE REQUIRED FOR LABORATORY ATTENDANT

- a. Certificate of animal handling and welfare from any recognised institution.
- b. 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), 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).
- c. 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.
- d. Handling of animals - precautions while handling animals - common injuries and ailments in animals - litter - weaning - maintenance - record keeping.
- e. 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.
- f. Emergency situations: escaping animals - use of fire extinguishers - emergency lamps - sirens.

Annexure – 8 (for reference)

Institutional Biosafety Committee (IBSC)

- (a) 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
- (b) 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.

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**CARE
AND
MANAGEMENT
OF
EQUINES USED IN
THE PRODUCTION
OF
BIOLOGICALS
2001**

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1. REQUIREMENTS OF EQUINES IN THE PRODUCTION OF BIOLOGICALS

Equines are employed in large numbers in India to produce hyperimmune sera and other biologicals. The choice of the species (equines) for the purpose is apparently due to the ease in management and handling, tolerance to huge doses of antigen and high volume of hyperimmune serum that can be harvested at periodic intervals to mention a few .

Nevertheless unscientific and unscrupulous methods, the most agonizing ways of housing and management, unethical procedures of immunization and bleeding adopted in harvesting hyperimmune sera irrespective of the physiological competence and health status of the animal was observed in several large institutes in India. The equines of course had only two options- endure the torture or succumb to it.

This also results in poor quality of sera, affecting the recipient humans. The equines to be efficient donors of hyper immune sera should be physiological very fit. They should be housed as per standards and should be fed with easily digestible good food. The equines must be provided, in the least, with minimum exercise in order to have efficient digestion and general well being. Care must be given to hoof and daily grooming must be ensured. .

Presently most horses used by the institutes are sourced from army, police, racing stables, riding stables etc. They are given to the institutes after they out live their productive functions in the army or other stables, though the basic pre requisite in using equines for the production of biologicals is good health.

Equines, especially horses are very sensitive in nature and will react to micro or macro environmental alterations. in feed and handling. They must be treated with care and dignity, which are also basics of animal welfare.

The responsibility of horse care includes the understanding of a horses needs and knowledge of how horses live in the wild. It includes knowledge of the horses structure and how the systems in its body work, learning to recognize signs of ill health, ' know how to deal with injury and disease and the know-how to use horse equipment and tack.

The horse's anatomy, body systems and natural behaviour are all adapted for a life as a herd animal and dictate how it should be cared for. The horse is a herd animal and needs to be able to communicate with other herd members and they need companionship. Of course horses do not have philosophical discussions but they need to convey basic emotions such as fear etc. Wild horses have considerable tactile and social contact with other horses.

Individually stabled horses are denied these social interactions and this may contribute to the development of abnormal behavioural habits such as box walking, weaving, wind sucking and crib biting. Domesticated horses need contact with people instead and this is given through activities such as grooming and exercising. Horses enjoy rolling, especially in the mud and dust. Horses roll for pleasure and they also roll when they have colic or abdominal pain. Rolling involves almost all the muscles of the body and when they roll for pleasure they seem to enjoy it the same way as humans would enjoy a good stretch. Stabled horses will frequently roll in their beds. Bedding is essential for stabled horses. Daily grooming by stable attendants may help to compensate their reduced social interaction with their own species.

While horses do eat a lot, in their natural state they eat small amounts of food continually over extended periods of time. Put simply, horses are grazing animals. Horses have a small stomach for their size and their one way digestive system works best when it is continually supplied with small amounts of food, as in grazing. Equine stomachs can't handle an overload; nor can they expel it by vomiting. A strong muscle that admits food and fluids but prevents anything from going back out, encircles the entrance to a horse's stomach. Thus a horse can't even burp up excess stomach acid, let alone regurgitate disagreeable fodder.

So when a horse eats the wrong thing or even too much of the right things, the food is trapped in his stomach. It stacks up in soggy layers that his digestive system is unable to break down or expel, making him susceptible to several digestive problems. This vulnerability is heightened by any stressful situation. Forage is the foundation of a horse's diet, and nutritionists caution that protein rich grain should be fed only when hay and pasture don't meet caloric requirements. Shortchanging fiber with too much grain and supplements will disrupts the ability of a horse's sensitive digestive system to absorb nutrients, leading to problems.

Teeth of course, are the primary food processors, and digestive efficiency depends on their condition. Horses grasp food with the upper lip, aided by the tongue or front teeth, depending on the type of fodder. Before they chew hay or grain, they mix it with large quantities of saliva, which is secreted by three large salivary glands. These glands also produce a protein that helps break down starches. The water the horse drinks before eating usually stimulates the salivary glands.

The food then moves back in the mouth, where it is ground up, down, and finally sideways by the teeth. This lateral movement gradually wears down tooth enamel, creating sharp edges on the inside of the lower teeth and the outside of the uppers, often causing painful injuries to the tongue and cheeks unless filed regularly.

Horses eat slowly as a rule, in keeping with natural grazing habits suited to the configuration of their jaws. The upper mandible is larger than the lower,

allowing them to chew on only one side at a time. What and how much a horse should be fed is determined by his age, breed, and weight, as well as by the type and amount of work he is doing. Young horses have different dietary needs from older individuals and those in their prime. Thoroughbreds have the highest metabolic rate, burning nutrients the most quickly.

Equine intestines teem with diverse colonies of ravenous parasites waiting to cadge a meal. Botfly larvae and the eggs of large and small strongyles, roundworms, and tapeworms, to name just a few, will be first to feast on the nutrients of any fodder a horse eats, depriving the bloodstream of energy-producing elements that the horse needs for peak performance. These parasitic pests invade the mouth as eggs and larvae, swimming on a salivary sea into the hundred-foot alimentary canal, attaching themselves at various points along it, and burrowing in until they reach maturity and are expelled in the feces. If left unchecked, these minuscule gourmands will permanently damage the horse's blood vessels and intestines, causing chronic digestive problems and general debilitation. Wormy horses have a lethargic attitude that translates into poor performance. Their coats are dull and resist shedding, potbellies swell under their visible ribs, and episodes of colic and diarrhoea are frequent. To prevent these conditions, all horses must be regularly dewormed.

A healthy hoof should be full, round, open at the heel and proportionate to the horse's size. A horse should stand evenly on all four feet, with the front hooves squarely on the ground. Although they often shift their back legs, healthy horses never lift the front feet in like manner. The attention of a farrier will be regularly required to maintain the health of hoof, especially in stabled horses.

Majority of equids used in research are brought in from outside sources. Ex-race horses - sourced for physiological research, will adjust to stable routine and they are usually amenable to most minimally invasive procedures, such as collection of blood samples. Ponies obtained directly from breeders/dealers, may have had minimal exposure to humans and will need regular and patient handling and training.

2. BASICS OF SELECTION AND QUARANTINE

The equines selected for production of biologicals must be young, strong and must be able to endure the stress of hyperimmunisation and the bleeding schedule. It is not important if it is a thorough bred or native breed or pony or mule.

Age

Young equines in the age group of 5-14 years alone can be used. The minimum age of the equines used in these programme must be not less than 5 years.

No animal should be in the programme for a period exceeding 3 years and plasmapheresis must be an integral part of the bleeding. The equines must be tested for liver function test (LFT) and serum profile at the end of every year after introduction into the programme. These animals can continue in the programme only if these tests indicate that the animal is normal.

The animal may be permitted to continue in the programme in the fourth year only after a complete health check up and it is observed that the animal is in a state of perfect good health.

Prepurchase Screening Procedures

A set of screening procedures must be in place to ensure the selection of fit animals than accepting any animal given free of cost or lesser cost. Indiscriminate admission of animals will result in poor standards of immunization and the ultimate biological product, which will be undesirable.

Soundness examination

The animal is critically examined by a qualified and registered veterinarian to detect any apparent or hidden defects in the musculo-skeletal system and for other vices. Examination of mouth and dentition will reveal if it can handle feed properly. Examination of eyes, ears will inform the fitness of these systems. Assessment of clinical parameters such as temperature, pulse, respiratory system and general tests for agility will indicate the general health and fitness of the animal. Examination of feet will reveal hoof health.

Diagnostic tests and laboratory investigations

The animals before purchase should be subjected to the following diagnostic tests by a qualified veterinarian to identify any occult disease

- Mallein test (Glanders)
- Examination of blood smears (Haemo- protozoan parasites)
- Coggins test (Equine infectious anaemia)
- Dung examination (Endoparasites)
- Hematology
- Liver function tests
- Renal function tests

The examining veterinarians must enter all the reports of investigation in the forms appended in enclosure-"Soundness examination form" which includes:

1. History sheet
2. Soundness certificate
3. Diagnostic tests and vaccination details
4. Haematology, liver function and renal function tests

Veterinarian

It is mandatory that a qualified and registered veterinarian with adequate experience in equine practice, be available in all the institutes that possess equines for production of biologicals. This is very important as a bioethical measure just as it is a mandatory pre requisite to have microbiologists for vaccine production or pharmacologists for drug production or pathologists in diagnostic laboratories.

The veterinarians should inspect the equines every day for health and fitness and are directly responsible for all interventions such as immunization or bleeding etc. His/her opinion based on laboratory records of hematology, renal and hepatic profile is a must before harvesting blood from equines. He/she should also ensure the use of steriware and safeguard the health of horses.

Diagnostic laboratory

A fully equipped diagnostic laboratory to study hematology, serum protein and lipid profile, renal and liver function tests, examination of materials for endo- and haemoprotozoan parasites etc. with qualified technicians and headed by a veterinary pathologist should be in place in all the institutes producing biologicals from equines. This laboratory will ensure periodic screening and maintenance of records from which the health profile of equines can be assessed. Scientifically this will be the basis for immunization and bleeding schedules than the dates on the calendar. Accordingly the veterinarians must draw the technical programme.

QUARANTINE AND MANAGEMENT OF NEW COMERS

All the purchased/acquired equines should be isolated for a quarantine period of a minimum 21 days to a maximum of 40 days to be screened, observed and prepared before entry into main stables.

During the quarantine period, the following are to be attended to:

1. Weight of the animal to be recorded.
2. All non specific infections, wounds etc. to be attended to
3. Hoof care to be provided.
4. Immunisations /vaccinations to be administered
5. Deworming to be done
6. Detailed hematology and liver and kidney function tests to be conducted. (if below normal levels are encountered animal to be segregated - special feeding and veterinary supplements to be given.)
7. The collection of naso-pharyngeal swabs for *Streptococcus equi* isolation,
8. Dentition should be checked and teeth rasped if necessary.
9. Animals to be named/numbered/tagged. Ear tags are the ideal form of identification. However if branding is resorted to only cold branding permitted, with a minimum figure size of two inches. Hot branding is not permitted.

SUGGESTED IMMUNIZATION SCHEDULE FOR EQUINES

Disease / vaccine	Frequency	Comments
Tetanus Toxoid	Annual	Booster at the time of penetrating injury / surgery- if the last dose is not administered within 6 months.
Equine Encephalitis (EEE, WEE) (Optional)	Annual	In endemic areas booster every 6 months
Equine Rhinopneumonitis (EHV 1 & 4)	Every 3 months / Annual	-
Anti - Rabies	Annual	Compulsory

SOUNDNESS EXAMINATION FORM

A. DESCRIPTION OF THE ANIMAL

Name of the horse:

Breed

Tattoo

Sex*

Colour ***

Age **

Markings

Seller's statement before examination:

Seller's Name:

Address:

Phone No.

CPCSEA Regd.No:

Duration for which the animal has been in his possession (years/months)

Seller's knowledge of the animal's health (past or present conditions)

Diseases _____

Lameness _____

Treatments/Medications _____

Vices _____

Disabilities _____

Signature

of seller

Date:

Address:

Phone No.:

To what use do you intend to put this horse (define whether ARS/ASVS/ATS etc.)

Name of the buyer:

Address of the buyer:

Signature of the buyer

Date:

* Colt- upto 3 years

Stallion - infant male of 4 yrs / older

Gelding - castrated male

Filly - female upto to 3 yrs

Mare - female over 4 yrs

* * Age should be based on:

1. Age proof supplied by seller- brand, tattoo etc.

2. Inspection of dentition

The first, second and third permanent incisors erupt at 2.5, 3.5 and 4.5 yrs respectively. All permanent teeth (incisors, pre molars & molars) are present by 4.5 years.

*** Coat colour-Bay, Black, Chestnut etc.

B. SOUNDNESS CERTIFICATE

Place _____ Date _____
Time _____

General Health and appearance _____

Approximate height (at withers- cms) _____

Approximate weight (kgs) _____

Temperature (Rectal) _____

(N- Normal; AB - Abnormal)

A. Bilateral symmetry

- | | | |
|----|-------------|--------|
| 1. | Head & neck | N. AB. |
| 2. | Body | |
| 3. | Legs | |

B. Eyes

- | | | |
|----|----------------------------|-------|
| 1. | Symmetry | N.AB. |
| 2. | Reflexes | |
| 3. | Lids | |
| 4. | M. Membrane | |
| 5. | Cornea | |
| 6. | Ophthalmoscope examination | |

C. Mouth

- | | | |
|----|-------------|-------|
| 1. | Lips | N.AB. |
| 2. | Tongue | |
| 3. | Teeth | |
| 4. | Gums | |
| 5. | M. Membrane | |
| 6. | Odour | |
| 7. | Bite | |

D. Nasal

- | | | |
|----|--------------|-------|
| 1. | Symmetry | N.AB. |
| 2. | Airflow | |
| 3. | Odour | |
| 4. | M. Membranes | |
| 5. | Exudates | |

E. Pharynx, larynx, trachea

- | | | |
|----|-----------------------|--------|
| 1. | Palpation | N. AB. |
| 2. | Cough induction | |
| 3. | Auscultation- at rest | |
| | - after exercise | |

F. Cardio-vascular

1. Palpation N. AB.
(heart and pulse)
2. Auscultation- at rest
- after exercise

G. Pulmonary

1. Percussion N. AB.
2. Auscultation - at rest
- after exercise
3. Respiratory rate (at rest)

H. Digestive

1. Percussion N. AB.
2. Auscultation
3. Inspection of dung

I. Genital-urinary

1. External N. AB.
2. Inspection & Palpation

J. Integument

N. AB.

Note especially for "used" marks

(Interference with saddle, girth sores, firing or other treatment
dermatoses etc.)

K. Musculo- Skeletal

a) Vertebral Column

N.AB.

1.Symmetry

2.Palpation

3.Manipulation

b) Limbs

1. Symmetry

N.AB.

2. Palpation

3. Manipulation

c) Gait

N.AB

1.Symmetry

2.Freedom of movement on hard surface

3.On soft surface

4.On a straight way

5.Turning both ways.

L. Vices

- | | |
|---|------|
| 1. Cribbing - Weaving - Digging - Savaging-Others | N.AB |
| 2. Stables Manners | |
| 3. Field manners | |

M. Nervous system

- | | |
|--------------------------|--------|
| 1. Is the horse nervous | Yes/No |
| 2. If so when and where? | |

N. Hoof Health

Whether overgrown/wounded/normal

Conditions other than normal found in the animal. Give particulars

Signature of the Veterinarian_____

Qualification_____

Registration Number_____

Date _____ Place _____

C. DIAGNOSTIC TESTS AND VACCINATION DETAILS

Diagnostic Tests Results

1. Glanders - Mallein test

Results_____

2 .Trypanosomiasis (Surra) - Screening blood smears

Results_____

3.Babesiosis - Screening blood smears

Results_____

4.Equine infectious anemia - Coggins test

Results_____

5.Screening for Endoparasites

Results_____

6. Skin scrapings test (if necessary)

Results_____

Vaccination Details

1. Against tetanus - date-
2. Against rabies - date -
3. Others - Specify - date-

Name of Laboratory _____

Signature of the Veterinarian _____

Qualification_____Registration Number_____

Date_____ Place_____

**D. HAEMATOLOGY, LIVER FUNCTION AND RENAL
FUNCTION TESTS**

Results of Haematology tests

Results of liver function and renal function tests

Name of Laboratory _____

Signature of the Veterinarian _____

Qualification _____

Registration Number _____

Date _____ Place _____

3. HOUSING AND HYGIENE

HOUSING

Horses may be housed in individual stables, with provision for daily and regular exercise and socializing, or in "open barns" which includes a sheltered area with an open paddock for exercise, grazing, socializing etc.

The Stabled Horse

Living in a stable is not natural for a horse. The horse will feel confined and isolated against its natural instincts of feeding and socializing. If you have to stable a horse you must provide good food, water and bedding and the psychological needs of the horse should also be attended to.

The minimum size of horse stables should be a minimum of 12' (length) x 10 (breadth) x 9 (height). The floor must be hard wearing, impervious to moisture, have a non-slip surface and should slope gently for drainage. The stable should be well ventilated from all sides.

They may be loose boxes or stalls. Loose boxes are individual 'rooms' for horses and may open to the outside or are enclosed in a larger barn. Stalls have solid partitions and a single bar across in the front.

In the American Barn type of stabling, loose boxes face each other across a central aisle with the whole area covered over. This is recommended next to the open barn type of housing as it provides stimuli for the animals, which can see each other and communicate with each other. The only disadvantage being the common air space they share.

Whether the animals are housed in individual loose boxes, stalls or in the American Barn type of housing, these animals should be provided daily exercising, grooming and socializing in an open field. Hence a large open grazing field with provision for sand baths should be an essential part of the housing unit. Clean warm bedding is a must for stabled horses. Bedding provides comfort and it insulates and prevents horse feet from being jarred by standing for too long a time on hard surface and encourages a horse to pass urine and droppings. Although horses sleep standing they like to lie down from time to time.

Straw, wood shavings, shredded newspaper may be used as bedding material. Care should be taken to ensure that straw is not mildewed or infected with fungal spores, which in equines can trigger respiratory problems. Wet bedding, droppings and urine in stables should be removed in the least twice a day. Stables should be well ventilated with an air vent near or in the roof of the stables to enable air circulation. Roofing should not be noisy when hit by rain, etc. and must not become too hot in direct sunlight. There should be an overhang on the roof to protect the horse and its bedding from the rain. The roof should have excellent guttering so that the captured rainwater runs into a drain.

The door of stables should be at least 3 1/2 ft wide and 7 ft in height. Horses that are stabled should be exercised/rolled 2-3 times day compulsorily.

The Open Barn

The better alternative to stables is the 'Open Barn' system, which includes a sheltered area with as open paddock. A large barn in a field has the advantage that a number of horses can be sheltered together and have continuous social interaction. The sheltered area (barn) should have sufficient and enough area to provide cover for all the animals in summer /winter /monsoon seasons. The covered areas should have total area equivalent to individual(12 ft x 10 ft x 9ft) stables into the number of horses being housed. The common barn should be provided with adequate feeding and water troughs.

The paddocks should be provided for with grazing area and sand baths.

Fencing of paddocks and the open field area for stabled horses should be of safe metal/wood material. Barbed wire / wire mesh cannot be used. Timber or metal fencing and gates are to be used.

HYGIENE

Sanitation and disinfection of stables, barns and exercising yards

- All manure, litter & combustible materials should be removed and transported away from stables and disposed.
- At least 4 inches of top soil should be removed from any contaminated dirt surfaces.
- The flooring in animal stables should be graded to eliminate any areas of water stagnation.
- All the stables and surfaces should be thoroughly cleaned with water and an effective animal friendly detergent and disinfectant.
- All equipment used for the removal of manure and for cleaning should be thoroughly cleaned.
- All building surfaces and equipments should be kept clean and disinfected.
- If buildings or other facilities are not adequately disinfected by spraying, they should be sealed and fumigated. Allow facilities to dry and remain vacant for a day or two before restocking.
- Fly control measures to be undertaken using safe eco friendly fly repellants.

NOTE:

- 1) Bleaching powder - a good disinfectant may be employed in the routine cleaning of stables. However it should be applied only after the animals are removed from the stables.

All the dung and litter should be removed by scraping dung and litter material from the floor and walls and disposed off by burning. The walls up to 6 feet high should be thoroughly scrubbed with water and so also the floor.

The entire area should be coated with animal friendly disinfectant, by means of a spray with as much pressure as possible.

The disinfectant (bleaching powder) should be left to act for 24 hours.

After 24 hours, the building or the stable should be washed out thoroughly with cold water and then allowed to dry thoroughly. The animal may be brought in only after the stable is dry and has no odor of the bleaching powder.

- 2) Phenolic compounds not permitted in disinfecting animal housing facilities.

4. STANDARDS OF NUTRITION AND FEEDING

The horse is a non-ruminant herbivore with microbial fermentation occurring in the cecum and colon. The stomach is only about 8% of the capacity of the total digestive tract, relatively small in relation to body size. Hindgut comprises 62% of the capacity of the total digestive tract. Unlike cattle, horses cannot digest & utilize crude fibre efficiently. As an herbivore, the horse is and behaviourally accustomed to continuous feeding, they spend most of time grazing or browsing.

In stabled horses, their movements are restricted and socialization is reduced. There is an increased possibility of both gastro-intestinal colic problems arising from individual housing and intermittent feeding.

The equines used for production of biologicals must have an ensured input of nutrition in order to maintain the health of the animal and yield quality products. They are invariably stall fed and therefore standards of nutrition can be maintained with the feed ingredients and computation of ration.

Principles of feeding

- The animals should be fed with concentrates three times a day.
- The freshly computed concentrate should be fed as per the needs of individual animals.
- The concentrate feed is filled in mangers, which are fixed at chest level, for comfortable intake and to avoid contamination, wastage or spillage.
- The manger provided should be of optimum size so that the ration will occupy only $\frac{3}{4}$ of the height to avoid spillage.
- The manger should be emptied every time and cleaned well before refilling for the next feed.
- Roughages (green and dry) are also allotted on the body weight basis.
- Roughages are provided in the stable in separate hay racks / hay nets and should be fixed at chest height.
- Fresh and good quality hay must be ensured and fed at specified timings in appropriate quantities to avoid spillage and wastage.
- The hay racks / nets must be cleaned well before refilling.

- The equines should have constant access to clean and potable water whether at pasture or in stable.
- The source should have large surface area for animals to have easy intake on an average 25 to 30 liters of water may be required daily.
- It is again preferable if the water source is at chest height for comfortable access and to prevent contamination and pollution.
- In winter, rainy, chilly days or in cases of higher altitudes where the ambient temperatures will be low, the horses must be fed with warm water that will encourage more intake.

Equine feed components

Rodent and moisture free facilities for storage of feed and fodder should be ensured in every institute.

Concentrates

Under our conditions maize is one of the most energy dense grains and it should be fed on a basis of weight and not volume. Oats and maize can be fed as a whole, crimped, rolled or ground. Supplementation with vitamins and salt are also recommended. Vitamins at the rate of 5 mg / kg feed and salt at about 50 g (daily) is the most useful supplement for all horses.

Roughages

Hay requirements of equines may range between 1.5 and 2.0 kg per 100 kg live weight. Hay occupies the horse's attention, an important consideration in stabled horses, if behavioural problems are to be avoided. Hay provides most of the dietary intake, of providing both fibre and nutrients.

Straws are deficient in energy, protein and minerals when compared to good quality hay. Wheat and rye straw are not suitable for feeding to horses because of their high lignin content.

Water

Whether stabled or at pasture, equines should have constant access to clean water. The water supply should be sufficiently large to allow several horses to drink at one time in pasture / paddock. Potability of the water to be checked periodically.

When on a excessive concentrates and hay diet, stabled horses require 5 litres of water per 100 kg live weight per day.

During winter, the water intake is reduced, and it is important that horses should be provided with highly digestible feeds in order to minimize the risk of intestinal impaction.

Energy Requirements

The energy requirements of horses vary according to size, activity level, ambient temperature and individual metabolic activity.

The digestible energy (DE) requirements for the maintenance of horses weighing up to 600 kg live weight can be calculated using the following formulae:

$$DE \text{ (Mca1/day)} = 1.4 + (0.03 \times LW)$$

Where LW is the live weight in kgs.

The DE requirements increase by 25 - 100 % for mature horses in light to intensive physical/physiological work as in equines used in production of biologicals.

Feed ration for equines used in the production of biologicals**Concentrate feed (for 100 animals)**

S.no.	Items	Morning Kg	Noon Kg	Evening Kg	Total Kg
1	Oats	16	20	20	56
2	Barely	10	14	10	34
3	Soyabean (crushed)	16	20	20	56
4	Maize (crushed)	20	29	25	74
5	Horsegram crushed	5	5	5	15
6	Wheat bran	5	5	5	15
7	Rice bran	2	1	2	5
8	Linseed (crushed)	10	12	10	32
		84	106	97	287

Feed supplements (for 100 animals)

S.No	Items	Morning Kg	Noon Kg	Evening Kg	Total
1	Common Salt	2	3	3	8
2	Mag. Sulphate	1	1	1	3
3	Dical. Phosphate	400 g	200 g	400 g	1
4	Liv.52 powder	400 g	200 g	400 g	1
5	Agrimin powder	1	1	1	3
6	Jaggery	3	4	3	10
		7.8	9.4	8.8	26

Green grasses

S.No.	Items				
1	Lucerne		10-15 kg	Animal/ day	
2	Green maize		5-10 kg	Animal/ day	
3	Carrots		1 kg	Animal/ day	

Dry grasses

Hay

1.5 - 2.0 kg

Animal/day

5. ENDOPARASITE CONTROL

Stall-fed animals have far lesser chance than those in paddocks or field grazing to acquire endoparasitic infections. In order that the equines maintained for production of biologicals be maintained free from endoparasites, it will be appropriate to examine the dung samples once in three months and the animal dewormed as and when the need arises. The ill effects of endoparasites will include loss in general condition, loss of body weight, anaemia, digestive disturbances and debility.

The drugs/dosage available for treating endoparasites is appended herewith. Anthelmintic drugs are administered to treat control and prevent parasitic infections. They are administered therapeutically or prophylactically to minimise morbidity or mortality associated with parasitic infections.

The decision to administer anthelmintic treatments must be made in the light of the level of parasitic challenge present in the environment of the animal and the health of the animal. The frequency of treatment depends solely on the rate at which the animal acquires parasitic infections.

Equines are generally infected with internal parasites, round worms, tape worms and bots (larvae of bot fly). Large and small strongyles are found in horses of all ages and are potentially very pathogenic. Small strongyles (particularly the larvae) undergo a prolonged period of development in the large intestinal mucosa, and are associated with several clinical syndromes such as diarrhoea and weight loss and which demonstrates seasonal pattern. Tapeworms are common and occasionally associated with ileo - caecal colic.

Use of an appropriate dewormer at the correct time of the year for the particular target parasite, together with good pasture management is an important part of equine management. All horses grazing the same pasture should be treated with the same anthelmintic at the same time.

Specific treatments for bots, tape worms, small strongyles and migrating larvae should be given at the appropriate time of the year of the climatic region as per the decision of the veterinarian.

All new comers should be treated with a larvicidal dose of Fenbendazole followed by a double dose of Pyrantel and kept housed for 48 hours after last treatment, before allowing them to graze with the resident population.

Anthelmintics used routinely should be rotated on an annual basis to reduce the possibility of development of resistance. However it should not be changed every time the horse is dosed as this makes it easier for the worms to become resistant to the dewormer.

COMMONLY USED ANTHELMINTICS IN EQUINES

Drug organism	Dosage	Target
Ivermectin	200 mg / kg body wt.	Nematodes / bots
Thiabendazole	44 mg / kg body wt.	-do-
Mebendazole	8.8 mg / kg body wt.	-do-
Oxyfendazole	10.0 mg / kg body wt.	-do-
Fenbendazole	10 mg / kg body wt.	Nematodes
Pyrantel Ascarids	6.6 mg / kg wt.	Strongyles

Note:

MORAMECTIN Horse worming paste (30g)	Available in a syringe. The contents of this syringe will treat one horse of 600 kg. body wt.
(Avermectin 4 mg/ml Morantel Tartarate 167 mg / ml)	For ponies 5 ml / 100 kg body wt.
PANCUR PASTE (1 dose applicator containing 24 g paste)	For nematodes (large and small) Ascarids, Oxiurids
EQVALAN PASTE (MSD) (Ivermectin)	A complete horse dewormer Nematodes and bots One syringe contains sufficient paste to treat one 600 kg horse – (at 200 mg / kg body wt.)

6. IMMUNIZATION & BLEEDING

The recipient animal should be screened for physical fitness and good health, liver and kidney health profile and haemogram prior to being inducted into the program. The fitness of the animal should be certified by the veterinarian before every immunization and bleeding. Post-immunization the veterinarian should observe the animal for a period of 3 days for any possible immediate /delayed; local or systemic reactions. Only sterileware should be used for immunization.

IMMUNIZATION

During the immunization period the following parameters /tests should be conducted:

1. Weight of the animal to be recorded at monthly intervals. Any animal, which shows a loss/drop in weight, should be removed from the program and subject to a thorough veterinary examination. .
2. Screening for ecto/ endo parasites to be done once every three months.
3. Hematology, liver and kidney function tests to be recorded once in two months.
4. Adequate and proper feeding and nourishment to be given to immunized animals.
5. Veterinarian to be present at the time of every immunization. Health of horse to be monitored continuously and first aid made available in the case of anaphylactic shock etc.
6. **If the required and/or necessary titer values are not obtained from an animal, the same animal is not to be exposed/subject to a different permutations and combinations of antigen and adjuvant. The animal has to be removed from the program.**

BLEEDING

Bleeding should be done only by a veterinarian in the specially designed bleed room. Bleeding is to be done in calm surroundings after gentle and firm restraint of the animal. A veterinarian must do prebleeding examination and his certification must be in record. Adequate precautions must be in place in the bleeding room to tackle contingencies such as hypovolaemic shock. The animals in bleeding programme should undergo routine comprehensive (physical examination, Eye test, LFT, RFT, haemogram) health check every 3 months to ensure good laboratory procedures.

Whenever equines are used for collecting the blood samples, minimizing any pain and distress they suffer should be as important an objective as achieving quality products. The refinement of procedures to make them more humane should be an integral part of all scientific research. **It is in the interests of good science, as well as of animal welfare, that stress should be kept to a minimum.**

Scientists should be aware that the process might well be unnecessarily stressful for an animal simply because of handling or the discomfort associated with a particular technique. The chemical and physiological changes associated with increased stress may affect the quality of the blood drawn. It has been observed that stress affects the levels of prolactin, cortisol, corticosterone, glucose, RBC and WBC counts, platelet count and the packed cell volume. Hence minimizing stress during blood collection is helpful for the animal as well as the operators.

Bleeding / Immunization chambers

Every institution should fabricate special sterile chambers into which the equines can be brought for immunization and bleeding. A post bleed room should be attached to the bleeding room to monitor the animals for at least 3 hours after bleeding. The chamber must have good facilities to calmly restrain the animals and enough room for interventions. At any time only one animal should be held in the chamber, with cool and clean pollution free atmosphere all of which is required as good laboratory procedures. In short the chamber must have tranquility and sanitary standards of an aspiration theatre with lesser sophistication. Enough number of chambers can be had in an institute as per its needs.

PRE-BLEEDING CONSIDERATIONS

- Blood collection environment/room should be clean, sterile and neat and well lit with temperature control.
- All equipments used for bleeding should be sterilized preferably disposables.
- The animal should be identified and a general physical examination carried out to ascertain the health of the animal.
- Baseline tests and observations should have been conducted to get a clear picture of the normal hematology especially RBC, Hb, Packed Cell Volume, plasma protein in order to assess the health status of the animal.
- The color of the mucous membrane and capillary refill time, rectal temperature, pulse and nature of respiration should be monitored.

NOTE: BLEEDING SHOULD NOT BE DONE IN ANAEMIC / SICK ANIMALS

RESTRAINING THE ANIMAL

Large animals are normally physically restrained for venepuncture without anaesthesia. The animal should be gently restrained by an experienced handler who, should ideally be known to the animals. The key role played by the person holding the animal and raising the vein cannot be overemphasized. The animal may well show signs of discomfort but it should be reassured by gentle handling and talking.

Special frames (stocks) designed to restrain the animal for veterinary examination may be used for bleeding. The frame should not have any sharp projections or too narrow that it will hurt the abdomen. The entire frame should be wrapped with cushioning material (removable and washable).

The horizontal bars should be well rounded and the floor surface non-slippery. Some means of a quick side release should be available should a horse slip and go down.

Most horses and ponies will accept being restrained for collection of blood if they have been well – handled previously. A head collar should be put on with a long lead, preferably with a quick release catch. For collection of venous blood horses usually do not require additional control.

If more control is needed, then grasping a fold of skin in the neck with one or both the hands and twisting it (neck twitch) is usually sufficient to keep the horse still until the blood is collected. Horses are commonly physically restrained for venepuncture without anaesthesia. For more fractious animals, a twitch can be applied to the upper lip. **However twitches should only be applied by staff experienced in their use and should only be used for a short period of time.**

Excessive force used in restraint will stress the animal and raise catecholamine and glucocorticoid levels in the blood. This in turn will alter the blood parameters such as packed cell volume and blood glucose level.

Equipment

1. Disposable needle with canula 14-16 gauge x 25-40mm needle with suitable silicon tubing
2. Hair clipper
3. Anti-septic
4. Percussion hammer
5. Cotton
6. Towel
7. Collection flasks
8. Plasmapheresis equipment

PREPARATION OF THE SITE OF BLOOD COLLETION AND LOCALIZING THE VEIN

Collection of blood samples are usually made from the jugular vein which is readily visible when the vein is raised by manual pressure in the jugular groove.

It is important to locate the vein accurately before taking a sample. Obstruction of the venous return may be required in order to distend the vein and to prevent excessive movement of the vein. This makes location and introduction of a needle much easier. Percussion may help to determine the course of a vein. **It is important that time be spent making an accurate location and blood dilation of the vein before puncturing the vessel.**

Important point to consider is that the thickness of the skin varies between sites on the same animal. Repeated injections may lead to fibrosis of the vein and thickening of the skin.

It is important to maintain asepsis throughout the procedure, so hair and superficial skin debris over the vein should first be removed. Hair can be removed using a pair of clippers. Clip the hair over an area approximately 10cm long and 5 cm wide on either the right or left hand side of the animals neck. The clipped area should be cleaned with warm water to which is added a disinfectant such as cetrimide or an antiseptic lotion like Savlon (1:30) dilution. These agents should be subsequently removed with plain water to prevent contaminating the sample.

INSERTION OF NEEDLE AND TAKING THE SAMPLE

- Having located and tracked the course of the vein, dilated and immobilized it, prepared aseptically the next stage is to pierce the skin with a needle (Sometimes with the a syringe attached). The skin should be pierced with one movement by directing the tip of the needle, a little way up the vein, so that the angle of penetration is almost parallel to the vein. (The angle of perforation should not be steep since the steeper the angle of needle entry the more likely it is to pass through the vein)
- The maximum volume that can be bled from an equine should not exceed 1 % of the body weight or 10% of circulating blood volume weight with plasmapheresis. The plasma so depleted should be restored by resuspending the solid suspended material with the equivalent volume of warm (30-35 C) Ringers lactate or normal saline infusion.

If too much blood is withdrawn too rapidly, or too frequently without replacement an animal may go into short-term hypo-volaemic shock and in the long term suffer from anemia. Again the vein will collapse if the sample is taken too quickly in a large quantity and so care should be taken to ensure that it is taken at an appropriate rate.

Hence as a rough guide upto 10 % of the circulating blood volume can be taken on one single occasion from a normal hardy animals on an adequate plane of nutrition with minimal adverse effect. **This does not mean the animal does not experience any after effects - merely that it does not show any.**

This volume may be repeated only after 4 weeks. If 5% of the circulating blood volume is removed a 2-week rest period is to be given between 2 bleeds. An annual rest of 3 months from bleeding is mandatory for all animals used in bleeding.

WITHDRAWAL OF THE NEEDLE AND POST -BLEED MONITORING

- After the needle has been withdrawn, continuous pressure should be applied immediately to the puncture site for latest 30-60 seconds.
- The puncture site should be observed for further 30 seconds to ensure that bleeding does not recur.
- The animal should be retained in the post- bleed room and checked every 10-15 minutes for the next 3 hours.
- If there is any chance that the bleeding may restart the animal must be isolated at once so that it can be closely monitored.
- Care must be taken in handling the animals after blood withdrawal. Since bad handling can stimulate bleeding due to physical trauma or raised blood pressure.
- If the bleeding persists it may be advisable to apply a haemostatic preparation or tincture benzoin to arrest bleeding. However thermocautery artificial skin sealants should not be used as they cause discomfort.
- Rectal temperature, pulse, heart rate and respiration should be monitored.
- Urine flow should be observed.

CARE OF THE ANIMAL IN HYPO VOLAEMIC SHOCK AND ANEMIA

It is essential to be able to recognize the signs and symptoms of shock and anemia and appropriate action must be taken.

Hypo-volaemic shock manifests as a fast and thready pulse, pale dry mucous membrane, cold skin and extremities, restlessness, hyperventilation and a subnormal body temperature. Central venous pressure should be monitored to avoid overloading and pulmonary oedema. The animal should be kept warm and well ventilated but direct heat should not be applied. In these animals therapeutic intervention consists of substituting the blood volume lost with an equivalent amount of warm isotonic intravenous infusion.

Systemic administration of broad-spectrum antibiotics is indicated in hypovolaemic shock to avoid secondary infection, which can occur due to impaired reticulo-endothelial system. The temperature, pulse and respiration have to be monitored periodically.

Signs of anemia includes pale mucous membrane of the conjunctiva or inside the mouth, pale tongue, gums, intolerance to exercise and at a more extreme level an increased respiratory rate when at rest. Monitoring of the individual animal is very important and the base line data of each animal i.e. PCV, HB, RBC and reticulocytes counts should be monitored throughout the series of bleeds. Any deviation from normal should be taken seriously and the animal attended to.

In case of anemia the animal should be treated with iron and vitamin B12 for the above mentioned blood parameters during therapy until normal values are reached again.

7. MAINTENANCE OF RECORDS /DOCUMENTATION

Records and documentary proof of the equines in possession and production with necessary and important information must be scrupulously maintained in every institute and they must be open to verification and inspection.

The following registers must be maintained:

1. Livestock register with details of age, sex, source, identity etc.
2. Individual animal health card
3. Individual animal production record of immunizations, bleed volume, harvest etc.
4. Feed and stock register
5. Daily diary of veterinarian
6. Sick Bay register and treatment register
7. Roaster of deworming and vaccinations
8. Quarantine and Isolation register
9. Mortality and Postmortem register

8. CARE OF SICK AND INJURED EQUINES

There are disorders of equines consequent to domestication and confinement in stables or paddocks. Commonly they will be of digestive or respiratory or behavioural in nature that should be watched for and appropriately handled.

The staff at stables must be trained to recognize common ailments and must be aware of first aid and nursing. Basically such animals should be kept in a clean, spacious well-ventilated loose box with adequate bedding and a separate attendant should be on 24-hour duty.

RECOGNITION OF PAIN IN EQUINES

The following signs are indicative of pain in equines:

1. Periods of restlessness
2. Interrupted feeding with food held in the mouth uneaten
3. Anxious appearance with dilated pupils and glassy eyes
4. Increased respiration and pulse rate with flared nostrils
5. Profuse sweating
6. Rigid stance
7. Frequent yawning
8. Frequently lying down

In prolonged pain, behaviour may change from restlessness to depression with head lowered.

In pain associated with musculo-skeletal damage, limbs may be held in unusual positions and there is reluctance to move, with the head and neck "fixed". There may be a pain-induced tachycardia. In abdominal pain a horse may look at, bite or kick its abdomen; it may get up and lie down frequently; walk in circles; roll and injure itself as a result of these activities with bruising especially round the eyes. This state may progress and last for several hours. When near collapse, the horse may stand quietly rigid and unmoving but with signs of deteriorating circulatory status such as mucosal cyanosis and prolonged capillary filling time. Horses in pain generally show a reluctance to be handled.

NURSING EQUINES

Nursing a sick animal does not necessarily mean that the animal is free from pain, but that everything has been done to make its life as comfortable and pleasant as possible in the given circumstances.

Most importantly never leave a horse in even the slightest pain for more than 24hours without identifying the cause. Call for a vet immediately.

When a horse needs nursing, keep it in a large, well-lit, draught free box. There should be an electricity point and a source for hot water nearby. A sick horse needs constant attention to keep it warm, clean and if the condition permits well fed. An attendant should be on hand 24hours to respond to its needs and any change in its condition.

Bring a horse in from the field if does not appear to be eating normally, if it is lethargic, if it feels colder than you would expect, or if it has diahorrea or it is not passing normal droppings. If required immediate first aid should be administered before calling in the vet. Medicines can be mixed with small amounts of the horse's normal feed. If it refuses this, try adding a strong flavor such as molasses or try hiding the drug in a hollowed apple or carrot.

Give a sick horse a good bed to lie on, but do not make it too thick, especially if it is straw. If a horse stands miserably shifting its feet it may build up a pile of straw between its legs and makes further movement difficult.

You can tell whether the horse is feeling cold by feeling its ears gently. If the horse is cold put on a rug. However the ears will not show you if the horse has a high temperature or not.

A horse's nostrils and airways can become clogged with mucous, a steam inhalation will loosen the mucus and soften any crusting, which might be uncomfortable. Put a few drops of vapor inhalant into a bowl of hot water. Wrap a towel around the bowl and loosely around the horse's muzzle, so that the horse can breathe only the air containing the medicated steam.

Horses like routine, and when they are ill, this is all the more important. Give meals and do other tasks at the normal times. Grooming is vital, even for the sick horses, it really freshens them up unless it evinces any pain in doing so.

First Aid Kit

The first aid kit should contain:

Antiseptic liquid (ideally chlorhexidine)

Antiseptic aerosol spray

Bandages- elastic adhesive bandage, crepe bandage, self-adhesive bandages etc.

Scissors

Gauze

All purpose dressing materials

Gamgee

Freeze pack

Cold pack, etc

Equine Examination Equipment

Weigh Bridge

Records (examination sheet, health record sheets, request forms etc.)

Head collars, Halters, Rope

Farrier equipment

Hoof pick

Grooming equipment

Hair clippers

Thermometer

Clock with second hand

Stethoscope

Twitch

Rectal Sleeves and tube

Nasogastric tube

Hausman's gag

Teeth rasps

Mare catheters

Stallion catheters

Infra red radiation source

Diathermy

Enema can

Symm's abscess knife

Hoof knife and testers

Stretcher trolley

SICK BAY AND RETIREMENT FACILITIES

Every institute is to be provided with an exclusive sick bay where sick animals are to be given 24 hr veterinary attention and care. The institute should have a large animal ambulance with a hydraulic lift.

Institutes must allocate land, funds and staff for rehabilitation of equines after the production period during which they were used for the production of anti-toxins/serum. Retired animals should be given all necessary care and nutrition and should not be reused or disposed for other reasons.

Sick and dying animals are to be given the best of care and veterinary assistance. Euthanasia is not recommended unless the animal is in absolute distress or trauma and cannot be treated.

Euthanasia if ever done has to be done only with sedatives and barbiturates and with the permission of CPCSEA. If the animal is in sudden and severe pain /distress possibly due to an accident etc. or fatally injured the authorities are requested to contact the CPCSEA telephonically, day or night, to seek permission for euthanasia and not let the animal suffer.

Pentobarbital or a pentobarbital combination is the best choice for equine euthanasia. Because a large volume of solution must be injected, a catheter should be placed in the jugular vein. To facilitate catheterization of an excitable or fractious animal, a tranquilizer such as acepromazine, or an alpha-2-adrenergic agonist can be administered, but these drugs may prolong the time to unconsciousness because of their effect on circulation. Opioid agonists or agonist/antagonists in conjunction with alpha-2 adrenergic agonists may further facilitate restraint.

In certain emergency circumstances, it may be difficult to restrain a dangerous horse or other large animal for intravenous injection, and the animal might cause injury to itself or to bystanders before a sedative could take effect. In such cases, which might include euthanasia of a horse with a serious injury, the animal can be given an immobilizing agent such as succinylcholine, but an anaesthetic must be administered as soon as the animal can be controlled. After the animal is anesthetized, an overdose of the anaesthetic can be used to accomplish euthanasia. Succinylcholine alone or without sufficient anaesthetic must not be used for euthanasia.

NORMAL EQUINE PARAMETERS

Respiration

Horse normally takes 8-16 breaths per minute.(A breath is taken as one out-in movement of the ribs)

Temperature

A healthy horse has a temperature of 100.5-101.5 °F)

Pulse

The normal pulse rate is 32-44 beats per minute.

Blood Parameters

Circulating blood volume (ml/kg)	: 75
Packed Cell Volume (%)	: 32-53
Red Blood Cell ($\times 10^6$ / μ l)	: 6.8-12.9
Haemoglobin (g/dl)	: 11-19
White Blood Cell ($\times 10^3$ / μ l)	: 5.4-14.3
Plasma protein (g/dl)	: 5.8-8.7

9. COMMON DISORDERS IN EQUINES USED IN THE PRODUCTION OF BIOLOGICALS

1. Adverse effects after venepuncture

There are four main adverse effect that may be observed after venepuncture:

1. Hemorrhage

2. Bruising

3. Thrombosis and phlebitis

4. Stress caused by inappropriate handling

The appropriate treatment depends on the site, cause, and individual animal. Advice on treatment should be sought from a veterinary surgeon.

1. Haemorrhage due to poor haemostasis is not a common problem unless the animal has a clotting defect and in most cases gentle continuous pressure applied for several minutes will stop the bleeding.

2. Bruising is due to subcutaneous bleeding at the time of venepuncture or after the animal has been returned to the stable, when the site might be aggravated by the animal itself through licking or rubbing. The animal should be checked after 30 minutes and if necessary appropriate action taken.

3. Thrombosis (clotting) and **phlebitis** (inflammation of the vein) are usually caused by unclean techniques or leaking of an irritant substance (eg. alcohol based chemicals) around the vein, or may result from self-mutilation.

Repeated bleeding can also lead to phlebitis and scarring, which can also occur as a result of repeated attempts at venepuncture. This can be reduced by improving the technique (using disposable cannulas and needles) and by rotating blood collection sites.

One can begin collecting at one end of a length of vein normally starting at the end furthest away from the heart. Haematoma's, which may occur, will gradually be resorbed but may form a temporary focus for infection resulting in inappetance and a rise in body temperature.

There is also possibility of damage of the nerves, which accompany a vein, when a needle is misdirected. Venous occlusion may result from thrombophlebitis and very rarely embolisms due to dislodging a thrombus in a needle as a result of an accidental injection of a small amount of air can occur. (Emboli have the potential to cause death)

4. Stress due to improper handling.

The correct level of restraint is that which allows a satisfactory sample to be taken at the first attempt and does not cause the animal to be unnecessarily distressed. In the event of bleeding an animal in a stressed condition it is observed that blood glucose levels, blood pressure etc. increase leading to both scientific and animal welfare complications.

2. Amyloidosis

Although a rare clinical entity in the general horse population amyloidosis is a frequent post-mortem finding in horses used for hyper immune serum production, the liver and the spleen being the more commonly affected organs.

Since liver rupture is common cause of death in such horses, on welfare and economic grounds, regular monitoring of Gamma Glutamyl Transferase (GGT) activity in serum is advisable.

Studies in hyper immune serum producing horses once in a 5 year period have shown that GGT levels increase within 6-7 years of first starting the immunization procedure, and that constantly high values correlate with advanced liver Amyloidosis.

3. Equine Recurrent Uveitis (ERU)

There are many causes of uveitis in horses, which include keratitis, associated trauma, lens associated, generalized viral and bacterial diseases.

On many occasions there is no obvious cause and this category encompasses the endogenous type of immune - mediated uveitis, known as Equine Recurrent Uveitis, where the characteristic feature is hypersensitivity to a variety of antigens.

Impaired vision or total blindness (either unilateral or bilateral), corneal oedema, secondary cataract formations are the clinical features characteristic of ERU.

Current evidence suggest that most cases of chronic recurrent uveitis are immune mediated rather than from infections. (Equine Medicine & Surgery -Mair & Love, 1998).

Experimental studies have shown that the uveal system can develop and retain antibodies to a specific antigen. Later exposure to this antigen via systemic or local means initiates immune mediated inflammation, a delayed hypersensitivity reaction. (Equine Medicine & Surgery, Colahen et al., 1999).

In most cases, it is impossible to verify a specific etiology and affected horses are treated symptomatically for immune mediated ocular inflammation. Immune mediated uveitis is a common uveal disease and the recurrence of inflammation cumulatively destroys the vision in one or both the eyes. Repeated stimulation with the original antigen causes rapid recurrence of uveitis. Inflammation of the uvea results in a permanent increase of vascular permeability. Clinical signs include severe blepharospasm, lacrimation, photophobia, congested conjunctiva, corneal oedema, opacity, cataract and blindness. Proper eye inspection and treatment with NSAID antibiotics and atropine eye drops should be used if necessary.

4. Liver Dysfunction

Repeated immunization of the animal with venom/toxins for the production of hyper immune sera causes severe liver damage. If neglected the damage is irreparable.

Supportive therapy has the objective of allowing time for regeneration of hepatocytes. This may initially involve i/v glucose administration followed by oral feeding of glucose.

For horses suffering with severe hepatic dysfunction, dietary management should ensure the following:

- The ration should be divided into atleast 3 daily meals.
- The ration should contain the highest quality protein in adequate amounts, but not in excess.
- An amino acid supplement of glycogenic branched chain amino acids, isoleucine and valine (lg / kg diet of each) may help.
- Soluble fibre sources, like beet pulp, are useful, together with wheat bran and other insoluble fibre sources and a moderate level of several cooked starch sources.
- Vitamin E (1500 I.U. /day) and a water-soluble B vitamin supplement, including 1000 mg choline / kg diet are advisable.
- A supplement of 0.5 kg DL - Methionine / ton of feed is recommended

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Cover Photograph-Courtesy RSPCA Complete Horse Care Manual – Colin Vogel
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Amendments in the protocol for use of equines for production of hyper immune sera (ASVS)

1. Lower and upper age Limit for equines to be used in sera production:

- i) The bleeding of horses for production of hyper-immune sera should not start before the age of 5 years.
- ii) The horses can however be inducted into the hyper-immune production programme before attaining 5 years age but the minimum age for bleeding will be 5 years.
- iii) That subject to strict health, blood and biochemical parameters to ensure that the animals are physically & clinically sound and Immunologically responsive for continuation in the hyper-immune sera production, the species wise upper age limit of the equines will be as follows:

Ponies	:	18 years
Horses	:	22 years
Mules	:	25 years
- iv) That the maximum age limit of equines for production of hyper-immune sera that has been relaxed upto 21 years effective till March 2005 will continue till notification of the amended protocol.
- v) The para in the Original Protocol – 2001 stating “No animal should be in the programme for a period exceeding 3 years” stands omitted.

2. Species – wise body weight for equines to be used in sera productions:

The species wise minimum body weight for equines to be used in hyper-immune sera production will be as follow:

Ponies	:	Minimum 150 kgs
Mules	:	Minimum 250 kgs
Horses	:	Minimum 300 kgs

3. The bleeding schedule and quantum of blood to be collected:

- a) 5% of circulatory blood volume or 0.5% of total body weight repeated every two weeks with plasmapheresis and transfusion in practice, or
- b) 15% of circulatory blood volume or 1.5% of total body weight repeated every four weeks with plasmapheresis and transfusion in practice

The above limits are however subject to strict health, blood and biochemical parameters to ensure that the animals are physically & clinically sound and immunologically responsive for continuation in the hyper-immune sera production.

4. Rehabilitation of equines after their use in hyper-immune sera production:

- i) The responsibility of rehabilitation of the equines after their use in hyper immune sera production will continue to remain with the respective organizations.
- ii) Ministry of Environment & Forests (Animal Welfare Division) will initiate identification and notifying of NGO's for rehabilitation of these equines.
- iii) The prescribed rate to be paid by the sera producing organizations to identified NGOs for rehabilitation of the equines will be decided later.
- iv) Till such time, the sera producing organizations will continue to maintain theses equines.
- v) The rehabilitation of these equines by sale, auction or donation cannot be done.

**ADVISORY to be adhered by all the equine holding establishments registered with
CPCSEA for Hyperimmune plasma production.**

- 1. Microchip identification to be made a mandatory condition for the equines used in the hyperimmune plasma production.**
2. Equids should be groomed regularly and two sets of “Curry comb” dandy, jute glove and “Body brush” should be available in each paddock.
3. Paddock should have 50% kuchcha floor.
4. The floor of paddocks should not be slippery.
5. Paddocks should not be overcrowded and only compatible animals to be housed/stalled/paddock together.
6. Sufficient attention on HOOF TRIMMING and hoof care should be paid.
7. Sufficient stock of dry fodder should be in the premises green and dry fodder to be chaffed and made in kutty. Storage place should be seepage free.
8. Bedding material need to be provided to all the equines including sick and rehabilitation stock.
9. Every establishment should have standard size sand bed, round shape especially padded walled Colic box.
10. Sufficient green fodder, dry fodder and concentrate should be offered to the equines. Biannually proximate principle analysis, microbiological and toxicological analysis of the feed fodder and concentrate to be done either by Animal Nutrition Department of Veterinary College or ICAR/CSIR or any Govt Institution.
11. Horse specific mineral mixture should be fed to the equids.
12. All “trevices” should be of Bamboo logs covered and padded with hay filled or foam stuffed rexin/ gunny bags.
13. All the establishments should have SOP for management of excreta. Dung disposal should be far away from the paddocks.
14. The open wounds to be dressed up regularly, site of immunization to be applied with heparin or DMSO local application.
15. Sufficient quantity of Liquid Paraffin should be available in the establishments.
16. Basic equipment such as STOMACH TUBE should be available in the dispensary.
17. Foot bath should be available.

18. Health Checkup should be done regularly especially neck swelling after immunization should be looked after properly.
19. Breeding is not permissible without approval of CPCSEA.
- 20. The establishments should bleed equids as per the guidelines of CPCSEA or as per that communicated in the approvals of the specific protocols.**
21. Veterinary Clinic should be preferably near sick bay.
22. Veterinary doctors need to be sent for Refresher training in the field of “Equine management/ Nutrition/ Farriery/ Lab diagnostics” for a duration of 10 days in a year in reputed institutes like NRCE, Hisar, TANUVAS, GADVASU, IVRI or nearby stud farm, racecourse RVC hospitals or their NCC wings/units any National Institutes imparting ibid training. A separate budget should be earmarked by the authorities.
23. For disease diagnosis samples (Haemoprotozoa, viral, faecal) should be sent regularly to reputed laboratories.

THE CPCSEA GUIDELINES FOR THE
REUSE AND REHABILITATION OF DOGS
2015

A. The Rationale and need

The Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA), a statutory body of the Government of India, regulates the use of animals before, during and after use in experimentation. The CPCSEA, as mandated by law Rule 9 (c) of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 (which states that “animals intended for the performance of experiments are properly looked after both before and after experiments”) finds it necessary to frame guidelines which limit the use of animals in testing /research and their care after use in experiments.

These guidelines define a time limit for which dogs can be tested and/or housed in laboratories. The guidelines are based on the premise that animals in laboratories undergo psychological, physiological and physical trauma, not just from the interventions made on them, but also from solitary confinement, lack of natural conditions, caging, handling and absence of appropriate social interaction. The concept of Rehabilitation has been recognised in India as the 4th R and evolved as an official policy of the CPCSEA in 2004¹

Re-use of animals of higher phylogenetic order such as dogs is more common for several reasons, most often to save costs incurred in purchasing new animals. The advent of newer and less invasive methods of analysis, such as telemetry and imaging technologies, have also increased the possibility of re-using animals. Often, animals that have been used for a study and have not been subjected to an invasive procedure are used for a further scientific study. However, these animals are sometimes reused overlooking the physiological, psychological and physical trauma endured by them and hence these guidelines have been evolved to ensure the welfare of the animals before any repeat use in experimentation or prolonged housing in laboratories.

The effects on individual animals and their welfare must be considered on a case-by-case basis before reuse of laboratory animals can be advocated. Re-using animals as a reduction strategy must be promoted with extreme caution because reuse increases the potential of increased harm and trauma to individual animals and hence increases the quantum of an individual animals suffering. Re-use of animals for invasive procedures for reasons related to convenience and cost savings are never appropriate and cannot be approved for.

The point at which an animal should be rehabilitated or removed from experimentation/laboratory housing cannot be strictly defined, due to variations in study protocols, intensity of pain / distress an animal is subject to, inherent variations from animal to animal, degree of invasiveness of the study, volume of blood taken, repeated doses of toxic substances, age of animal, health of animal, handling, housing etc.

These guidelines define „use“ and „rehabilitation“ and sets time limits to the use of dogs in breeding and experimentation. Though special mention has been made on pharmacokinetic (PK), breeding, and telemetry studies, it is important to note that all and any re-use should have the special permission of the CPCSEA for every individual animal being considered for inclusion in a second/subsequent protocol of experimentation.

B. Definitions of ‘Rehabilitation’ and ‘Reuse’ of laboratory animals

(i) Rehabilitation of laboratory animals

The concept of 4th R “Rehabilitation” of laboratory animals is defined as “the aftercare rendered to animals that have been (i) bred for the purpose of experimentation (ii) subject to any form of experimentation (iii) retained in laboratory animal houses or breeding houses for the purpose of experimentation, both for education and research, with the sole intention of alleviating the pain/distress or suffering due to the physical, physiological and psychological trauma that the animals have been exposed to and to provide the animal a life distinctly different from laboratory housing and care, until the point of natural death”.

Rehabilitation norms are elaborated in the “CPCSEA guidelines for rehabilitation and euthanasia of laboratory animals in the “REPORT OF THE CONSULTATIVE GROUP ON REVIEW OF THE NORMS AND PRACTICES FOR REGULATION OF ANIMAL EXPERIMENTATION - Sept 2004”, Ministry of Environment and Forests, Government of India.

(ii) Reuse of laboratory animals

“Reuse” of laboratory animals is a term used where in, after completion of an experiment (experiment as defined in Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 and as amended in 2004) an animal is used again in the same or a different protocol, where an unused animal would have equally sufficed to meet the objectives of the second/or subsequent use.

C. Reuse of dogs in experiments

The CPCSEA's consent for reuse would be generally conditional upon the animal having suffered no significant adverse effects as a consequence of the first use, and the animal not having been subjected to any intervention which compromises its welfare and suitability on scientific terms, as a subject for the second or subsequent use. The CPCSEA reserves its right to make a decision on matters of reuse.

Any and all re-use of a dog after the completion of its use in an approved experimental protocol, must be further authorized/approved by the CPCSEA for each individual animal, limiting their reuse/stay in laboratory housing to a maximum period of three years. Hence all reuse or continued use within the three year period for studies/experiments, must be specifically authorized with a written consent of the CPCSEA.

1. The CPCSEA's consent for reuse will be conditional upon the animal having suffered no significant adverse effects as a consequence of the first use, and the animal not having been subjected to any intervention which compromises its welfare or suitability in scientific terms, to be used as a subject for the second or subsequent use.
2. The reuse of animals in an approved study may be reconsidered for second/repeated use when it may serve as a way to reduce the number of animals used, without causing any incremental pain/distress to the animal which results from second/repeat use.

3. When considering subsequent use of experimental animals- the physical and psychological health and wellbeing of the animal must be considered.
4. Before seeking permission with the CPCSEA for reusing an animal, the health of the animal and the opinion of the veterinarian and consent of IAEC must be in order.
5. Health certificate for sound health and fitness of animals intended for reuse must be obtained from a qualified veterinarian and should include a complete clinical examination, including vital signs (TPR), skin condition, behavior of animals, CBC, TPR, kidney (KFT) and liver function tests (LFT). The veterinarian should clearly certify that there has been no adverse effects including psychosomatic disorders, by way of the first experiment/caging and due to laboratory housing/procedures. Animals showing stereotypic behavior, fear, freezing on human touch; genetic or physical defects; permanent implants, etc. should be declared unfit for re-use and recommended for proper rehabilitation.
6. The laboratory must maintain records of re-use with detailed documentation.
7. Re-using animals as a reduction strategy can be promoted/considered by the IAEC only with extreme caution taking into consideration the potential of increased quantum and duration of pain and distress to individual animals caused by reuse. The IAEC should be asked to closely monitor end points and determine the suffering of animals before recommending reuse.
8. Dogs used in toxicity studies must be healthy and limit of use of individual dogs should be for a maximum period of 3 years for pharmacokinetic studies subject to the health status of the dog as reflected by general body condition, CBC, liver and kidney function tests. If the dog/s shows any liver or kidney impairment, within the three year period, the animal cannot be reused, even if within the 3 year period and must be rehabilitated with special care. Appropriate washout periods, with a minimum of three months, should be applied when studying the metabolism of a series of drugs to avoid confounding drug interactions and least physiological stress to the dog when repeatedly used within the 3 year period. LFT and KFT and blood profile should be done at the end of each wash out period and only if the animal is found healthy and normal, can the dog be reused.
9. Dogs used in breeding may be limited to 5 whelping cycles and must be rehabilitated on completion of this. Dogs used in toxicity studies should not be used for breeding.
10. In the case of telemetry studies, dogs from which the device has been explanted should not be used to implant another second device. Appropriate washout periods, with a minimum of three months time period should be adhered to, when studying the impact of several drugs to avoid drug interactions and least physiological stress to the dog. Telemetered dogs may be used till as such time the dogs shows normal physiological functions (TPR, liver, kidney) or until the device is no more functional and limited to a maximum period of three years.

11. The responsibility for all non-terminal research animals shall remain the responsibility of the PI and study veterinarian following the completion of the study until final disposition is accomplished. To safeguard the animal's welfare through the study and until re-use / rehabilitation/ euthanasia, the Veterinary Surgeon named in the study should be actively involved, together with the PI and other named persons, ensuring the welfare of the animal.

D. Provision of identity number/s for individual dogs

In order to facilitate and ensure humane limits in reuse as per CPCSEA guidelines it is imperative to assign a unique number to each animal by way of micro chips. Once every animal is given a unique identity number this information should be made available in FORM B and the institute should have this information/database for all dogs and which may be made available if required by CPCSEA. The Institute should update this information for each animal as and when an experiment is completed.

E. Rehabilitation

Dogs that have completed the three year experimental term or if not permitted for reuse within the three year period should be promptly rehabilitated by the institute with information to the CPCSEA.

In the case of dogs there is immense possibility to be adopted by families. This may be encouraged, after the animals have been spayed/castrated by the institute and adoptions facilitated through trustworthy Animal Welfare Organization/s (AWO/s), after due approval of CPCSEA. Members / Representatives of the CPCSEA would be designated to liaise with institutes and ensure rehabilitation of the dogs not permitted for reuse and those whose three year experimental term is completed. Otherwise institutes should bear the costs of rehabilitation in their own facilities, until the natural death of the animal. AWOs may facilitate rehabilitation, if required by rehabilitator.

ROLE AND RESPONSIBILITIES OF NOMINEES OF CPCSEA

PART A

DOs AND DON'Ts FOR NOMINEES

The primary responsibility of a person who has been nominated to represent the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) on an Institutional Animal Ethics Committee (IAEC) is the well being and welfare of the animals housed or kept for experiments / breeding. With this in mind, the nominee should be familiar with the rules governing housing, experiments and after care of the animals. It is also imperative that the nominee upholds the dignity of the CPCSEA at all times.

1. Ensure that meeting notices and associated papers sent by the Institution on which IAEC the nominee is a member are carefully read and understood. All Institutions are requested that papers should be sent to IAEC members before 20-30 days (depending on bulk) to allow reasonable time for the concerned to go through the papers and make suggestions/ recommendations at the meeting.
Go through the protocol of the experiment/ proposals and if in doubt regarding the justification for the experiment and whether it could be carried out using smaller or a lesser number of animals, please raise the issue in IAEC meeting and clarify. Any protocol which uses animals other than guinea pigs, rabbits, rats, mice, hamsters and invertebrate animals should be first cleared by the IAEC and then sent to CPCSEA for clearance.
2. During the meeting,
 - a) The nominee should be polite, yet ensure that the points raised are taken note of.
 - b) Do not allow yourself to be intimidated by the others.
 - c) Ask for clarifications to make an informed decision on points discussed.
3. In the best interests of animals it is important that the nominee secures the co-operation of the other members of the IAEC by persuasion, rather than by confrontation. To do this, it would be helpful for the nominee to collect as much information as possible on the subject and familiarize himself/ herself with the kind of experiments being carried out at the laboratory – for example, if regulatory law for a chemical requires its mandatory testing on six animals, it is futile for the nominee to argue that four would be sufficient.
4. Since feeding and watering of the animals must be provided for during non-working hours as well as on holidays, the nominees should check the animal houses at such times whenever possible. No prior intimation is required as per rules (PCA Act, 1960).

WHAT TO LOOK FOR IN ANIMAL HOUSES

An animal which grows and behaves normally and is free of disease is usually considered to be in a state of “Well Being”. All aspects of Animal care should be directed towards the achievement and preservation of this state.

- | | |
|------------|---|
| A. Housing | : Location and space requirement, type of cages, material, environment. |
| B. Feed | : Feeding Schedule, type of diet. |
| C. Water | : Clean sterile water, type of bottle, nozzle. |

- D. Exercise : Inside the cage if it is large enough –otherwise in open space, especially for large animals.
- E. Health : Diseases, health checkup records
- F. Handling : Whether personnel are trained?
- G. Companionship : Do they provide companionship of compatible members of the same species? Solitary confinement is not recommended except in specific cases.

PART B

EQUIP YOURSELF

As a nominee of the CPCSEA it is important that you believe in yourself, be proud to serve this noble cause and develop the confidence to do so. In ‘Equip Yourself’ the norms of the CPCSEA and finer details of animal experimentation which need to be adhered to by the Institute / Establishment is spelt out in three parts – (1) Documentation (2) Status of Animal House (3) Useful hints for an IAEC meeting.

1. DOCUMENTATION

1. Ensure that all ongoing projects and projects to be implemented have been represented and documented in ‘Form B’ (‘Form B’ comprises of Para A; Part B for experiments using animals other than non-human primates and Part C for experiments using non-human primates).
2. Ensure that the ‘Form B’ is duly filled, all details provided and carries the signature of the investigator with date.
3. Only projects that involve small laboratory bred animals (i.e., guinea-pigs, rabbits, rats, mice and hamsters etc.) come under the purview of the IAEC. All other projects (involving large animals) shall be sent to CPCSEA for further scrutiny after recommendation of IAEC.
4. Carefully scrutinize and study the filled in ‘Form B’. Be specially attentive to details regarding –
 - i. Number of animals used.
 - ii. Species used, breed in case of dogs and genus in case of primates.
 - iii. Whether contract/collaborative research.
 - iv. Who is the funding agency.
 - v. Substance tested.
 - vi. Name of client for whom the test/ experiment is being conducted.
 - vii. Method of euthanasia (Annexure 1)
 - viii. Scrutinize ‘Form C’ – Check for any discrepancies regarding number of animals declared and number of animals in the animal house. Do a physical count.
 - ix. Scrutinize ‘Form D’ – check for any discrepancies. Cross check with other available documents such as animal house records.
 - x. If animals are not sacrificed after the experiment, what happens to them? Will rehabilitation be necessary?

In case of Breeder :

1. Scrutinize documents – i.e., ‘Form A’ and ‘Form C’ (‘Form B’ and ‘Form D’ are not applicable)

2. STATUS OF ANIMAL HOUSE

On visiting the animal house ensure that experimental animals are treated well and attended more often than non-experimental animals. Hence as a CPCSEA nominee, you may rescue the animals or relieve their trauma.

Inspect/ensure for the following:

1. Animals should be located in a quiet atmosphere, undisturbed by traffic.
2. Premises should be kept tidy and hygienic conditions to be maintained.
3. Animals should be protected from drought and extremes of weather and suitable bedding provided.
4. Animal cages for small animals and stables for large animals should be in such a way that the animal lives in comfort and overcrowding is avoided.
5. Enrichment of environment and provision for socializing.
6. Method of housing – ensure excreta of one cage does not enter other cages.
7. Animal attendants should be suitably trained and experienced in handling animals.
8. Arrangements for feeding and care of animals are made for holidays/weekends/emergencies.
9. Only trained persons should be allowed to carry out the experiments.

3. USEFUL HINTS FOR AN IAEC MEETING

1. Ensure that a study requires the use of animals. Mandatory use of animals arise in the case of regulatory testing of pharmaceuticals, cosmetics and immuno- biologicals.
2. If alternatives are available in the case of fundamental/ basic research, it may be emphasized to follow. Check whether the study is repetitive.
3. See if the number of animals used be reduced.

PART C

EUTHANASIA METHODS NOT ACCEPTABLE FOR ANY SPECIES OF ANIMALS.

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 embolism |

It is strongly recommended that an over dose of Thiopentone Sodium be used for euthanasia of all species, except under very exceptional cases.

PART D

ROLE OF NOMINEE

- 1) Nominee should be familiar with the CPCSEA guidelines, the concept of 4Rs 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. He/she must learn/be familiar with alternatives, reduction and refinement procedure available in biomedical research studies/programmes.
- 2) 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 overall 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 pharmacology, biotechnology 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.
- 3) 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 related to experiments, avoidance of repetitions of animal studies, numbers of animals used and possible reduction without losing scientific conclusions etc.
- 4) Nominee should not to indulge in arguments and heated debate but understand the merit of a study based on above principles.
- 5) Nominee is expected to sign the necessary forms of each protocol and maintain a copy/list in his/her records.
- 6) 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.
- 7) If meetings are not 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.
- 8) Nominee should visit animal house at least once in a calendar year to look at the well being and maintenance of animal and relevant record books and submit the annual report in the prescribed annual report format to CPCSEA office within a month from the date of inspection.
- 9) The nominee would be paid sitting fee and reimbursement of travel expenditure by the establishment / institute as determined by CPCSEA, from time to time.

What are the things a Nominee is not supposed to do

1. Nominee should not decide the merit and demerit of any specific research but he should ensure that experiments are performed in humane manner with minimum suffering to animals and minimum possible use of animals. [Note: Subject Experts in funding agencies decide the merit of research].
2. Nominee is not allowed to print visiting cards, letter heads with his/her name with Government of India official seal as IAEC nominee.
3. 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.
4. Nominee should not sign the minutes of the meeting/Forms/Register without attending the meeting in person.
5. Nominees should not allow any tele/audio conference with a non-participating member during the IAEC meeting.
6. Nominee should not allow any outside member to attend the IAEC meeting.
7. The nominees must keep themselves away from the media and press and will not disclose the confidential information related to the institution they are attached with or the CPCSEA.
8. Although all the nominees are very accomplished and dignified, Nominees are requested to abstain from entertaining any kind of favour in cash or kind other than sitting fee. Institutions have right to complain against a nominee, if the nominee exceeds his/her limit considering himself/herself as authority of licensing or passing any inspection etc. Since several nominees also belong to some research institution, they may appreciate this clarity of communication.
9. It is responsibility of the nominee to be truthful in evaluation and reporting and he/she should not challenge or threaten any organization. In Nutshell, a nominee should feel graceful in having recognised by CPCSEA as a responsible person to guide and upgrade quality of researchers and institutions and he should not feel that he is empowered by CPCSEA to take actions or decisions. His role is to report the discrepancy, if any, to CPCSEA.

FORM 'A' [As per rule 5(a)]

Application for Registration with CPCSEA

1. Details of establishment :

Name :
Address :
State :
Tel No. :
Email :
Fax No. :

(a) Whether Government or Private :

(b) Established Under (Ministry/ Deptt./ Council/ Act / or any other):

Name and Number:
Date :

(c) Sister Organization (*if any*) :

Name :
Address :

(d) Whether premises is rented/leased/self owned :

2. Details of the Head of Organization :

Name :
Address :
Contact Number:

3. Objective(s) of the Organization :

4. Type of Animal House Facility (Small/ Large / both) :

5. Purpose of Registration :

- (i) Research for Education purpose
- (ii) Research for Commercial purpose
- (iii) Research
- (iv) Breeding for in-house use
- (v) Breeding for the purpose of trade
- (vi) Production of Hyperimmune Plasma and Serum.

6. Proposed source of animal procurement:

S.No.	Name of the supplier	Address	CPCSEA Registration No.	Mode of Transportation

7. Details of animals (*species wise*) to be housed (Small / Large):

S.No.	Name and Breed of Animals	No. of animals	Sex	Age	Type of Animal House Facility	Purpose of Registration

8. Location of Animal House Facility for conduct of animal experimentation :

9. Staff trained for animal experimentation :

Name	Designation	Qualification	Experience

10. Post-experimental facilities for animals:

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

11. Institutional Animal Ethics Committee :

a) Date of Constitution of IAEC:

Name of Member	Date of Birth	Designation	Qualification	Experience	Mobile	Email	Organization to which they belong	Resume Consent of Members

b) Minutes of IAEC in which the proposal of registration with CPCSEA is approved, with signature of all the members.

c) Recommendation of IAEC for registration alongwith the minutes of internal IAEC meeting.

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

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.

Name of Head of the organization / Chairman, IAEC

Designation of Head of the organization/ Chairman, IAEC

Signature
Seal

Place

Check-List with Form-B for Submission of Research Protocol (s) on Large Animals

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	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....., CPCSEA Reference number, New proposal / revised proposal

Signature of Expert Consultant, CPCSEA

**Form B (per rule 8(a)* for Submission of Research Protocol (s)
on Large Animals**

Application for Permission for Animal Experiments

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

Section -I

1. Name and address of 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, Forest & Climate Change
5th Floor, Vayu Wing, Indira Paryavaran Bhawan
Jor Bagh Road, New Delhi-110 003.

Section -II

Protocol form 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 (alongwith details) :
- d. Reuse :

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)

Rodent study Data

Declaration to be signed by PI and enclosed with Project Proposal

The following information should be submitted by the PI along with each project proposal which contains the protocol for undertaking studies using mammals of higher sentience, such as dogs, goats, pigs, cattle, monkeys etc.

INFORMATION REGARDING TOXICITY TESTS CONDUCTED BY PI

I. Has the toxicity test been conducted in rodent model? Yes / No

[Please note that if the answer is No, the project proposal will not be considered for approval and the same may be re-submitted only after enclosing the toxicity data on rodents.].

II. If the toxicity test has been conducted, kindly provide the following information:

- (i) What were the doses used?
- (ii) Did any animal/s die during the study? Yes / No.
- (iii) If yes, how many?
- (iv) How many days after dosing did the animal/s die?
(Please provide information for each animal death)
- (v) Any additional information that you wish to provide?

[You may use additional sheets if required]

Declaration

I / We(Name of PI) do solemnly declare that the information provided by me / us above is true and correct to the best of my / our knowledge and that nothing material has been concealed.

I / We understand that if any false or wrong information has been provided by me / us, I / We take full responsibility for the same and that I / We will be liable for the actions that may be taken by the CPCSEA as per its regulations.

.....
.....

Name (s) of the PI

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

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)

Conditions for the permission of trading of Laboratory Animals

- a. Trading shall be done only with those establishments which are registered with CPCSEA;
- b. The protocols against which animal procurement is done by any establishment should have the approval of their respective IAEC;
- c. The details of trading each time should be informed to the IAEC; and
- d. A report in Form-E should be sent to CPCSEA on quarterly basis (i.e. 1st April, 1st July, 1st October and 1st January of every year).

FORM- E
Record of animals sold

(to be maintained by the establishment)*

Date	Species & number of animals sold	Name, address and Registration Number of the establishment to whom animals sold	Date & IAEC No. of the protocols against which animals sold

[* This record is required to be forwarded to O/o CPCSEA on quarterly basis. (1st April onwards)]

Proforma for Inspection Reports of Animal House Facility

CHECK LIST FOR INSPECTION OF ESTABLISHMENT /INSTITUTE

Date of Inspection:

1.	Name and address of the Institute/Establishment (with contact no. Fax no. and mobile)	
	(a) No. and Date of registration as per Company Act/Council or any other Act.	
	(b) Whether the premises of the Institute/Establishment is on rent/lease or self owned (specify)	
	(c) Name of the Sister concern (if any), where animal experiments are being carried out.	
	(d) Location of the Animal House Facility (whether inside the premises or away from the premises)	
2.	Name of the Head of the organization & address with contact details	
3.	Objective(s) of the organization	
4.	Purpose for Registration with CPCSEA	
	(a) Research for Education purpose	
	(b) Research for Commercial purpose	
	(c) Research	
	(d) Breeding for in-house use	
	(e) Breeding for the purpose of trade	
	(f) Production of Hyperimmune Plasma, Serum etc. (Non-research Commercial)	
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.	Recommendation:	
	1) Recommended for approval (without any stipulations)	
	2) Recommended for re-inspection (Please specify here)	
	3) Recommended for rejection with specific grounds (Please specify here)	

(Name & Signature of the Nominee/ Representative of CPCSEA)

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

(To be filled up by the Nominee)

INSPECTION REPORT OF ANIMAL HOUSE FACILITY

1. Date of Inspection:
2. Name of Organization:
3. Purpose of Inspection:
4. Inspection Details:

(a) Details of animals (Small / Large animals):-

(i) Species wise animals to be housed (for New Registration):

Details of Animals	Species	Number	Sex	Age

(ii) Species wise animals 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

(i) Recommended for approval (without any stipulations).

(ii) Recommended for approval with suggestions for improvement
(please specify here)

(iii) Recommended for fulfilment of stipulated conditions before consideration for
approval
(please specify here)

(iv) Recommended for rejection with specific grounds
(please specify here)

Signature of the Nominee/
Representative of CPCSEA
with Date

Signature of the Nominee/
Representative of CPCSEA
with Date

Signature of the Nominee/
Representative of CPCSEA
with Date

**FORMAT OF CHECKLIST AND INSPECTION REPORT FOR ANNUAL
INSPECTION OF ESTABLISHMENTS REGISTERED WITH CPCSEA**

1.	Name and address of the Institute/Establishment (with contact no. Fax no. and mobile)	
	(a) No. and Date of registration as per Company Act/Council or any other Act. (b) Whether the premises of the Institute/Establishment is on rent/lease or self owned (specify) (c) Name of the Sister concern (if any), where animal experiments are being carried out. (d) Location of the Animal House Facility (whether inside the premises or away from the premises) (Enclosed annexure I)	
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.	Type of work to be taken: (a) Research for Education purpose (b) Research for Commercial purpose (c) Research (d) Breeding for in-house use (e) Breeding for the purpose of trade (f) Production of Hyperimmune Plasma, Serum etc.	
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.	

(Signature of the Nominee)

Date:

Name:

Continued...

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

Inspection Report of Animal House Facility for continuation of Registration with CPCSEA
(To be filled up by the Nominee/ Inspecting authority)

1. Date of Inspection:
2. Name of Organization:
3. Purpose of Inspection: Routine/ annual, for continuation of CPCSEA registration
4. Category of the Animal House Facility: GLP/AAALAC or others
5. Inspection Details:

(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) Physical Facilities:

Drainage: Good/Bad/ need changes (specify):

Temperature.:

Noise:

(e) Food:.....

(f) Water:.....

6. Recommendation / Any other remarks:

(i) Recommended for approval (without any stipulations).

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

(iii) Recommended for rejection with specific grounds

.....
Signature of Nominee

(In case of Non availability of Main Nominee, Link Nominee is required to submit the Annual Inspection Reports)

**ANNUAL STATEMENT OF LARGE ANIMAL USE
(TO BE SUBMITTED FOR EACH SPECIES
SEPARATELY WITH ANNUAL INSPECTION
REPORT)**

Sr. No.	Title of Project	Approved by IAEC/CPCSEA	No. of Animals requested	No. of Animals sanctioned	Status of Project ongoing/ Completed/ Terminated/ Cancelled	No. of animals used as on 31 st December of every year

Summary of animal use and stock

No. of Animals as on 1st January of Every Year:

No. of Animals purchased from external breeders:

No. of Animals from in – house breeding:

Total No. of Animals used in the current year:

Total No. of Animals (large Animals) rehabilitated (not re-used):

No. of Animals in stock as on 31st December of Every Year.

**MID TERM EXTERNAL INSPECTIONS FOR
ASSESSING THE STATUS OF LARGE ANIMAL RESEARCH PROTOCOLS**

The approvals are granted by the Committee for the research protocols on large animals. In order to assess the status of large animal research protocols, a mid-term inspection shall be conducted with the purpose to inspect the health status of the experimented animals and to check the development of the research protocol. Relevant representatives of CPCSEA shall be authorised along with the Nominee of the establishment, by the Member Secretary, CPCSEA, to conduct the mid-term external inspections. The performa for the mid-term external inspection is placed below:

**PROFORMA FOR MID TERM EXTERNAL INSPECTIONS FOR
ASSESSING THE STATUS OF LARGE ANIMAL RESEARCH PROTOCOLS
(To be filled separately for each protocol)**

1. Name and address of the Establishment
(with contact /mobile number and email)
2. Registration number of Establishment:
3. Name of the Principal Investigator:
(with contact /mobile number and email)
4. Title of Project:
5. Date of IAEC recommendations:
6. Date of CPCSEA approval:
7. Duration of the protocol for which approval has been given:
8. Status of large animal research protocols (Ongoing/ Completed / Terminated / Cancelled):
9. Duration of the active phase of protocol (*in Year Months Dates from the start date*)
10. Species:
Common name:..... Age:.. Gender:.. No. of Animals
sanctioned:....
11. No. of animals used till date:
12. No. of animals euthanised (*if any*):
13. Euthanasia method:
14. No. of animals Rehabilitated (*enclose CPCSEA NOC for Rehabilitation in case of dogs*):.
15. No. of Animals in stock as on date:
16. No. of animal reused:
17. If reused then mention the protocol for which they have been procured:
.....
18. No. of times they have been reused:
19. Health status of animals (Please enclose the Certificate by the Veterinarian):
20. Recommendations:

Signatures of
Nominee with date

Signatures of
Representatives of CPCSEA with date

Proforma for undertaking by the Establishment in case of rehabilitation of dogs through adoption.

1.	Name and address of the Institute/Establishment. (with contact no. Fax no. and mobile)	
2.	Name of the Head of the organization & address with contact details	
3.	Name and address of the Animal Welfare Organization (AWO).	
4.	Registration details of AWO	
5.	Number of dogs to be Rehabilitated	
6.	Experimental period of use (start and end date)	
7.	Whether the dogs have been spayed/castrated by the institute.	
8.	The health Status of dogs. (Whether the dog/s is/are fit for Rehabilitation)	
9.	Any other comments	

Declaration by the Head of the organization:

I hereby give my undertaking that I have identified (Name and address of the AWO) for facilitating rehabilitation of the dogs through adoption by families. I undertake to send the details of the families to the CPCSEA after adoption of the dogs.

Signatures of
Head of organisation with
date

Proforma for seeking permission of CPCSEA for import of transgenic animals

To,

The Member Secretary,
CPCSEA, 5th Floor, Vayu Block,
Indira Paryavaran Bhawan,
Jor Bagh, New Delhi

Subject: Import of transgenic animal (species) – regarding

Sir,

Please find enclosed herewith the Minutes of the Meeting where a project has been approved entitled “.....” by our Institutional Animal Ethics Committee (IAEC) having Nominees of CPCSEA.

2. The IAEC has also approved the necessity of importing transgenic animal (species) (Name of the strain). The Institutional Biosafety Committee (IBSC) having representatives of RCGM has also approved the same (copy enclosed).

3. On the basis of these documents it is requested to provide us approval for importing the above animal (species).

Yours' faithfully

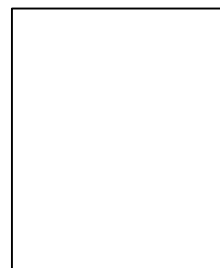
Head of the Institute/Chairman, IAEC

**Biodata and consent format for
Members of the Institutional Animal Ethics Committee**

Name:		Sex:	
Date of Birth (dd/mm/yy):			
Professional Mailing Address (Include institutional name)			
Telephone (Office) :		Mobile Number :	
Telephone (Residence):		E-Mail:	
Academic Qualifications (Most current qualification first):			
Degree / Certificate	Subject	Year	Institution, Country
Professional Experience:			
Month and Year	Title	Institution / Company, Country	
Experience in animal handling/ research:			
Month and Year	Area of Specialization	Institution / Company, Country	
Consent: I hereby give my consent to be the member of the IAEC of (Name of the establishment) I undertake to follow all the rules and guidelines of the CPCSEA.			
Signature:			
Date:			

CPCSEA NOMINEE APPLICATION FORM

Name of the Applicant :
Category of Application : Nominee / Socially Aware Nominee
(Please Tick)
Sex :
Date of Birth :
Qualification :
Profession :
Organization :
Communication Address :
Telephone :
Fax :
Mobile :
E-Mail :
Experience in Animal Welfare :
No Objection Certificate (Yes / No) :
(In the prescribed proforma)



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 (Detailed Resume, Certificate of education qualification, Certificate of Animal Welfare experience, Photo ID proof and Date of Birth Proof) should be sent to :-

The Member Secretary,
CPCSEA, Ministry of Environment, Forest & Climate Change,
5th Floor, Vayu Block, Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi – 110003.
E-mail: cpcsea-mef@gov.in

Note: The application forms complete in all respect shall only be entertained in CPCSEA and the incomplete applications shall state forwarded be rejected without entering into any communication with the applicant.

No Objection Certificate

Date:

This is to certify that Dr./Mr./Ms./Miss _____ is an employee in our Institute / Organization viz. (Name of the Institute / Organization) _____ located at _____.

He/ She wishes to apply for Nominee of CPCSEA. The Institute / Organization has no objection for working him/her as Nominee of CPCSEA.

Signature : _____ Seal with date _____

Name : _____

(Head of Institute/Head of Department/Placement Officer/Head of Organization)

Name of the Institute / Organization: _____

Manual of Website of CPCSEA

CONTENTS

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Website of CPCSEA

(<http://cpcsea.nic.in>)

The Website of CPCSEA has been launched on 24th April, 2015 by the Hon'ble MEF&CC on the occasion of 'World Laboratory Animal Day' for timely disposal of work and to maintain a database for easy retrieval and exchange. It will help to provide online facilities to the Bio-medical research Organizations who are involved in the animal experimentation. The Website marks yet another step in ushering in more transparency in the functioning of the CPCSEA. This initiative will impact in the **Digital India Programme of the Government of India** with a vision to transform *India* into a digitally empowered society.



Objectives of the Website of CPCSEA:

- To provide '*online*' facilities to the establishments for registration, renewal, revision and submission of Research Protocols on Large Animals.
- Make it easy to use for the registered establishments by providing latest updates of CPCSEA and to function as the two way communication mode.
- To maintain the database for easy retrieval and exchange.
- To facilitate quick and easy communication with CPCSEA by Nominees of CPCSEA and the establishments registered with CPCSEA.

New Registration

In terms of Rule 3 and 4 of the '*Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998*', every establishment involved with handling (Education, Research, Breeding, Trading and Production of Hyper-immune Plasma and Serum) of laboratory (Small and Large) animals is required to register with CPCSEA.

List of requisite documents for registration:

1. Application as per revised Form 'A' for registration. (Each column of Form A is to be filled online).
2. The Blueprint / Layout plan of the Animal House Facility/ animal farm of the establishment, having the details of the various rooms/area with measurements for keeping animals, feed storage, wash room, office room etc as per CPCSEA guidelines, duly signed by the Head of the establishment and the Architect.
3. Minutes of the internal IAEC meeting, wherein recommendation for CPCSEA registration has been approved by the IAEC.
4. Approval letter from the Government/ Autonomous Council (viz. AICTE/ PCI/MCI) or Company Registration Certificate.
5. The biodata and consent letters of 5 internal IAEC members (Biodata format available on the website).
6. The registration fee will be submitted through '*online payment gateway*' as per prescribed fee structure available on the website (<http://cpcsea.nic.in/WriteReadData/LnPdf/NewFeestructureofCPCSEA16.02.2017.pdf>).
7. The animals (Large animals in farms/ large animal house facility and Small animals in small animal house facility) may be kept only once the inspection is done by a team constituted by CPCSEA and after the registration with CPCSEA.

Procedure for applying online:

Step 1: It is required to sign up in the User Login Window available at Home Page of Website of CPCSEA (<http://cpcsea.nic.in>).

Step 2: Fill the requisite details available at sign up page

Step 3: The user is required to login through User Login Window at Home Page by selecting '*Establishment Login*' in User type and put their User Name & Password which were entered during sign-up Form.

Step 4: After successful login, click on New Registration Tab from the left side, fill the registration form as per Form A in 3 mentioned steps. After completion of details of one step, click **on Save and Proceed** for next step.

Step 5: After filling up the details in all the 3 steps, click on **Finish** Button; the complete filled form will display, click on the **Make Payment** Button at the bottom of this page; pay the registration fee through '*online payment mode* i.e. Debit Card, Credit Card and Internet Banking.

Renewal of registration & Reconstitution of IAEC

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

List of requisite documents:

1. The biodata and consent letters of Five (5) IAEC members (all from science background including one Veterinarian having at least *BVSc degree*). At least half of the internal members are required to be replaced at the time of Reconstitution of IAEC.
2. The minutes of IAEC meetings of the previous five years, bearing the signature (with date) of all the IAEC members. The minimum of 6 members are required to compose a quorum.
3. The Annual Inspection Report of the Animal House Facility and Annual statement of **large animals** use of the previous five years duly signed (with date) by the Main Nominee / Link Nominee (if Main Nominee is not available).
4. The establishments are required to deposit the renewal fee through 'online payment gateway' as per revised fee in the prescribed column at the time of the submission of online application for renewal of registration (<http://cpcsea.nic.in/WriteReadData/LnPdf/FeeStructureorder.pdf>)

Procedure for applying online:

- Step 1:** The user is required to login through User Login Window at Home Page of Website of CPCSEA (<http://cpcsea.nic.in>) by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.
- Step 2:** The establishment is required to upload the biodata and consent letters of each existing IAEC members (*in a single PDF file; Maximum file size: 1 MB*) on click on the tab IAEC members.
- Step 3:** The establishment is required to click on tab viz. **Renewal Reconstitution request**; and fill the details of proposed Five (5) IAEC members for reconstitution of IAEC, Upload their biodata and consent letters alongwith the details in a single PDF file (*Maximum file size: 1MB*).
- Step4:** After furnishing the above details, the establishment is required to click on **Final Submit** button; payment detail page will display; click on **Make Payment**; pay the renewal fee through 'online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Note:

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

The establishments to ensure the following:

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

Revision of IAEC

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

Procedure for applying online:

- Step 1:** The user is required to login through User Login Window at Home Page by selecting 'Establishment Login' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.
- Step2:** Click on the **Revision of IAEC** tab.
- Step 3:** Click on **edit** button in front of the IAEC member to whom the establishment wants to change/revise and then click on **update** to save the changes. (Ensure that all the details of each IAEC members are filled in complete manner).
- Step 4:** Furnish the reason for Revision of IAEC, date of the IAEC meeting, Minutes of the IAEC meeting with the signed attendance sheet, wherein the proposal of revision of IAEC has been recommended for approval by the IAEC, in a single PDF file (Maximum file size: 1MB) and the Remarks related to Minutes of IAEC meetings.
- Step 5:** Click on **Submit**; After submit, payment detail page will display; Click on **Make Payment** and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Change Nominee request

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

Procedure for applying online:

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

Step2: Click on the **Change Nominee** tab.

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

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

Step 5: Click on **Submit**.

Submission of Minutes of IAEC meeting

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

Procedure for applying online:

- Step 1:** The user is required to login through User Login Window at Home Page by selecting '*Establishment Login*' in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.
- Step 2:** Click on the tab viz. **Upload Minutes**; furnish the details such as Date of Minutes of IAEC meeting, copy of the Minutes of IAEC meeting with the signed attendance sheet and Remarks related to Minutes of IAEC meetings; Click on **Submit** Button.
- Step 3:** The establishment can see the status / submit the reply in response to the clarification sought by CPCSEA on click on View Minutes Tab in reference to the Minutes of IAEC meeting submitted by the establishment.

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

Submission of Research Protocol (s) on Large Animals

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

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

List of requisite documents for protocol:

1. Checklist of the Protocol (Completely filled and duly signed by the Principal Investigator).
2. Completely filled form 'B' (Section I & II) duly signed by the Principal Investigator alongwith Investigator's declaration and Certificate (signed by Main Nominee of CPCSEA and Chairman of IAEC).
3. Minutes of the IAEC meeting with the signed attendance sheet, wherein the protocol has been recommended by the IAEC and forwarded to CPCSEA for approval. The IAEC meeting should be conducted with all the approved IAEC members, wherein the presence of CPCSEA nominee and Socially Aware Nominee is mandatory. In case the Main Nominee conveys his/ her unavailability, Link Nominee may be invited in place of Main Nominee.
4. Rodent Study Data (wherever required).
5. The establishments are required to deposit the fee for Research Protocol through 'online payment gateway' as per revised fee (Rs. 1000/-for educational Protocols and Rs. 5000/-for non-educational Protocols) in the prescribed column at the time of the submission of Research Protocol (s) online.

Note:

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

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

Procedure for Submission of online Protocol:

- Step1:** The user is required to login through User Login Window at Home Page by selecting ‘Establishment Login’ in User type and put the User Name & Password which is given to each establishment(s) registered with CPCSEA.
- Step 2:** Click on the Tab viz. **New Research Protocol**; a form will display wherein requisite details to be filled for submission of Research Protocol such as title of the protocol, details of species etc.
- Step 3:** Upload the requisite files in the above form such as Checklist, Form B, Investigator Declaration, Certificate, Minutes of IAEC meeting, Rodent Study data (if applicable) and Guidelines/ References related to your research protocol. *(The maximum size of each file is displaying in front of the column)*
- Step 4:** Tick in front of the IAEC members who have attended the IAEC meeting and recommended the research protocol to CPCSEA for approval *(Ensure the required quorum of the IAEC meeting as per the CPCSEA guidelines and the presence of CPCSEA nominee and Socially Aware Nominee).*
- Step 5:** Click on **Submit Button**, After submit, payment detail page will display; Click on **Make Payment** and pay the requisite fee through online payment mode i.e. Debit Card, Credit Card and Internet Banking.

Amendment of Registration:

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

Procedure for applying online:

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

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

- (i) Amendment in the Name of the establishment.
- (ii) Amendment in the Address of the establishment (Location of the Animal house Facility).
- (iii) Amendment in the Purpose of registration with CPCSEA.
- (iv) Amendment in the Type of Animal House Facility (Small / Large).

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

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

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

- i. Inspection Reports / Annual Inspection Reports will be filled online by the concerned Nominee of the establishment. CPCSEA have provided the User ID and password to Nominees of CPCSEA for online processing. Therefore, Nominees are requested to visit their online panel to fill up the Inspection Reports / Annual Inspection Report of the Animal House Facility (s) of all the establishments allotted as and when required. Annual statement of large animals use will also be uploaded by the Nominees.
- ii. Annual Inspection Reports and Annual statement of large animals use of the previous five years are must for considering the renewal of registration of the establishments.
- iii. In case of Small and Large animal House Facility, the concerned Nominee of the establishment required to upload the Inspection Reports / Annual Inspection Reports of Both the facilities (Small and Large).
- iv. The Main Nominee of the concerned establishment is required to ensure conduct of the IAEC meetings as stipulated in the guidelines of CPCSEA and to upload the Annual Inspection Report of the Animal House Facility in the prescribed format regularly to the O/o CPCSEA.
- v. While filling up the online Inspection reports, nominees need to specify each column as per the CPCSEA Guidelines for Laboratory Animal Facility 2015. Nominees must avoid to write “as per guidelines or satisfactory or as per norms” in the columns of inspection report.
- vi. Nominees need to clearly indicate in the concerned column whether the Animal House Facility of the concerned establishment is recommended for consideration of Registration / Renewal.
- vii. Nominees will not upload the minutes of IAEC meetings as the same will be uploaded by the establishments.

Procedure for Submission of online:

- Step 1:** The user is required to login through User Login Window at Home Page by selecting ‘Nominee Login’ in User type and put the User Name & Password which is given to each Nominee(s) of CPCSEA.
- Step 2:** Nominee can see the details of Inspection ordered to him/her in three separate tabs viz. **Inspection ordered for New Registration, Inspection ordered as an external nominee and CPCSEA Nominee in the IAEC of the establishments.**
- Step 3:** The nominee can submit the Inspection Report(s) of the establishment(s) allotted to him/her from the above mentioned two tabs and submit the Annual Inspection Report(s) of any establishment(s) allotted to him/her through the third tab viz. CPCSEA Nominee in the IAEC of the establishment. The Annual Statement of Large Animal Use will also be submitted from this tab.

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

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

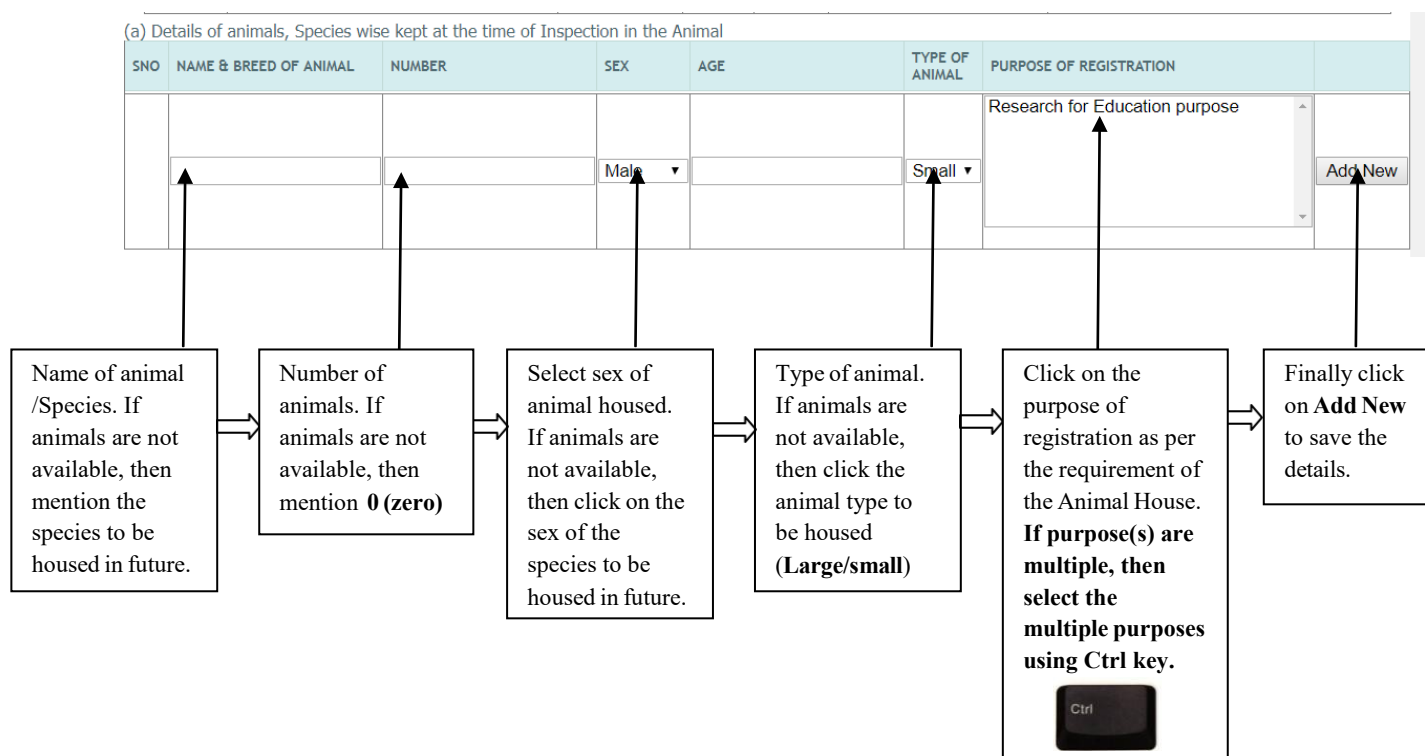
Step 6: For submission of Inspection Reports/ Annual Inspection Reports, the nominee(s) need to specify the details in each column as per the CPCSEA Guidelines and upload him/her signature and photographs of Animal House Facility at the time of Inspection in a single PDF file (*Maximum File Size: 1 MB*).

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

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

Note:

1. Details of the Animals/ species housed/ to be housed should be mentioned as per the requirement of animal house facility. Please refer the instructions given below:



2. Every CPCSEA Nominee is required to fill the Inspection Report / Annual Inspection Report (as per the prescribed checklist format) regularly of the Animal House Facility of the establishment assigned to him/her, to the O/o CPCSEA within 15 days of conducting the inspection of their Animal House Facility.



Government of India
Ministry of Environment, Forest & Climate Change
Animal Welfare Division
Committee for the Purpose of Control and Supervision of
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