

1. Recommended for approval (without any stipulations).
2. Recommended for approval with suggestions for improvement (please specify here)
3. Recommended for fulfillment of stipulated conditions before consideration for approval (please specify here)
4. Recommended for rejection with specific grounds (please specify here)

\_\_\_\_\_  
Member's Signature

\_\_\_\_\_  
Member's Signature

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Member's Signature

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

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

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

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

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

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

(v) For animals recommended for euthanasia post-experimentation, the relevant criteria could be that:

- (a) the animal is not able to perform its natural functions and left in pain & suffering.
- (b) the animal has been exposed to contagious/infectious diseases of zoonotic importance.
- (c) the animal has been exposed to radioisotope experiments.

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

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

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

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

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

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

(x) As regards the generic guidelines in respect of small animals, the mandate for examining proposals relating to small animals is with the IAECs.

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

Annexure-I

**Experimental Animal Health Records**

**Instructions and guidelines**

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

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

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

**Following forms are compulsory for rehabilitation**

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

**Following forms should be maintained for supportive information**

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

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

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

- I Species:
- |    |           |
|----|-----------|
| 01 | Dog       |
| 02 | Monkey    |
| 03 | Cat       |
| 04 | Sheep     |
| 05 | Goat      |
| 06 | Cattle    |
| 07 | Horse     |
| 08 | Any other |
- II Sex
- |   |        |
|---|--------|
| M | Male   |
| F | Female |
- III Year of Birth
- |      |    |
|------|----|
| 1997 | 97 |
| 2001 | 01 |
- IV Institutional Number Starts with CPCSEA  
Registration no.:
- |       |
|-------|
| 0159  |
| 00401 |
- V Individual number as per the institution
- |     |
|-----|
| 002 |
| 009 |
| 019 |

Example

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

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

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**2. Details of the Animals**

a. Animal No: <table border="1" style="width: 100%; height: 20px;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>						b. DOB
c. Animals procured / Trapped from:	d. Date of procurement / trapping					
e. Supplier / Source	f. Colony bred / Wild caught					
g. Dam Number	h. Sire Number					
i. Color	j. Date of Induction	k. Body Weight and Date				

**3. Physical Examination on arrival**

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

**4. Quarantine period**

a. Introduced on	b. Released from quarantine on
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**5. Microscopic examination for parasites**

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

**6. Any Treatment given during Quarantine**

Date	Clinical Symptoms	Diagnosis	Treatment	Recovered on

**7. Tuberculin Testing as per the animal:**

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

**8. \* Chest X ray**

a. Date	
b. Report contents	

**9. Transferred to which Experiment**

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Signature  
Name  
Designation

**Experimentation details**  
[Separate sheet for each experiment]

1. Animal No <input style="width:100%; height: 15px;" type="text"/>	2. Body weight / Date
3 Details of the Experiments:	
a. Title/s of the project	
b. Principal Investigator	
c. Details of the protocol	
4. Age and weight range at the time of Initiation of the experiment	
5. Experimental Endpoint Criteria	
6. Date of Termination of experiment as per IAEC approval	
7. Infectious agent used if any give details	
8. Radioisotope used if any give details	

**Signature of the Principal Investigator**  
Name  
Designation

**Post Experimentation Details of Animal & Suitability Certification**

1. Name of Organization currently possessing the animal	
2. Animal No <input style="width:100%; height: 15px;" type="text"/>	
3. Title of the experiment	
4. Investigator/s	
5. Duration under experimentation	
6. Experimental Procedure	
7. Body Weight & Date	
8. Details of Experiment/ procedures:	
9. Number of times anesthetized	10. Number of times blood withdrawn
11. Infectious organisms involved	
12. Radioactive substance used	
13. Is the animal suffering from any Zoonotic disease?	
14. Physical abnormalities if any furnish details	
15. Any clinical symptoms	
16. Any attention of a veterinarian required during rehabilitation and how long	
17. Special nutritional requirements if any during rehabilitation	
18. Present condition of the animal for rehabilitation. [Mark $\checkmark$ ]	
<b>Excellent</b> [Answers to 11-17 are No]	<input type="checkbox"/> It can be Retained
<b>Good</b> [Answer to 11-16 are No]	<input type="checkbox"/> It can be given for Experimentation
<b>Satisfactory</b> [Answers to 11-15 are No]	<input type="checkbox"/> Fit for transfer to NGO for Rehab
<b>Poor</b> [Answers 11-14 are Yes]	<input type="checkbox"/> Can be sent for Euthanasia

**Signature of Veterinarian**  
Name  
Designation

**Transfer Certificate for Rehabilitation**  
[To be filled in for every animal separately]

1. Animal No <input type="text"/>	2. Body weight / Date
3. Name & CPCSEA No. of Organization handing over the animal/s	
4. Name & CPCSEA No (if any) of the Organization taking over the animal/s	
5. CPCSEA Registration No of the Rehabilitation unit:	
6. In case of Emergencies Contact person/s details	
Name Telephone No(s) Fax:	Name Telephone No(s) Fax:
7. Person handing over the animal	8. Person under taking over the animal
Signature Name Designation Date	Signature Name Designation Date

**Tuberculin Testing**

Animal No <input type="text"/>					
Date	Source & Batch number	Result of readings			Remarks
		First	Second	Third	

Signature of Veterinarian  
Name  
Designation

**X - Ray**

Animal No <input type="text"/>		
Date	Organ / Site	Radiological Findings

Signature of Radiologist  
Name  
Designation

**Blood Drawn**

Animal No					<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Quantity	If any anesthetic used & Quantity	Purpose	Name of the Person drawn the blood					

Signature of Animal Technician  
Name  
Designation

**Body Weight**

Animal No		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Weight					

Signature of Animal Technician  
Name  
Designation

**Microbiology**

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

Signature of Veterinarian/ Microbiologist  
Name  
Designation

**Parasitology**

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

Signature of Veterinarian/ Parasitologist  
Name  
Designation

**Treatment**

Animal No					<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Clinical Symptoms	Diagnosis	Treatment	Remarks					

Signature of Veterinarian  
Name  
Designation

**Hematology**

Animal No											<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	RBC Millions/cc	WBC Cells/cc	PCV	HB g%	Differential Leukocyte Count					ESR					
					N	L	M	B	E						

Signature of Pathologist / Veterinarian  
Name  
Designation

**Surgery**

Animal No					<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date	Type of Surgery	Purpose	Treatment	Remarks					

Signature of Veterinarian  
Name  
Designation

**Post Mortem Report**

1. Animal No	[ ][ ][ ][ ][ ][ ]	2. Source
		3. Date of Induction
4. Was the animal Sacrificed / Died naturally		
5. Condition of Carcass		6. Date of Death
7. History of Animal		

**8 External Examination**

a. Head	b. Body	c. Limbs
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**9. Discharges if any**

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

**10. Internal Examination**

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

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

Samples for Microbiology	Findings
Samples for Parasitology	
Samples for Histopathology	

**12. Important Findings:**

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**13. Cause of Death**

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Signature of Pathologist / Veterinarian  
 Name  
 Designation

**Histopathology**

1. Animal No			[ ][ ][ ][ ][ ]
Date	Material	Findings	

Signature: Pathologist / Veterinarian  
 Name:  
 Designation:

## Rehabilitation

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

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

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

### Following conditions also preclude successful rehabilitation:

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

## Annexure -II

### Check list for examining response of NGOs to be considered for rehabilitation of retired laboratory animals

1. Name of the Organisation:
2. Address:
3. Tel: Fax: Email:
4. Registration No. Status: Trust/ Society/  
Any other:
5. Registration No. with Animal Welfare Board of India / CPCSEA  
(Enclose copy of registration Certificate)
6. Specify choice of animals for rehabilitation :  
a) Dogs b) Goats / sheep c) Cattle d)  
Monkeys e) Others
7. Number of animals proposed to accommodated ?
8. Details regarding location of shelter

Where is the shelter located? Specify place relating climatic condition.

9. Details of availability of Veterinary care including surgical facilities available.
10. Details of amenities available at Shelter:
  - (i) Food
  - (ii) Water
  - (iii) Bedding
  - (iv) Safety/security
  - (v) Hygiene / sanitation



## ROLE OF NOMINEE

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

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

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

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

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

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

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

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

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

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

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

### Nominee not supposed to do

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

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